ACC, HIMSS and RSNA

Integrating the Healthcare Enterprise

IHE Patient Care Coordination Technical Framework

Volume I
(PCC TF-1)
Integration Profiles

Revision 3.0
2007-2008

For Public Comment -

Comments Due July 27, 2007

Forward

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. And it organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the American College of Cardiology (ACC), the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Francaise de Radiologie ([www.sfr-radiologie.asso.fr SFR]), and Società Italiana di Radiologia Medica (SIRM). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and [www.medis.or.jp MEDIS-DC]; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are actively involved and others are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (Patient Care Coordination, IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) define specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. These are expanded annually, after a

period of public review, and maintained regularly through the identification and correction of errata. The current version for these Technical Frameworks may be found at www.ihe.net.

The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. Volume I provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. Subsequent volumes provide detailed technical descriptions of each IHE transaction.

Content of the Technical Framework

This technical framework defines relevant standards and constraints on those standards in order to implement a specific use cases for the transfer of information between systems. This document is organized into 2 volumes as follows:

Volume 1 - Overview

This volume is provided as a high level overview of the profiles including descriptions of the use case, the actors involved, the process flow, and dependencies on other standards and IHE profiles. It is of interest to care providers, vendors' management and technical architects and to all users of the profile

Volume 2 – Transactions and Content Profiles

This volume is intended as a technical reference for the implementation of specific transactions in the use case including references to the relevant standards, constraints, and interaction diagrams. It is intended for the technical implementers of the profile.

Comments shall be submitted before July 27, 2007 to:

http://forums.rsna.org under the "*IHE*" forum

Select the Patient Care Coordination Technical Framework

How to Contact Us

IHE Sponsors welcome comments on this document and the IHE initiative. They should be directed to the discussion server at http://forums.rsna.org or to:

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Contents

1 Preface to Volume 1 of the PCC Technical Framework

1.1 Intended Audience

The intended audience of this document is:

- Healthcare professionals involved in informatics
- IT departments of healthcare institutions
- Technical staff of vendors participating in the IHE initiative
- Experts involved in standards development
- Those interested in integrating healthcare information systems and workflows

1.2 Related Information for the Reader

The reader of volume 1 should read or be familiar with the following documents:

- Volume 1 of the Cross-Enterprise Document Sharing (XDS) Integration Profile documented in the ITI Infrastructure Technical Framework
- Volume 1 of the Notification of Document Availability (NAV) Integration Profile documented in the ITI Infrastructure Technical Framework
- Volume 1 of the Audit Trail and Node Authentication (ATNA) Integration Profile documented in the ITI Infrastructure Technical Framework

(See http://www.ihe.net/Technical_Framework/index.cfm for all of the above).

- ASTM/HL7 Continuity of Care Document
- HL7 Clinical Document Architecture Release 2: Section 1, CDA Overview.
- Care Record Summary – Implementation Guide for CDA Release 2 (US Realm): Section 1

1.3 How this Volume is Organized

Section 2 describes the general nature, structure, purpose and function of the Technical Framework. Section 3 and the subsequent sections of this volume provide detailed documentation on each integration profile, including the Patient Care Coordination problem it is intended to address and the IHE actors and transactions it comprises.

The appendices following the main body of the document provide a summary list of the actors and transactions, detailed discussion of specific issues related to the integration profiles and a glossary of terms and acronyms used.

1.4 Conventions Used in this Document

This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based should be applied.

1.4.1 Technical Framework Cross-references

When references are made to another section within a Technical Framework volume, a section number is used by itself. When references are made to other volumes or to a Technical Framework in another domain, the following format is used:

<domain designator> TF-<volume number>: <section number>

where:

<domain designator>

is a short designator for the IHE domain (PCC= Patient Care Coordination, ITI = IT Infrastructure, RAD = Radiology)

<volume number>

is the applicable volume within the given Domain Technical Framework (e.g., 1, 2, 3), and

<section number>

is the applicable section number.

For example: PCC TF-1: 3.1 refers to Section 3.1 in volume 1 of the IHE Patient Care Coordination Technical Framework, ITI TF-2: 4.33 refers to Section 4.33 in volume 2 of the IHE IT Infrastructure Technical Framework.

1.4.2 IHE Actor and Transaction Diagrams and Tables

Each integration profile is a representation of a real-world capability that is supported by a set of actors that interact through transactions. Actors are information systems or components of information systems that produce, manage, or act on categories of information required by operational activities in the enterprise. Transactions are interactions between actors that communicate the required information through standards-based messages.

The diagrams and tables of actors and transactions in subsequent sections indicate which transactions each actor in a given profile must support.

The transactions shown on the diagrams are identified both by their name and the transaction number as defined in PCC TF-2 (Volume 2 of the PCC Technical framework). The transaction numbers are shown on the diagrams as bracketed numbers prefixed with the specific Technical Framework domain. In some cases, a profile is

dependent on a prerequisite profile in order to function properly and be useful. For example, Cross-Enterprise Sharing of Medical Summaries depends on Cross-Enterprise Document Sharing (XDS). These dependencies can be found by locating the desired profile in Table 2.6-1 to determine which profile(s) are listed as prerequisites. An actor must implement all required transactions in the prerequisite profiles in addition to those in the desired profile.

1.4.3 Process Flow Diagrams

The descriptions of integration profiles that follow include process flow diagrams that illustrate how the profile functions as a sequence of transactions between relevant actors.

These diagrams are intended to provide an overview so the transactions can be seen in the context of an institution's or cross-institutions' workflow. Certain transactions and activities not defined in detail by IHE are shown in these diagrams in italics to provide additional context on where the relevant IHE transactions fit into the broader scheme of healthcare information systems. These diagrams are not intended to present the only possible scenario. Often other actor groupings are possible, and transactions from other profiles may be interspersed.

In some cases the sequence of transactions may be flexible. Where this is the case there will generally be a note pointing out the possibility of variations. Transactions are shown as arrows oriented according to the flow of the primary information handled by the transaction and not necessarily the initiator.

1.5 Copyright Permissions

2 Introduction

This document, the IHE Patient Care Coordination Technical Framework (PCC TF), defines specific implementations of established standards. These are intended to achieve integration goals that promote appropriate exchange of medical information to coordinate the optimal patient care among care providers in different care settings. It is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The latest version of the document is always available via the Internet at http://www.ihe.net/Technical_Framework/ , where the technical framework volumes specific to the various healthcare domains addressed by IHE may be found.

The IHE Patient Care Coordination Technical Framework identifies a subset of the functional components of the healthcare enterprises and health information networks, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. The other domains within the IHE initiative also produce Technical Frameworks within their respective areas that together form the IHE Technical Framework. Currently, the following IHE Technical Framework(s) are available:

- IHE IT Infrastructure Technical Framework
- IHE Cardiology Technical Framework
- IHE Laboratory Technical framework
- IHE Radiology Technical Framework
- IHE Patient Care Coordination Technical Framework

Where applicable, references are made to other technical frameworks. For the conventions on referencing other frameworks, see the preface of this volume.

2.1 Relationship to Standards

The IHE Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their interactions in the healthcare enterprise. It further defines a coordinated set of transactions based on standards (such as HL7, IETF, ASTM, DICOM, ISO, OASIS, etc.) in order to accomplish a particular use case. As the scope of the IHE initiative expands, transactions based on other standards may be included as required.

At its current level of development, IHE has also created Content Integration Profiles to further specify the payloads of these transactions, again based on standards. This has become necessary as the healthcare industry moves towards the use of transaction standards that have been used in more traditional computing environments.

In some cases, IHE recommends selection of specific options supported by these standards. However, IHE does not introduce technical choices that contradict

conformance to these standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a standard. Conformance claims for products must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities in their products may publish IHE Integration Statements to communicate their products' capabilities. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration Statements from different products, a user familiar with the IHE concepts of actors and integration profiles can determine the level of integration between them. See PCC TF-1: Appendix C for the format of IHE Integration Statements.

2.2 Relationship to Product Implementations

The IHE actors and transactions described in the IHE Technical Framework are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g. HIS, Clinical Data Repository, Electronic Health record systems, Radiology Information Systems, Clinical Information Systems or Cardiology Information Systems), the IHE Technical Framework intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.

The reason for defining actors and transactions is to provide a basis for defining the interactions among functional components of the healthcare information system environment. In situations where a single physical product implements multiple functions, only the interfaces between the product and external functions in the environment are considered to be significant by the IHE initiative. Therefore, the IHE initiative takes no position as to the relative merits of an integrated environment based on a single, all-encompassing information system versus one based on multiple systems that together achieve the same end.

2.3 Framework Development and Maintenance

The IHE Patient Care Coordination Technical Framework is continuously maintained and expanded on an annual basis by the IHE Patient Care Coordination Technical Committee. The development and maintenance process of the Framework follows a number of principles to ensure stability of the specification so that both vendors and users may use it reliably in specifying, developing and acquiring systems with IHE integration capabilities.

The first of these principles is that any extensions or clarifications to the Technical Framework must maintain backward compatibility with previous versions of the framework (except in rare cases for corrections) in order to maintain interoperability with systems that have implemented IHE Actors and Integration Profiles defined there. The IHE Patient Care Coordination Technical Framework is developed and re-published annually following a three-step process:

1. The Patient Care Coordination Technical Committee develops supplements to the current stable version of the Technical Framework to support new functionality identified by the IHE Strategic and PCC Planning Committees and issues them for public comment.
2. The Committee addresses all comments received during the public comment period and publishes an updated version of the Technical Framework for "Trial Implementation." This version contains both the stable body of the Technical Framework from the preceding cycle and the newly developed supplements. It is this version of the Technical Framework that is used by vendors in developing trial implementation software for the IHE Connectathons.
3. The Committee regularly considers change proposals to the Trial Implementation version of the Technical Framework, including those from implementers who participate in the Connectathon. After resolution of all change proposals received within 60 days of the Connectathon, the Technical Framework version is published as "Final Text".

As part of the Technical framework maintenance the Committee will consider change proposals received after the publication to the "Final Text".

2.4 History of Annual Changes

In the 2005-2006 cycle of the IHE Patient Care Coordination initiative, the first release of the IHE PCC Technical Framework introduced the following integration profile:

- **Cross-Enterprise Sharing of Medical Summaries (XDS-MS) –** a mechanism to automate the sharing process between care providers of Medical Summaries, a class of clinical documents that contain the most relevant portions of information about the patient intended for a specific provider or a broad range of potential providers in different settings. Medical Summaries are commonly created and consumed at points in time of transfers of care such as referrals or discharge.

In the 2006-2007 cycle of the IHE Patient Care Coordination initiative, the following integration profiles were added to the technical framework.

- **Exchange of Personal Health Record Content (XPHR) –** provides a standards-based specification for managing the interchange of documents between a Personal Health Record used by a patient and systems used by other healthcare providers to enable better interoperability between these systems.

- **Basic Patient Privacy Consents (BPPC) –** enables XDS Affinity Domains to be more flexible in the privacy policies that they support, by providing mechanisms to record patient privacy consents, enforce these consents, and create Affinity Domain defined consent vocabularies that identify information sharing policies.
- **Preprocedure History and Physical Content Profile (PPHP) –** supports the exchange of information allowing for the assessment and amelioration of risks related to a procedure.
- **Emergency Department Referral Profile (EDR) –** provides a means to communicate medical summary data from an EHR System to an EDIS System.

In the 2007-2008 cycle of the IHE Patient Care Coordination initiative, the following integration profiles were added to the technical framework.

- **Antepartum Care Summary (APS) -** describes the content and format of summary documents used during antepartum care.
- **Emergency Department Encounter Record (EDER) -** describes the content and format of records created during an emergency department visit.
- **Functional Status Assessment Profile (FSA) -** supports the handoff of assessment information between practitioners during transfers of care by defining the Functional Status Assessment option on the XDS-MS and XPHR profiles.
- **Query for Existing Data (QED) -** allows information systems to query data repositories for clinical information on vital signs, problems, medications, immunizations, and diagnostic results.
- **Public Health Laboratory Report(PHLAB) -** extends the XD*-LAB profile to support reporting from public health laboratories for disease surveillance activities.

In addition, all content within the technical framework was revised in this cycle to encourage compatibility with the ASTM/HL7 Continuity of Care Implementation Guide.

2.5 About the Patient Care Coordination Integration Profiles

IHE Integration Profiles offer a common language that healthcare professionals and vendors can use to discuss integration needs of healthcare enterprises and the integration capabilities of information systems in precise terms. Integration Profiles specify implementations of standards that are designed to meet identified clinical needs. They enable users and vendors to state which IHE capabilities they require or provide, by reference to the detailed specifications of the IHE Patient Care Coordination Technical Framework.

Integration profiles are defined in terms of IHE Actors, transactions and their content. Actors (listed in PCC TF-1: Appendix A) are information systems or components of

information systems that produce, manage, or act on information associated with clinical and operational activities. Transactions (listed in PCC TF-1: Appendix B) are interactions between actors that communicate the required information through standards-based messages. Content is what is exchanged in these transactions, and are defined by Content Profiles.

Vendor products support an Integration Profile by implementing the appropriate actor(s) and transactions. A given product may implement more than one actor and more than one integration profile.

Content Profiles define how the content used in a transaction is structured. Each transaction is viewed as having two components, a payload, which is the bulk of the information being carried, and metadata that describes that payload. The binding of the Content to an IHE transaction specifies how this payload influences the metadata of the transaction. Content modules within the Content Profile then define the payloads. Content modules are transaction neutral, in that what they describe is independent of the transaction in which they are used, whereas content bindings explain how the payload influences the transaction metadata.

The figure below shows the relations between the Content Integration Profiles of the Patient Care Coordination Domain.

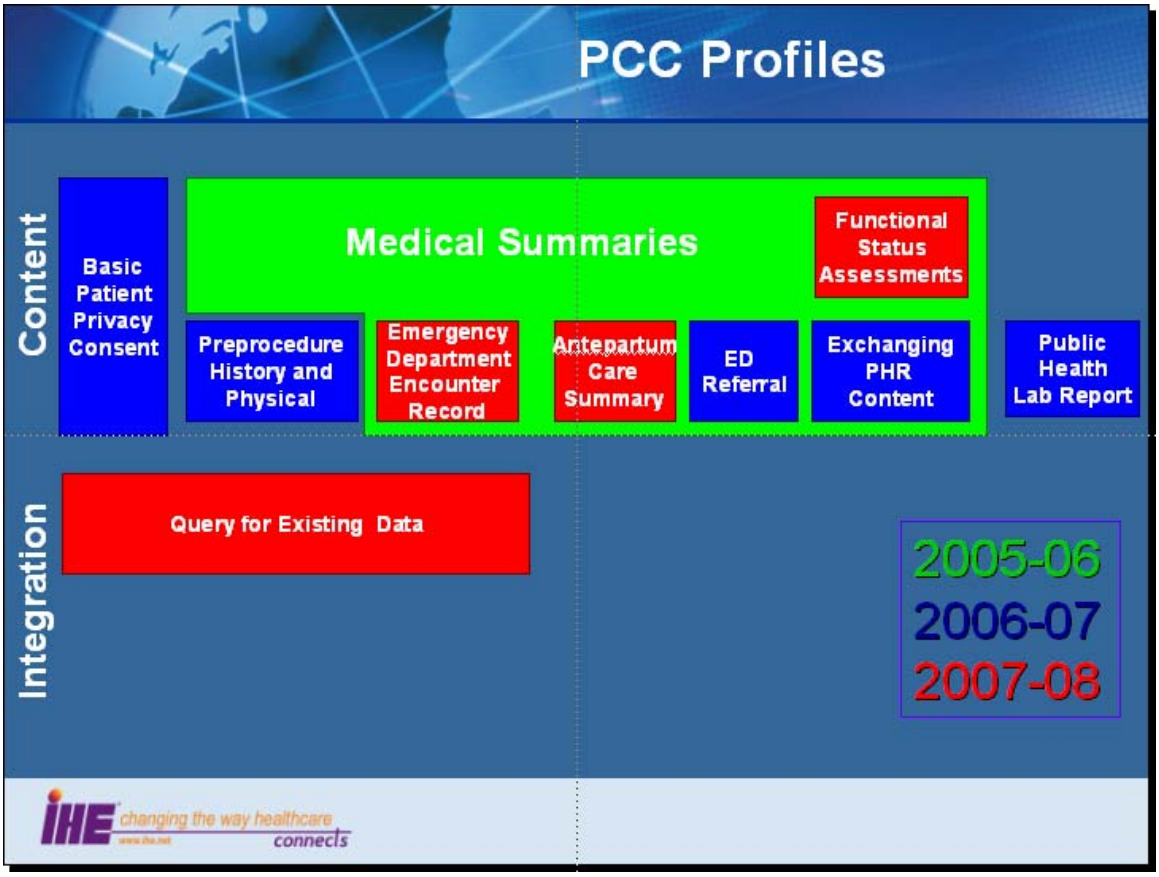

Figure 2.5-1 IHE Patient Care Coordination Content Integration Profiles

2.6 Dependencies of the PCC Integration Profiles

Dependencies among IHE Integration Profiles exist when implementation of one integration profile is a prerequisite for achieving the functionality defined in another integration profile. The table below defines these dependencies. Some dependencies require that an actor supporting one profile be grouped with one or more actors supporting other integration profiles. For example, Cross-Enterprise Sharing of Medical Summaries (XDS-MS) requires that different participating actors support the Cross-Enterprise Document Sharing (XDS) Integration Profile as well as that its actors be grouped with a Secured Node Actor of the Audit Trail and Node Authentication (ATNA) Integration Profile. The dependency exists because XDS-MS and XDS actors must support a secured communication channel with proper auditing of the exchange of patient identified information in order to function properly in an environment where protection of patient privacy is critical.

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Integration Profile	Depends on	Dependency Type	Purpose
All PCC Content Profiles	*Cross-Enterprise Document Sharing (XDS)*	Implementers of a PCC Content Profile may implement the XDS Profile to enable sharing of the clinical documents within an XDS Affinity Domain. When the XDS profile is used to provide document interchange, each PCC Content Creators must be grouped with an XDS Document Source actor, and each PCC Content Consumer must be grouped with an XDS Document Consumer actor.	Ensure that the sharing of PCC Document Content Profiles within an XDS Affinity Domain can co-exist with the sharing of other types of documents (e.g. imaging, ECG, etc.)
	Cross-Enterprise Document Media Interchange (XDM)	Implementers of a PCC Content Profile may implement the XDM Profile to enable sharing of the clinical documents using media. When the XDM profile is used to provide document interchange, each PCC Content Creator must be grouped with an XDM Portable Media Creator actors, and each PCC Content Consumer must be grouped with an XDM Portable Media Consumer.	Ensure that the sharing of PCC Document Content Profiles on media can co-exist with the sharing of other types of documents (e.g. imaging, ECG, etc.)
	Cross-Enterprise Document Reliable Interchange (XDR)	Implementers of a PCC Content Profile may implement the XDR Profile to enable sharing of the clinical documents using reliable point-to-point network messages. When the XDR profile is used to provide document interchange, each PCC Content Creator must be grouped with an XDR Document actor, and each PCC Content Consumer must be grouped with an XDR Document Recipient.	Ensure that the sharing of PCC Document Content Profiles through reliable point-to-point messages can co-exist with the sharing of other types of documents (e.g. imaging, ECG, etc.)
	Audit Trail and Node Authentication (ATNA)	Each Content Creator and Content Consumer actor shall be grouped with the ATNA Secured Node Actor	Required to manage audit trail of exported PHI, node authentication, and transport encryption.
	Consistent Time (CT)	Each Content Creator and Content Consumer actor shall be grouped with the Time Client Actor	Required to manage and resolve conflicts in multiple updates.
Exchange of Personal Health Record Content (XPHR)	*Document Digital Signatures (DSG)*	XPHR Actors should digitally sign the content, and verify the digital signature of the content before importing it.	Ensures that content is not maliciously or even accidentally altered when tranmitted between PHR and EHR systems.
Basic Patient Privacy	*XDS Scanned Documents*	Document Sources publishing Consent documents must use the XDS-SD profile	When the patient uses wet signatures (ink on paper),

Consents (BPPC)	*(XDS-SD) ITI TF-1: ?*	when creating documents containing scanned images of "wet" signatures.	XDS-SD is used to capture the actual copy of the consent that the patient signed.

Table 2.6-1 PCC Integration Profiles Dependencies

To support a dependent profile, an actor must implement all required transactions in the prerequisite profiles in addition to those in the dependent profile. In some cases, the prerequisite is that the actor selects any one of a given set of profiles.

2.6.1 XDS/XDR Option Requirements of the BPPC Profile

The tables below lists the XDS and XDR options that shall be supported by Document Registry, Document Sources and Document Consumers Actors in the BPPC profile.

Actor	Options	Vol & Section
Document Source	*Privacy Option*	ITI TF-2: 3.15.4.1.1
Document Consumer	*Privacy Option*	ITI TF-2: 3.17.4.1.1.1 ITI TF-2: 3.18.4.1.1.1
Document Registry	*Privacy Option*	ITI TF-2: 3.14.4.1.1.1 ITI TF-2: 3.18.4.1.1.1
Document Repository	*(none)*	

Table 2.6-2 XDS Option Requirements

2.6.2 XDM Option Requirements of the BPPC Profile

The table below lists the XDM options that shall be supported by XDM Actors in the BPPC profile.

Actor	Options	Vol & Section
Portable Media Creator	*Privacy Option*	ITI TF-2: 3.32.4.1.1.1
Portable Media Importer	*Privacy Option*	ITI TF-2: 3.32.4.1.1.1

Table 2.6-3 XDM Option Requirements

2.7 PCC Integration Profiles Overview

In this document, each IHE Integration Profile is defined by:

- The IHE actors involved
- The specific set of IHE transactions exchanged by each IHE actor.

These requirements are presented in the form of a table of transactions required for each actor supporting the Integration Profile. Actors supporting multiple Integration Profiles are required to support all the required transactions of each Integration Profile supported. When an Integration Profile depends upon another Integration Profile, the transactions required for the dependent Integration Profile have not been included in the table.

Note that IHE Integration Profiles are not statements of conformance to standards, and IHE is not a certifying body. Users should continue to request that vendors provide statements of their conformance to standards issued by relevant standards bodies, such as HL7 and DICOM. Standards conformance is a prerequisite for vendors adopting IHE Integration Profiles.

Also note that there are critical requirements for any successful integration project that IHE cannot address. Successfully integrating systems still requires a project plan that minimizes disruptions and describes fail-safe strategies, specific and mutually understood performance expectations, well-defined user interface requirements, clearly identified systems limitations, detailed cost objectives, plans for maintenance and support, etc.

2.7.1 Cross-Enterprise Sharing of Medical Summaries (XDS-MS)

This profiles provides a mechanism to automate the sharing process between care providers of Medical Summaries. Medical summaries are a class of clinical documents that contain the most relevant portions of information about the patient intended for a specific provider or a broad range of potential providers in different settings. Medical Summaries are commonly created and consumed by electronic medical record systems at points in time of transfers of care such as referrals or discharge.

Note that this Cross-Enterprise Sharing of Medical Summaries Integration Profile is specialized for regions or countries in term of detailed content of sections and information elements by a set of Document Content Profiles. This Integration profile has been structured to facilitate the inclusion of national extensions in the form of country or "realm" specific Content Profiles. When developed by the national IHE Chapters these will be included in the PCC TF-3.

2.7.2 Exchange of Personal Health Record Content (XPHR)

This integration profile describes the content and format of summary information extracted from a PHR system used by a patient for import into healthcare provider information systems, and visa versa. The purpose of this profile is to support interoperability between PHR systems used by patients and the information systems used by healthcare providers.

This profile does not address all the data exchange requirements of PHR systems. A PHR system may leverage other IHE Integration and Content Profiles for interoperability in addition to the XPHR Content Profile. For example, a PHR Systems may implement

XDS-MS to import medical summaries produced by EHR systems, XDS-I to import imaging information, XDS-Lab to import laboratory reports, et cetera.

2.7.3 Basic Patient Privacy Consents (BPPC)

This profile provides a mechanism to record the patient privacy consent(s), a method to mark documents published to XDS with the patient privacy consent that was used to authorize the publication, and a method for XDS Consumers to use to enforce the privacy consent appropriate to the use. The XDS profile provides little guidance on supporting privacy policies within an affinity Domain. Documents can be marked with a confidentialityCode, but no information has been provided on how to use this information to support patient privacy concerns. This profile corrects that deficiency by describing a mechanism whereby an Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. EHR systems). There are three key parts of the profile:

1. It provides a content module for capturing a patient consent to a privacy policy or policies.
2. It describes how the XDS metadata is used to support the consent policies.
3. Finally it describes the method by which XDS Actors can enforce the privacy policies determined by the document confidentialityCode and the patient privacy consents.

2.7.4 Preprocedure History and Physical (PPHP)

This purpose of this content profile is to provide a mechanism to record a pre-procedure assessment, and to communicate that assessment and other relevant documentation, such as laboratory and imaging reports to relevant parties prior to surgery.

2.7.5 Emergency Department Referral (EDR)

This profile provides a means to communicate medical summary data from an EHR System to an EDIS System during a referral from a provider to an emergency department.

2.8 Product Implementations

Developers have a number of options in implementing IHE actors and transactions in product implementations. The decisions cover three classes of optionality:

- For a system, select which actors it will incorporate (multiple actors per system are acceptable).
- For each actor, select the integration profiles in which it will participate.
- For each actor and profile, select which options will be implemented.

All required transactions must be implemented for the profile to be supported (for XDS-MS, refer to the transaction descriptions for XDS in ITI TF-2).

Implementers should provide a statement describing which IHE actors; IHE integration profiles and options are incorporated in a given product. The recommended form for such a statement is defined in PCC TF-1: Appendix C.

In general, a product implementation may incorporate any single actor or combination of actors. When two or more actors are grouped together, internal communication between actors is assumed to be sufficient to allow the necessary information flow to support their functionality; for example, the Document Source Actor of XDS-MS may use the Patient Identifier Cross-reference Consumer Actor to obtain the necessary patient identifier mapping information from its local patient id to that used in the document sharing domain. The exact mechanisms of such internal communication are outside the scope of the IHE Technical Framework.

When multiple actors are grouped in a single product implementation, all transactions originating or terminating with each of the supported actors shall be supported (i.e., the IHE transactions shall be offered on an external product interface).

The following examples describe which actors typical systems might be expected to support. This is not intended to be a requirement, but rather to provide illustrative examples.

An acute care EMR serving a hospital might include a Document Source Actor, Document Consumer Actor, a Document Repository Actor, a Patient Identification Consumer Actor, as well as a Secured Node Actor. An Ambulatory EMR serving a physician practice might include a Document Source Actor, Document Consumer Actor, a Patient Demographics Client Actor, as well as a Secured Node Actor.

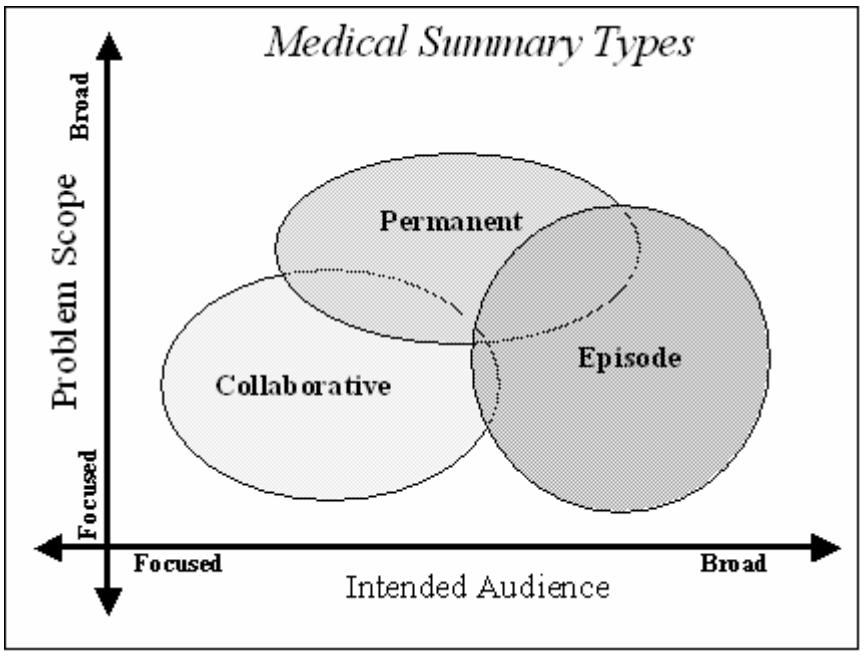
3 Patient Care Coordination Integration Profiles

3.1 Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile

3.1.1 Scope and Purpose

Patient, clinician, industry and governmental demands for improved healthcare quality have created increased focus to make patient healthcare information interoperability across disparate systems a reality.

A solution for interoperability is, however, not a simple undertaking. Unstructured textual data forms remains the predominate mechanism for information exchange among health care providers, and a good majority of data needed by physicians and other health care providers to make good clinical decisions is embedded in this free text. Efficient and effective interoperability therefore begins by identifying the most relevant documents and the most relevant sections within those documents.



By their nature, Medical Summaries form a class of clinical documents that contain the most relevant portions of this information. As the name would indicate they have the purpose of summarizing, both abstracting the most important pieces of information from the EMR and recording free-text summaries at the time of medical summary creation. Operationally, they are commonly created at points in time of transfers of care from one provider to another or from one setting to another.

Patient transfers and, therefore, the summary documents that accompany these transfers can be categorized into 3 primary types: Episodic, Collaborative, or Permanent. These categories are important because they represent a breadth of use case scenarios for

Medical Summaries. For example, summaries for collaborative transfers of care such as referral notes have a focused objective for providing the most relevant information about the patient intended *for a specific provider*. Collaborative summaries have a general audience that is generated as an artifact since they also provide the most relevant spot to obtain information about specific classes of patient problems that the patient has.

By contrast, episodic summaries have the primary purpose of highlighting the most relevant details of focused periods of time in a patient history. Examples include discharge summaries or history and physicals. Episodic summaries are written for a broad audience by intent.

Permanent transfers have yet a third purpose of summarizing the entirety of a patient's medical history and therefore covers a broader range of patient problems. The audience may be focused (as in a transfer to a new provider) or general (as in a discharge from the military).

The challenge is to identify the clinically relevant documents (and data elements those documents contain) that are used in typical "transfer of care" scenarios and then to provide interoperability standards to promote ease in transmission of those documents (and data elements). The Cross-Enterprise Sharing of Medical Summary (XDS-MS) Integration Profile facilitates this by defining the appropriate standards for document transmission and a minimum set of "record entries" that should be forwarded or made available to subsequent care provider(s) during specific transfer of care scenarios. In addition, this integration profile needs to define the utilization requirements/options for the receiving entity in order to ensure that the "care context" of the sending entity is appropriately maintained following the information transfer.

3.1.2 Process Flow

The basic process flow supported by XDS-MS mirrors current manual practices: someone gathers the appropriate documents from the patient medical record, copies them, packages them up with a cover letter explaining the reason the information is being sent, and then ships the package to the receiving provider. This is often accompanied by a telephone call from the sending provider to the receiving provider that indicates that such information is forthcoming.

Because the Collaborative care transfers and Episodic Care transfers differ significantly, these two use cases are defined. Users or implementers of this Integration Profile are offered options in the support of either of these two use cases. Permanent Care Summaries also differ significantly. However their use is less frequent; so this use case was deferred for future work.

3.1.2.1 Use Case 1: Ambulatory Specialist Referral

This use case involves a "collaborative" transfer of care for the referral of a patient from a primary care provider (PCP) to a specialist. This use case is a central component of an "e-

referral" process, which typically requires an appropriate level of agreement/collaboration between the two parties prior to the actual transfer of clinical information being initiated.

The preconditions assume a PCP sees a patient in his office. The PCP has talked to the patient and performed an examination, and has decided to refer the patient to a specialist. An assumption is made that the PCP has an EMR system with capability to write notes and manage data elements. The specific data elements managed by the PCP's EMR are expected to be the source for the information used in creating the medical summary document related to this transfer of care. A variety of EMR implementations and usage by clinicians may result in some variability in the content of the medical summary.

The detailed content of the medical summary to support this use case will be detailed as part of the document content profile specification (See the Referral Summary Content Module below).

Steps to identify the specialist and obtain insurance preauthorization have been placed out of scope for this Integration Profile.

Post conditions include the specialist physician receiving the notification of referral, locating the documents (via the Document Registry), retrieving the Documents and viewing them and optionally importing data. Import assumes the specialist with an EMR system with the capability for managing those discrete data elements.

3.1.2.2 Use Case 2: Acute Care Discharge to Ambulatory Care Environment

This use case involves an episodic transfer of care in the form of a patient discharge from a hospital to home. The attending physician in the hospital generates a discharge summary document that is used by the hospital record keeping and billing abstraction. The attending physician in the hospital may or may not also be serving as the ambulatory PCP. If not, a copy of this record is sent to the PCP as well as other specialist providers that will have ambulatory follow-up care.

The events of the use case involve creation of the discharge summary, sharing it, and notifying other providers such as the PCP's office and the surgeon's office.

The post conditions include the receipt and viewing of the discharge summary with optional import into the ambulatory EMR system.

The detailed content of the medical summary to support this use case will be detailed as part of the document content profile specification (See the Discharge Summary Content Module below).

Note that the two use cases above use the same set of transactions and differs only in the content of the Medical Summary. A process flow for these use cases using XDS and NAV is shown in the figure below. Other process flows are possible using XDM and/or XDR.

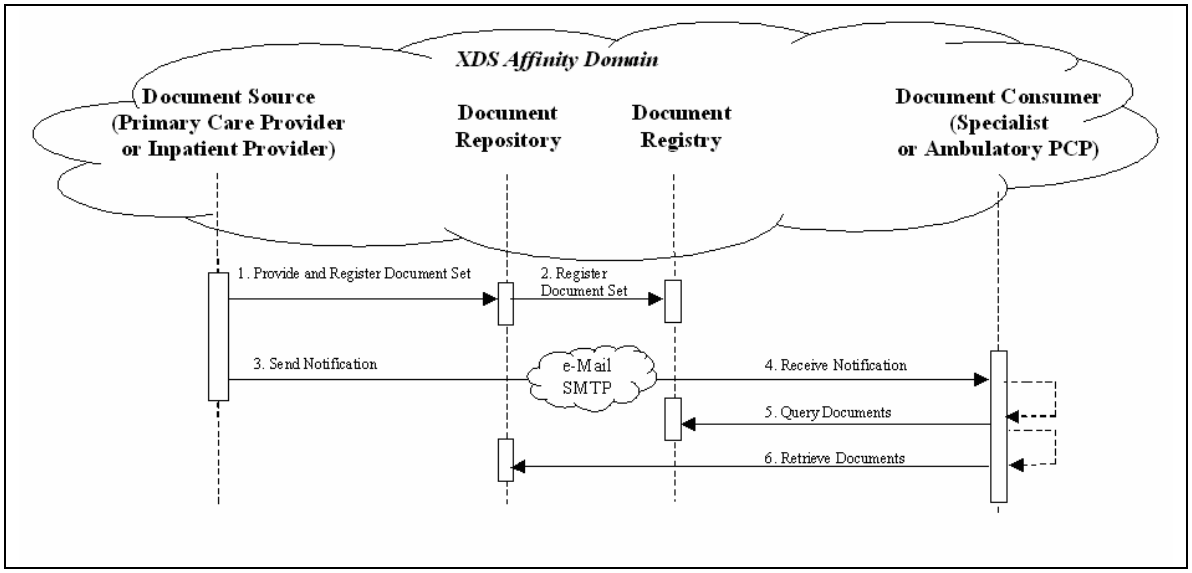


Figure 3.1-1 Use Case Process Flow Diagram

These steps are:

4. Extract/capture a collection of records into a set of documents packaged as an XDS Submission Set. This submission contains a Medical Summary, and may contain a number of other related clinical documents. Medical Summaries are clinical documents (already known in the paper world), which often serve a dual purpose of documenting an encounter, while providing the rationale for sending the information to another provider. This step utilizes the transactions provided by the ITI XDS profile to place the records in an XDS Repository (local or shared).
5. The Repository ensures that the documents of the submission set are registered with the XDS Registry of the Affinity Domain (set of cooperating care delivery institutions).
6. Notify the other provider that documents are now available for review. This step utilizes the transactions provided by the ITI NAV profile to perform the e-mail notification.
7. The e-mail notification that contains no patient identified information is received by the specialist EMR system.
8. The receiving provider can then utilize existing query transactions from the XDS profile to find the URL of the Documents.
9. Finally, the receiving provider may choose to display the document, or import relevant information from these records into their own EMR system.

3.1.2.3 Use Case for Unplanned Access to past Medical Summaries

In many cases, a provider may need to assess information from the patient care history, and patients may have Medical Summaries in the XDS repository from prior visits to other providers. For example, Medical Summaries, as well as other documents such as laboratory and radiology reports are critical for emergency physicians and nurses to provide the best care to patient in acute conditions. The figure below shows the transactions required for this use case, again, using XDS. Other process flows are possible using XDM and/or XDR.

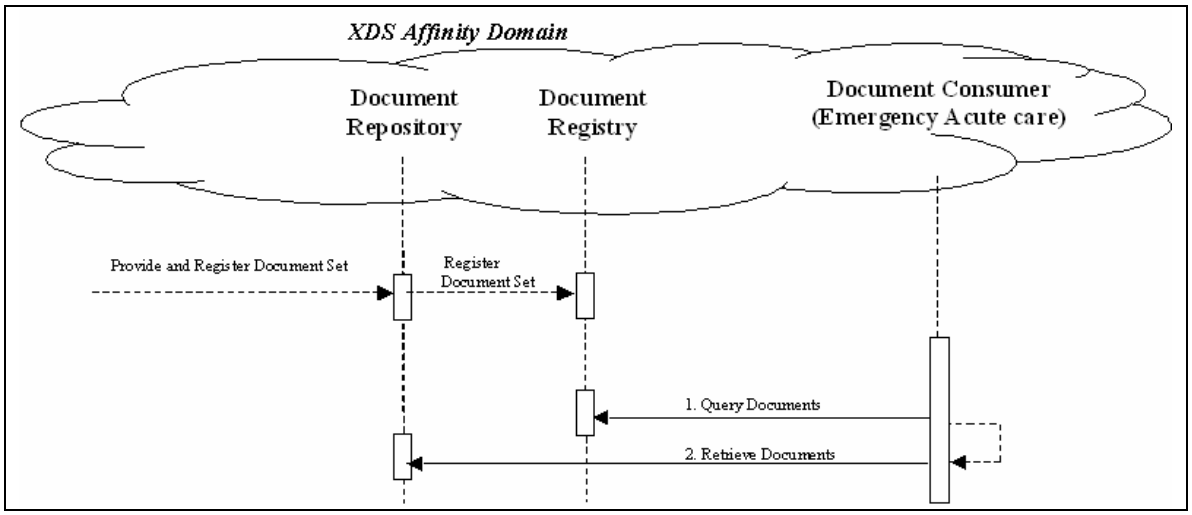


Figure 3.1-2 Unplanned Access Process Flow Diagram

3.1.2.4 Content Interoperability Levels

The use cases described above imply different levels of interoperability. At the lowest level, a clinician simply needs to be able to access and view some content such as a medical summary. At this level, minimal structured data elements must be present – just enough metadata to verify that access to that document can be accessed appropriately associated with a visual representation of the document.

Beyond this simple metadata, nearly all medical summary documents have organizational elements that group the relevant parts of the medical summary. For humans this allows for more rapid review because it is easier to skip to portions of interest for care. Computers too can take advantage of this structuring. For example, it is relevant to see the list of discharge medications from a discharge summary in relation to current medications for comparison and reconciliation.

At a very high level of interoperability, the ability to pass fully structured and codified data is necessary for computer processing and mapping. For example, the ability to import medications identified in medical summaries from another institution could have tremendous potential for ensuring that medication orders are transferred correctly.

Unfortunately, the cost for providing high levels of semantic interoperability is increased complexity of implementation, and therefore long implementation times.

The HL7 Clinical Document Architecture (CDA) standard and Care Record Summary (CRS) CDA implementation guides support progressive interoperability at multiple levels of complexity, from those needed to provide simple low level interoperability for supporting the most important use case of simple viewing to those providing a path to progressively higher levels of interoperability for vendors and providers wishing to implement it. CDA as constrained in the CRS implementation guides is therefore the base standard for the XDS-MS content profile.

The XDS-MS content profile builds on and further constrains the CDA-CRS implementation guide by defining the required and optional sections required for the Acute Care Discharge and Specialist Referral use cases. Additionally, it places constraints for the most important sections (Medication, Allergy and Problems) of Medical Summaries to ensure that structured field level data are provided.

The figure below shows how the XDS-MS Content profile defines these progressive levels of interoperability for sections of different importance. Header metadata must be present and coded. Most sections must define, at minimum, a section label to identify that section. For the Medication, Allergy, and Problems Sections, data must contain a more granular field level data as discrete text (for example dose or frequency). This is referred to as structured textual representation. Note that the textual strings in this structured text are not duplicates of the textual strings in the human readable text, but simply referenced extracts from the human readable text content, reducing the risk for inconsistencies

Granular field level data may then be optionally coded. If any coded terminology is used it shall be uniquely identified.

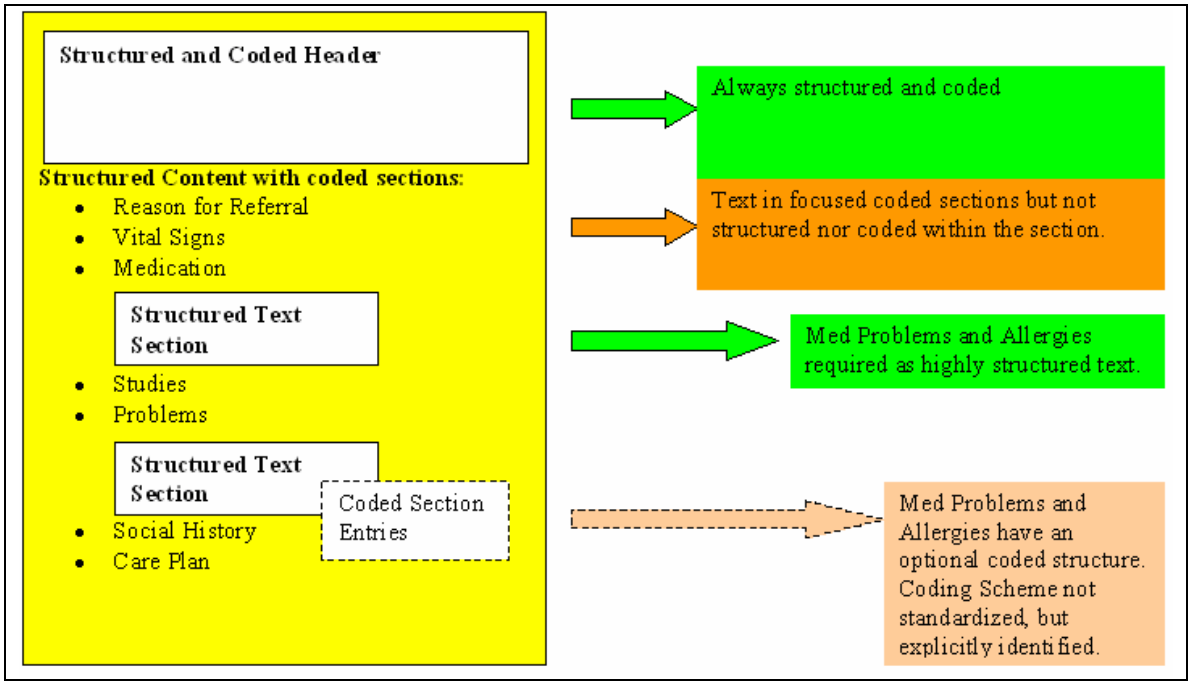


Figure 3.1-3 Tiered Interoperability Levels

Note: The lack of mature and broadly accepted standards for coded terminology requires that this integration profile not specify specific coded vocabularies. However, when agreements can be reached, the capability to exchange coded level information is possible. IHE has on its roadmap to continue working with appropriate standards bodies so that coded terminology standards can be added to this profile in the future.

3.1.2.5 Use Case Conclusion

The process flow of this profile exhibits a great deal more power and flexibility than the existing manual process. The physician workflow is improved by reusing an existing work product in the very first step (the summary report) to accomplish two purposes: recording care that has been provided, and communicating with another provider.

Secondly, each step utilizes the power of inter-connected EMR systems to make the entire process faster, easier, and less reliant on human labor to accomplish the same feats. This results in reduced time to transfer records between providers, safer transport of the information, and more reliable receipt.

Lastly, the process facilitates the import of relevant data from one set of patient records to the receiving physicians EMR system, resulting in more reliable transfer of information, reduced labor costs transferring information from one provider to another and less time required by the patient to provide information that is already in the physician's possession.

3.1.3 Actors/Transaction

There are two actors in the XDS-MS profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor. The sharing or transmission of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described in the section on Content Bindings with XDS, XDM and XDR.

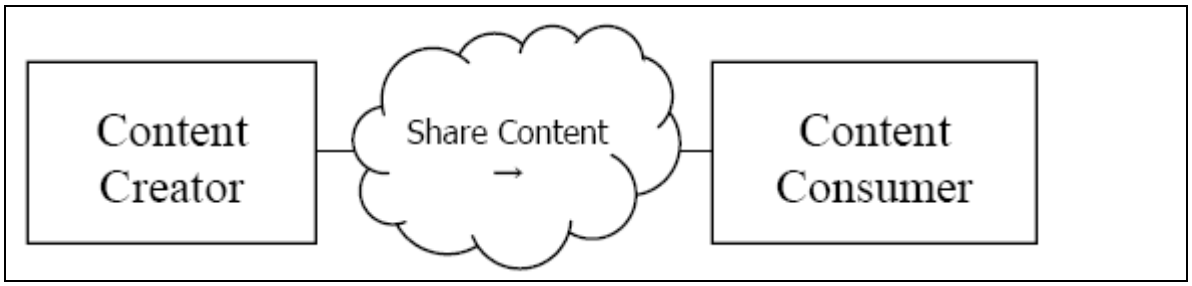


Figure 3.1-4 XDS-MS Actor Diagram

3.1.4 Options

Actor	Option
Content Consumer	View Option (1)
	Document Import Option (1)
	Section Import Option (1)
	Discrete Data Import Option (1)
Content Creator	Referral Option (1)
	Discharge Summary Option (1)

Table 3.1-1 XDS-MS Options

Note 1: The Actor shall support at least one of these options.

3.1.5 Content Consumer Options

3.1.5.1 View Option

This option defines the processing requirements placed on Content Consumers for providing access, rendering and management of the medical document. See the View Option in PCC TF-2 for more details on this option.

3.1.5.1.1 Display Transform

A Content Creator Actor should provide access to a style sheet that ensures consistent rendering of the medical document content as was displayed by the Content Consumer Actor.

The Content Consumer Actor must be able to present a view of the document using this style sheet if present.

3.1.5.2 Document Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing the entire medical document and managing it as part of the patient record. See the Document Import Option in PCC TF-2 for more details on this option.

3.1.5.3 Section Import Option

This option defines the processing requirements placed on Content Consumers for providing access to, and importing the selected section of the medical document and managing them as part of the patient record. See the Section Import Option in PCC TF-2 for more details on this option.

3.1.5.4 Discrete Data Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing discrete data from selected sections of the medical document and managing them as part of the patient record. See the Discrete Data Import Option in PCC TF-2 for more details on this option.

3.1.6 Content Creator Options

3.1.6.1 Referral Option

Content Creators implementing this option shall create Referrals that comply with the Referral Content Module found in PCC TF-2.

3.1.6.2 Discharge Summary Option

Content Creators implementing this option shall create Discharge Summaries that comply with the Discharge Summary Content Module found in PCC TF-2.

3.1.7 Coded Terminologies

This profile supports the capability to record entries beyond the IHE required coding associated with structured data. Content Creators and Content Consumers may choose to utilize coded data, but interoperability at this level requires an agreement between the communicating parties that is beyond the scope of this Profile.

To facilitate this level of interoperability, the applications that implement actors within this profile shall provide a link to their HL7 conformance profile within their IHE Integration statement. The conformance profile describes the structure of the information which they are capable of creating or consuming. The conformance profile shall state which templates are supported by the application (as a Content Creator or Content Consumer), and which vocabularies and/or data types are used within those templates. It should also indicate the optional components of the entry that are supported.

See the HL7 Refinement Constraint and Localization for more details on HL7 conformance profiles.

3.1.8 Content Bindings with XDS, XDM and XDR

It is expected that this profile will be used environment where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross-Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ), and notification of availability of documents (NAV).
- A media-based infrastructure is defined by the IHE Cross-Enterprise Document Media Interchange (XDM) profile.
- A reliable messaging-based infrastructure is defined by the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile.
- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework, found here: http://www.ihe.net/Technical_Framework/.

Such an infrastructure is assumed by the use cases that focus on the context for defining the specific clinical information content for this profile.

A content binding describe how the payloads used in IHE transactions are related to and/or constrained by the data elements contained within the content sent or received in those transactions. This section is where any specific dependencies between the content and transaction are defined. The Patient Care Coordination Technical Framework defines a binding to use when grouping the Content Creator of this Profile with the IHE ITI XDS, XDM or XDR Integration Profiles.

Content	Binding	Actor	Optionality
Referral Summary	Medical Document Binding to XDS, XDM and XDR	Content Creator	O (Note 1)
		Content Consumer	R

Discharge Summary	Medical Document Binding to XDS, XDM and XDR	Content Creator	O (Note 1)
		Content Consumer	R

Figure 3.1-5 Content Bindings

Note 1: Content Creators must support generation of at least one type of content from this table with a transaction in order for the transaction to meet the requirements of the XDS-MS profile. Content Consumers must support both types of content to meet these requirements.

3.1.9 Content Modules

Content modules describe the content of a payload found in an IHE transaction. Content profiles are transaction neutral. They do not have dependencies upon the transaction that they appear in. These dependencies are reflected in the Bindings listed above.

3.1.9.1 Referral Summary

All referral summaries shall be structured and coded as required by the Referral Summary Content Module described in PCC TF-2. The inclusion of the specific coded attributes explicitly defined as optional, may be supported by specific implementations of Document Sources using an IHE identified coded terminology of their choice. The requirements and manner in which implementations support such capabilities is beyond the scope of this Integration Profile.

3.1.9.2 Discharge Summary

All discharge summaries shall be structured and coded as required by the Discharge Summary Content Module described in PCC TF-2. The inclusion of the specific coded attributes explicitly defined as optional, may be supported by specific implementations of Document Sources using an IHE identified coded terminology of their choice. The requirements and manner in which implementations support such capabilities is beyond the scope of this Integration Profile.

3.1.10 Grouping with other Profile Actors

Content profiles may impose additional requirements on the transactions used when grouped with actors from other IHE Profiles.

3.1.10.1 Cross Enterprise Document Sharing, Media Interchange and Reliable Messages

Actors from the ITI XDS, XDM and XDR profiles embody the Content Creator and Content Consumer sharing function of this profile. A Content Creator or Content Consumer must be grouped with appropriate actors from the XDS, XDM or XDR profiles, and the metadata sent in the document sharing or interchange messages has

specific relationships to the content of the clinical document described in the content profile. These are described in Content Bindings with XDS, XDM and XDR above.

3.1.10.2 Notification of Document Availability (NAV)

A Document Source should provide the capability to issue a Send Notification Transaction per the ITI Notification of Document Availability (NAV) Integration Profile in order to notify one or more Document Consumer(s) of the availability of one or more documents for retrieval. One of the Acknowledgement Request options may be used to request from a Document Consumer that an acknowledgement should be returned when it has received and processed the notification.

A Document Consumer should provide the capability to receive a Receive Notification Transaction per the NAV Integration Profile in order to be notified by Document Sources of the availability of one or more documents for retrieval. The Send Acknowledgement option may be used to issue a Send Acknowledgement to a Document Source that the notification was received and processed.

3.1.10.3 Document Digital Signature (DSG)

When a Content Creator Actor of the XDS-MS Integration Profile needs to digitally sign a medical summary or any other documents in a submission set, it may support the Digital Signature (DSG) Content Profile as a Document Source.

When a Content Consumer Actor of the XDS-MS Integration Profile needs to verify a Digital Signature, it may retrieve the digital signature document and may perform the verification against the signed document content.

3.1.11 Security Considerations

The XDS-MS Integration Profile assumes that a minimum security and privacy environment has been established across all participants. There must exist security policies regarding the use of training, agreements, risk management, business continuity and network security that need to be already in place prior to the implementation of XDS-MS.

The IHE ITI ATNA Integration Profile is required of the actors involved in the IHE transactions specified in this profile to protect node-to-node communication and to produce an audit trail of the PHI related actions when they exchange messages.

In addition, the IHE ITI DSG Integration Profiles can be applied to the actors involved in the transactions specified in this profile to securely identify individuals involved in transactions and verify document integrity and authorizations (DSG).

Interested parties should also read the detailed Security Considerations sections provided for each of the aforementioned profiles in the IHE ITI Technical Framework and its supplements.

The XDS-MS profile does have a few security considerations of its own.

EMR systems should be thoughtfully designed so that providers are able to review and verify information before it is imported into their EMR system, and that positive user acknowledgements are made before import, and audit trails are recorded when imports occur.

Imported information should be traceable both to the source [the sharing EMR], and the receiver that accepted it into the EMR system. XDS Affinity domain policies should support policies and procedures for tracing information flows between EMR systems.

Because the information being transferred is in XML, it will be common that different EMR systems utilize different transformations to render the contents into human readable form. A Content Creator should make available the transforms used by the sending provider to review the documents, and a Content Consumer must support rendering the information as seen by the sending provider, allowing both providers to see what was sent in its original rendered form.

3.2 XPHR Integration Profile

The **Exchange of Personal Health Record Content (XPHR)** integration profile describes the content and format of summary information extracted from a PHR system used by a patient for import into healthcare provider information systems, and visa versa. The purpose of this profile is to support interoperability between PHR systems used by patients and the information systems used by healthcare providers. This profile does not address all the data exchange requirements of PHR systems. A PHR system may leverage other IHE Integration and Content Profiles for interoperability in addition to the XPHR Content Profile. For example, a PHR Systems may implement XDS-MS to import medical summaries produced by EHR systems, XDS-I to import imaging information, XDS-Lab to import laboratory reports, et cetera.

3.2.1 Exchange of Personal Health Record Content (XPHR)

Upon seeing a healthcare provider for the first time, patients are requested to provide a great deal of information, including, their address, telephone numbers, birth date, sex, marital status, emergency contacts, insurance information, a medical and family history, and current medications and allergies. This information is also reviewed and updated on subsequent visits. This information is usually obtained by having the patient fill out one or more forms, whose contents are then manually transferred in to the information systems used by the healthcare provider. Automating this process will reduce transcription errors during the transfer of information, speed up the registration and check-in processes for patients, and also makes it possible for patients to have more participation in the management of their health information.

Providers also need to participate in helping patients to manage their healthcare information, however, providers should not be solely responsible for updating the patient's health record, since they often are only participating in a portion of the patient's overall health activities.

While PHR systems will allow patients to manage their healthcare information, and EHR and other information systems allow healthcare providers to manage the electronic records they maintain for their patients, but these two systems, operating separately, are not sufficient to allow patients and providers to collaborate in the care of the patient. What is needed is a way to integrate the activities of patients using a PHR system and healthcare providers using an EHR or other information system to provide for collaborative care between the patient and their provider.

The XPHR profile is intended to provide a mechanism for patients to supply the information most often requested by their healthcare providers, and to allow those same providers to assist patients in keeping their personal healthcare information up to date. It achieves this by allowing patients to provide a summary of their PHR information to providers, and gives providers a mechanism to suggest updates to the patient's PHR upon completion of a healthcare encounter.

3.2.2 Actors/Transaction

There are two actors in the XPHR profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor. The sharing or transmission of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described in the section on Content Bindings with XDS, XDM and XDR.

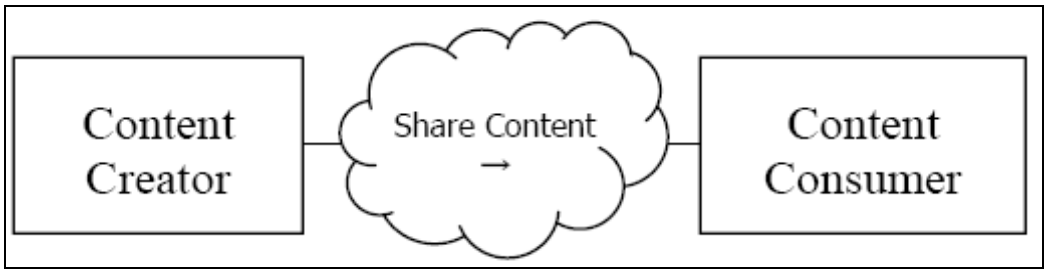


Figure 3.2-1 XPHR Actor Diagram

3.2.3 Options

Actor	Option
Content Consumer	View Option (1)
	Document Import Option (1)
	Section Import Option (1)
	Discrete Data Import Option (1)
Content Creator	Update Option

Table 3.2-1 XPHR Options

Note 1: The Actor shall support at least one of these options.

3.2.4 Content Consumer Options

3.2.4.1 View Option

This option defines the processing requirements placed on Content Consumers for providing access, rendering and management of the medical document. See the View Option in PCC TF-2 for more details on this option.

3.2.4.1.1 Display Transform

A Content Creator Actor should provide access to a style sheet that ensures consistent rendering of the medical document content as was displayed by the Content Consumer Actor.

The Content Consumer Actor must be able to present a view of the document using this style sheet if present.

3.2.4.2 Document Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing the entire medical document and managing it as part of the patient record. See the Document Import Option in PCC TF-2 for more details on this option.

3.2.4.3 Section Import Option

This option defines the processing requirements placed on Content Consumers for providing access to, and importing the selected section of the medical document and managing them as part of the patient record. See the Section Import Option in PCC TF-2 for more details on this option.

3.2.4.4 Discrete Data Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing discrete data from selected sections of the medical document and managing them as part of the patient record. See the Discrete Data Import Option in PCC TF-2 for more details on this option.

3.2.5 Content Creator Options

3.2.5.1 Update Option

3.2.6 Coded Terminologies

This profile supports the capability to record entries beyond the IHE required coding associated with structured data. Content Creators and Content Consumers may choose to utilize coded data, but interoperability at this level requires an agreement between the communicating parties that is beyond the scope of this Profile.

To facilitate this level of interoperability, the applications that implement actors within this profile shall provide a link to their HL7 conformance profile within their IHE Integration statement. The conformance profile describes the structure of the information which they are capable of creating or consuming. The conformance profile shall state which templates are supported by the application (as a Content Creator or Content Consumer), and which vocabularies and/or data types are used within those templates. It should also indicate the optional components of the entry that are supported.

See the HL7 Refinement Constraint and Localization for more details on HL7 conformance profiles.

3.2.7 Content Bindings with XDS, XDM and XDR

It is expected that this profile will be used environment where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross-Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ), and notification of availability of documents (NAV).
- A media-based infrastructure is defined by the IHE Cross-Enterprise Document Media Interchange (XDM) profile.
- A reliable messaging-based infrastructure is defined by the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile.
- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework, found here: http://www.ihe.net/Technical_Framework/.

Such an infrastructure is assumed by the use cases that focus on the context for defining the specific clinical information content for this profile.

A content binding describe how the payloads used in IHE transactions are related to and/or constrained by the data elements contained within the content sent or received in those transactions. This section is where any specific dependencies between the content and transaction are defined. The Patient Care Coordination Technical Framework defines a binding to use when grouping the Content Creator of this Profile with the IHE ITI XDS, XDM or XDR Integration Profiles.

Content	Binding	Actor	Optionality
PHR Extract	Medical Document Binding to XDS, XDM and XDR	Content Creator	R
		Content Consumer	R
PHR Update	Medical Document Binding to XDS, XDM and XDR	Content Creator	O
		Content Consumer	R

Table 3.2-2 XPHR Content Binding

3.2.8 XPHR Content Modules

3.2.8.1 PHR Extract Module

The content exchanged shall be structured and coded as required by the PHR Extract Module Content found in PCC TF-2. The Content Creator Actor creates a PHR Extract and shares it with the Content Consumer.

3.2.8.2 PHR Update Module

The content exchanged shall be structured and coded as required by the PHR Update Module Content found in PCC TF-2. The Content Creator Actor creates a PHR Update document as an addendum to a previously exchanged PHR Extract document. This Update is an addendum to the prior document, and reflects changes to that document that are suggested by the Content Creator Actor. A Content Consumer actor shall support viewing of an Update document, and may support import of the Update to reflect those changes to the PHR.

The purpose of this content module is to provide a mechanism whereby healthcare providers, using applications that implement the Content Creator Actor, can suggest updates to a PHR for a patient.

3.2.9 XPHR Integration Profile Process Flow

One key use scenarios has been identified as an example. This use case originated in the Cross-Enterprise Document point-to-point Interchange (XDP) profile, and is reproduced here.

3.2.9.1 Personal Health Record (PHR) to ED/Primary Care EHR

Precondition: A patient is using a Personal Health Record application system at home for the record keeping of patient-originated medical information (e.g. social history, family history), snapshots of clinical information that may have been provided from previous care encounters (e.g. medication list, immunization records, etc), and current observations from home care medical devices (e.g. blood pressure, blood sugar level, etc).

Events: The patient requests their provider give them initial information to initialize their new PHR system. Later the patient does an extract of his PHR onto a portable media (USB key, CD) to bring to the care facility as a current set of medical data for the clinician. The patient experiences a medical condition requiring that he needs to present at the ED or his PCP for care. The ED physician or primary care physician receives the portable media from the patient and loads it an office PC to display and/or import, as desired, the information provided on the portable media. Following the encounter, the provider does an extract of appropriate data elements from the office EMR to yield a snapshot of the patient's medical record. This snapshot is then transferred to an interchange media for the patient to bring home and update his private PHR. The patient imports this document and uses the information in it to update the content of their PHR: e.g., by applying the changes recorded in the PHR Update appropriately .

Postcondition: The patient's PHR is up to date.

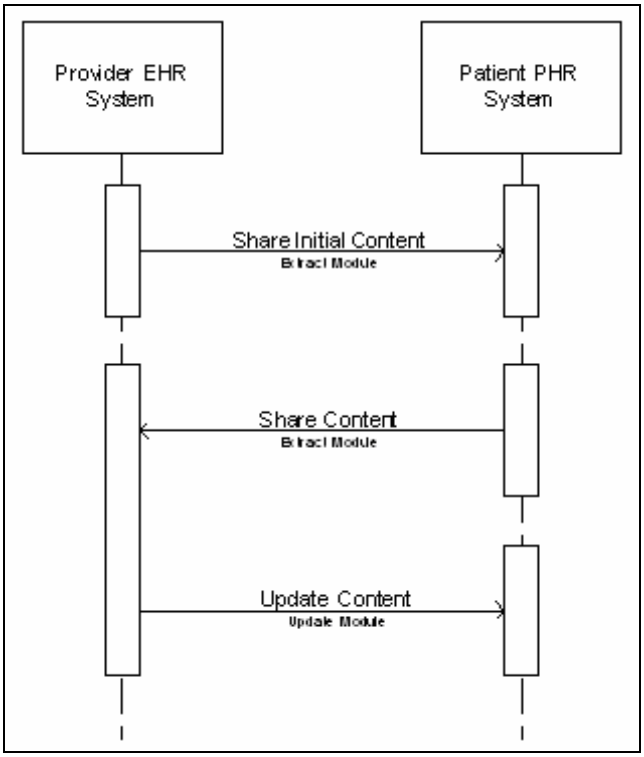


Figure 3.2-2 Basic Process Flow in XPHR Profile

3.2.10 Grouping with Other Actors

3.2.10.1 Cross Enterprise Document Sharing, Media Interchange and Reliable Messaging

The Content Creator and Content Consumer Actors shall be grouped with appropriate actors from the XDS, XDM or XDR integration profiles to support sharing of PHR Extracts and PHR Updates.

3.2.10.2 Document Digital Signature (DSG)

Content Creator actors should digitally sign all documents using the Digital Signature (DSG) Content Profile.

Content Consumer actors should verify the Digital Signature of the submission set before use of the information it contains.

3.3 BPPC Integration Profile

The document sharing infrastructure provided by XD* allow for the publication and use of clinical documents associated with a patient. The XDS/XDR system requires that the

Affinity Domain create and agree to a single policy (See IHE-ITI Vol 1:Appendix L). The Affinity Domain Policy is enforced in a distributed way through the inherent access controls of the systems involved in the Affinity Domain. This profile will use terms consistent with ISO 22600 - Privilege Management and Access Control (PMAC), but is not restricted to systems that implement PMAC. The systems involved in XDS are expected to support sufficient Access Controls to carry out the Policy of the Affinity Domain.

Today this single Affinity Domain Policy restriction means that much of the useful data is not entered into the XDS, or that the access to this data is too liberally allowed. This profile allows for the Affinity domain to have a small number of privacy consents. This allows for more flexibility to support some patient concerns, while providing an important and useful dataset to the healthcare provider.

Healthcare providers utilize many different sets of data to carry out treatment, billing, and normal operations. This information may include patient demographics, contacts, insurance information, dietary requirements, general clinical information and sensitive clinical information. This information may be published to XDS as independent documents under different privacy consent policies.

Healthcare providers in different functional roles will have different needs to access these documents. For example, administrators may need to be able to access the patient demographics, billing and contact documents. Dietary staff will need access to the dietary documents but would not need access to insurance documents. General care providers will want access to most clinical documents, and direct care providers should have access to all clinical documents.

This profile provides a mechanism by which an affinity domain can create a basic vocabulary of codes that identify affinity domain privacy consent policies with respect to information sharing. Each privacy consent policy should identify in legal text what are the acceptable re-disclosure uses, which functional roles may access a document and under which conditions. Each privacy consent will be assigned a unique XDS Affinity Domain wide OID by the administration of the XDS Affinity Domain with care to respect any inheritance of previous privacy consent policies. Future profiles may include structured and coded language that can be used to support dynamic understanding of the patient's directives (see HL7 and OASIS).

3.3.1 Basic Patient Privacy Consent Use-Cases

This section gives examples of some possible patient privacy consent policies and how the systems publishing documents and using documents might act. This is an informative section and should not be interpreted as the only way to implement the BPPC profile.

3.3.1.1 Wet Signature

Big Hospital has not yet fully digitized their patient consents process. They have a paper document that describes their Privacy Consent Policy. In our example this Privacy Consent Policy will be referenced as policy 9.8.7.6.5.4.3.2.1. Our example is ridiculous, but points out that the content of the policy is legal text, and that we provide no structured or coded way to interpret. This policy looks like:

> It is the policy of Big Hospital that when a patient signs a consent that says "It's OK" then big hospital can do anything it wants with the patient's data.

Figure 3.3-1 Simplistic Policy Example

Big Hospital has the patient acknowledge this consent through ink on paper. This act produces the Patient Privacy Consent, For Example:

Sample Consent: by A. Patient. It's OK

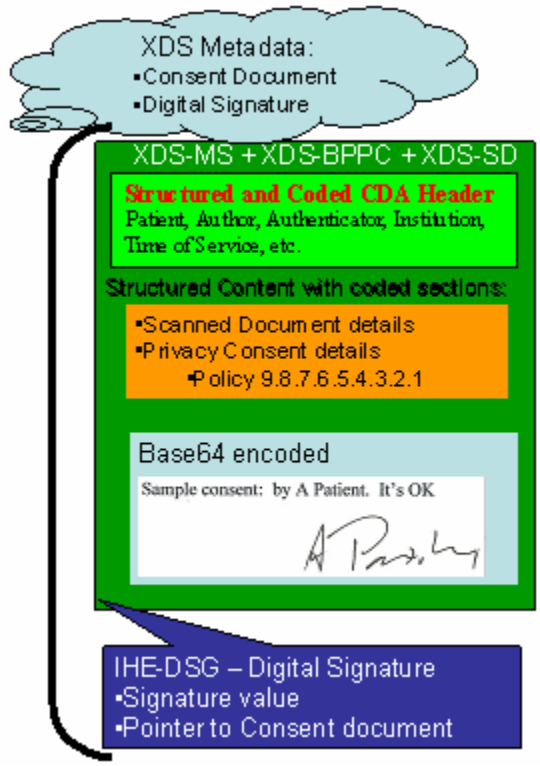
Figure 3.3-2 Simplistic Consent Example

This acknowledgement is captured according to the XDS-SD profile, with the additional parameters specified in the BPPC profile also applied to the CDA wrapper. This is registered with the XDS as proof that the patient has consented to policy 9.8.7.6.5.4.3.2.1. This acknowledgement will have its own OID as any document registered in XDS will have, but this instance OID is not further used.

This example is available on the IHE wiki for educational purposes.

If the hospital wants to further provide authenticity protections they may apply a DSG digital signature to the whole package with the appropriate purpose and signed by an appropriate signing system/person.

The following shows this graphically:



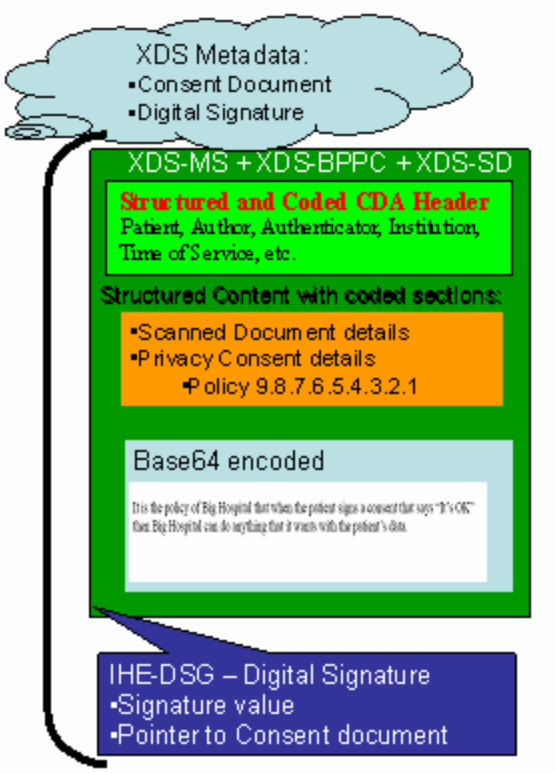
3.3.1.2 Implied Consent vs Explicit Consent

This profile supports both Implied Consent as well as Explicit Consent environments. In order to provide a profile with global appeal we have supported both environments. In an implied consent environment a Document Consumer will not find an instance of a Patient Privacy Consent document in the XDS, as capturing the act of consenting would not be required. This may be true in an Explicit Consent environment as well in cases where getting the explicit consent is delayed due to medical reasons (e.g. emergency).

In an implied Consent environment, the clinical documents submitted to the XDS would need to be marked with the general use consent, where other documents may have additional explicit consents.

3.3.1.3 Electronic Patient Consent

In this use case we move forward to a XDS Affinity Domain where the patient has a unique Public Certificate. This use case has the patient digitally signing the consent. In this case we don't capture a wet signature. For this example we include the PDF of the consent text, and this is what the patient signs. The patient's digital signature is captured using the IHE Digital Signature (DSG) profile, as shown below:



3.3.1.4 Administrative Use

Healthcare providers utilize many different sets of data to carry out the treatment, billing, and normal operations. When a patient presents, often the patient must fill out volumes of information used for patient demographics, contacts, and insurance.

For this example we might illustrate a registration system that captures a scanned image of the patient's insurance card. This scanned image can be submitted to the XDS using the confidentiality code indicating that it is available for administrative uses. This registration system could additionally capture the typical demographics and such in a form of coded clinical document that is also published as available for administrative use. Both of these documents don't have clinical information and thus wouldn't need to be restricted to direct care providers.

Now that we have shown how this information can be captured. We can see cases where the patient presents at a different clinic in the same XDS Affinity Domain. The administrative staff can now query the XDS and simply confirm that the information is the same.

3.3.1.5 Clinical Support Staff Use

The patient when staying for a few days might have special dietary needs based on their conditions. These dietary needs could be documented in the XDS and marked as for

clinical support staff. This document could be accessed by the dietitian when preparing the meals.

3.3.1.6 Mixed Patient Privacy Consents

As can be seen by the use-cases shown already over time an XDS Affinity Domain may have a mixture of implied consent, wet signature consents and patient digital signature consents. The XDS Affinity Domain will also have multiple generations of patient consents.

3.3.1.7 Policies in an environment with comprehensive access controls

An Affinity Domain may have jurisdictional or organizational policies that require support for more complex patient privacy consent policies. These privacy policies may require that a patient explicitly consent to disclosure of protected or sensitive health information to specific entities. The BPPC profile provides a starting point for implementing these types of privacy consent policies, but does not explicitly specify how additional information needed to enforce the policy would be conveyed.

For example, in a jurisdiction that requires explicit patient consent to disclose psychotherapy notes:

1. The Affinity Domain would define sufficiently explicit functional roles as well as contextual and user specific role information to support these policies in the consent provided.
2. The Affinity Domain would include a sensitivity marker for psychotherapy notes and may only permit access by the functional role
    1. "named entity", where the named entity identifier must match the identifier of the named entity in the patient's associated consent document associated with the patient's health document;
    2. an "unnamed entity" based on a time limited and non-transferable "shared secret key" supplied to the entity by the patient and authenticated by some algorithm the information in the patient's associated consent document; or
    3. an emergency provider who submits a "break the glass key" administered by the Affinity Domain that has an appropriate audit trail with documentation of the provider's reason and context for use per Affinity Domain policy.

The psychotherapy notes would then be submitted to the XDS using the confidentiality code indicating that it is available only to these entities.

In addition to document type level sensitivity markers, e.g., psychotherapy notes, an Affinity Domain might also support sensitivity markers for types of health information that might be included in documents of many types. There may be sensitivity markers for any document that includes diagnosis, procedure, medication, location, or provider

information which the patient believes may indicate that the patient has genetic, substance use, HIV-AIDs, mental health or other conditions, which the patient wishes to mask. Another use for sensitivity markers is for victims of abuse who wish to mask all records containing their demographic information.

3.3.2 Privacy Access Policies (Informative)

One possible implementation may have a collection of policies and sensitivity markers form an access control matrix. A simple access control matrix is shown in the table below.

Sensitivity / Functional Role	Billing Information	Administrative Information	Dietary Restrictions	General Clinical Information	Sensitive Clinical Information	Research Information	Mediated by Direct Care Provider
Administrative Staff	X	X					
Dietary Staff		X	X				
General Care Provider		X	X	X			
Direct Care Provider		X	X	X	X		X
Emergency Care Provider		X	X	X	X		X
Researcher						X	
Patient or Legal Representative	X	X	X	X	X		

Table 3.3-1 Sample Access Control Policies

The matrix can be sliced vertically. By slicing the matrix vertically (by sensitivity marker), a single patient consent policy (aka. sensitivity marker) vocabulary can be established. This vocabulary must then be configured in the XDS Affinity Domain.

Using the example above, the privacy consent policies would be.

Privacy Consent Policy	Description
Billing Information	May be accessed by administrative staff and the patient or their legal representative.
Administrative Information	May be accessed by administrative or dietary staff or general, direct or emergency care providers, the patient or their legal representative.

Dietary Restrictions	May be accessed by dietary staff, general, direct or emergency care providers, the patient or their legal representative.
General Clinical Information	May be accessed by general, direct or emergency care providers, the patient or their legal representative.
Sensitive Information	May be accessed by direct or emergency care providers, the patient or their legal representative.
Research Information	May be accessed by researchers.
Mediated by Direct Care Provider	May be accessed by direct or emergency care providers.

Table 3.3-2 Privacy Consent Policies When Expressed by Document Sensitivity

The access control matrix can also be sliced horizontally by functional role. This requires that a separate vocabulary for document Privacy Consent Policy be configured in the XDS Affinity Domain.

Privacy Consent Policy	Description
Administrative Staff	May access documents that describe their sensitivity with the Billing Information or Administrative Information code.
Dietary Staff	May access documents that describe their sensitivity with the Administrative Information or Dietary Restrictions codes.
General care providers	May access documents that describe their sensitivity with the Administrative Information, Dietary Restrictions or General Clinical Information codes.
Direct care providers	May access documents that describe their sensitivity with the Administrative Information, Dietary Restrictions, General Clinical Information, or Sensitive Clinical Information codes.
Emergency care providers	May access documents that describe their sensitivity with the Administrative Information, Dietary Restrictions, General Clinical Information, or Sensitive Clinical Information codes.
Researchers	May access documents that describe their sensitivity with the Research Information code.
Patient (or legal representative)	May access documents that describe their sensitivity with the Administrative Information, Dietary Restrictions, General Clinical Information, or Sensitive Clinical Information codes.

Table 3.3-3 Privacy Consent Policies when Expressed by Functional Role

Other divisions of the access control matrix are possible, so long as a Privacy Consent Policy covers each cell granting access in the matrix.

3.3.2.1 References

The following list of references is provided as good references to understand the terms and concepts presented here. These references are not required by this profile.

- ISO/TS 21298 "Health informatics – Functional and structural roles".
- ISO/TS 22600 "Health Informatics – Privilege Management and Access Controls".
- CEN prEN 13606-4 "Health informatics — Electronic health record communication — Part 4: Security requirements and distribution rules"

3.3.3 Creating Privacy Consent Policies

A Privacy Consent Policy shall identify who has access to information, and what information is governed by the policy (e.g., under what conditions will a document be marked as containing that type of information). The XDS Affinity Domain shall publish privacy Consent Policies. The mechanism for publishing these policies is not described by this profile. The Privacy Consent Policies written by the XDS Affinity Domain must be able to be implemented by the technologies in all of the systems that have access to the XDS Affinity Domain. This means that the Privacy Consent Policies must be created with great care to ensure they are enforceable.

The implementation of Privacy Consent Polices under this profile makes it strongly advisable that policies describe under what situations a functional role shall have access to information, and do not include situations in which a functional role is not granted access. Take care when writing access control policies. The two policy statement examples below illustrate the problem.

1. A Researcher may >>only<< access documents that describe their sensitivity with the Clinical Trial 1 code.
2. A Researcher may >>only<< access documents that describe their sensitivity with the Research Project 1 code.

The first policy grants access to a researcher to one class of documents (those marked with the Clinical Trial 1 code), and due to the word "only", effectively revokes access to all other documents. The second policy does the same thing (for Research Project 1), and revokes access to all other documents. These two policies cannot be applied at the same time, as they are incompatible with each other. The solution is to strike the word >>only<< and thus the two Privacy Consent Policies are able to be aggregated.

An XDS Affinity Domain may have legacy documents that were published prior to all systems supporting the BPPC Profile, and thus will have confidentiality codes not defined under the BPPC Profile (e.g. For example, "N" from 2.16.840.1.113883.5.25). The XDS Affinity Domains will need to provide Privacy Consent Policies for granting access to documents that use these non-BPPC confidentiality code values.

Affinity domains should also determine their strategy for addressing the changing of Privacy Consent Policies and the policy vocabularies.

Finally, Privacy Consent Policies used within an XDS Affinity Domain will very likely be different than those used with the XDM or XDR Profiles. The patient may provide a consent given to share information on media to the provider creating the media for specific use, rather than for more general sharing within an XDS Affinity Domain. When transferring information that originated in an XDS Affinity Domain to media (XDM), the Privacy Consent Policies found in the XDS Affinity Domain might be changed during the publication process. There are also differences in the sensitivity that should be considered for consents shared on media or transmitted through XDR and those shared in an XDS affinity domain. See the section Security Considerations later in this volume for more details.

3.3.4 Implementation of Access Control

Consumers of documents that implement this profile are required to enforce access control based on the policies described by the Affinity Domain. This is because the consumers of the documents are best aware of the functional role, how the data will be used, the relationship between provider and patient, the urgency of access, etc. The mechanism by which consumers associate individual users with functional roles is not within the scope of this profile. However it does allow for mechanisms to be used that take into account the structural role of the user, their association with the patient, the functional role that they are assigned with the session in which they are accessing data, and the declared sensitivity of the data being protected.

3.3.5 Actors/Transaction

There are two actors in the BPPC profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor. The sharing or transmission of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described in the section on Content Bindings with XDS, XDM and XDR.

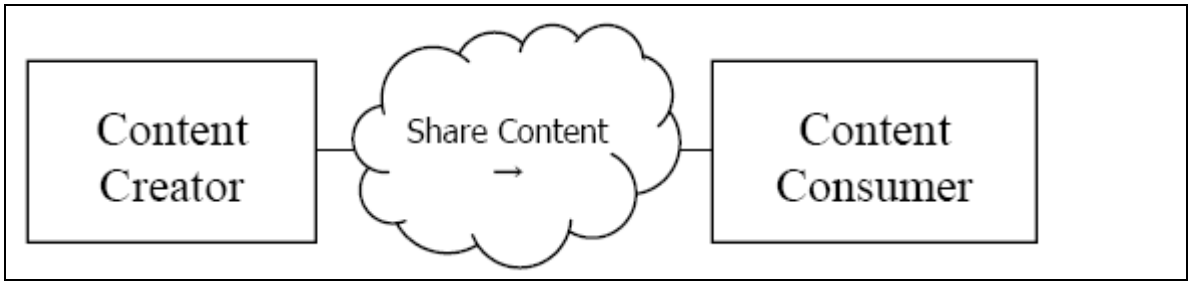


Figure 3.3-3 BPPC Actor Diagram

3.3.5.1 Affinity Domain Configuration

Within an XDS Affinity Domain, multiple consent policies and document sensitivity levels will need to be supported. Implementors of the Content Creator and Content Consumer Actors will need to be able to address the need to support a limited number of policies and sensitivity levels in order to meet the needs of affinity domains. Special purpose applications may need to create only one kind of consent policy, or recognize and act upon only one sensitivity level. Registries, repositories and general purpose Content Creators and Content Consumers will need to support the creation of, or processing of, multiple policies and sensitivity levels. In order to set reasonable limits, general purpose applications that support the BPPC profile shall be able to support at least 10 active policies and document sensitivity levels. The references below describe policies and functional roles that could lead to somewhat less than this number.

3.3.6 Options

Actor	Option
Content Consumer	View Option (1)
	Document Import Option (1)
	Section Import Option (1)
	Discrete Data Import Option (1)

Table 3.3-4 BPPC Options

Note 1: The Actor shall support at least one of these options.

3.3.7 Content Consumer Options

3.3.7.1 View Option

This option defines the processing requirements placed on Content Consumers for providing access, rendering and management of the medical document. See the View Option in PCC TF-2 for more details on this option.

3.3.7.1.1 Display Transform

A Content Creator Actor should provide access to a style sheet that ensures consistent rendering of the medical document content as was displayed by the Content Consumer Actor.

The Content Consumer Actor must be able to present a view of the document using this style sheet if present.

3.3.7.2 Document Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing the entire medical document and managing it as part of the patient record. See the Document Import Option in PCC TF-2 for more details on this option.

3.3.7.3 Section Import Option

This option defines the processing requirements placed on Content Consumers for providing access to, and importing the selected section of the medical document and managing them as part of the patient record. See the Section Import Option in PCC TF-2 for more details on this option.

3.3.7.4 Discrete Data Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing discrete data from selected sections of the medical document and managing them as part of the patient record. See the Discrete Data Import Option in PCC TF-2 for more details on this option.

3.3.8 Consents Content Bindings with XDS, XDM and XDR

It is expected that exchanges of BPPC will occur in an environment where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross-Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ), and notification of availability of documents (NAV).
- A media-based infrastructure is defined by the IHE Cross-Enterprise Document Media Interchange (XDM) profile.
- A reliable messaging-based infrastructure is defined by the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile.
- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework, found here: http://www.ihe.net/Technical_Framework/.

Thus, implementors of the Content Consumer and Content Creator Actors must also implement either the ITI XDS, XDM or XDR Profiles to exchange content, using the bindings listed below.

Content	Binding	Actor	Optionality
Consent to Share Information	Consent Binding to XD*	Content Creator	R
		Content Consumer	R
Medical Documents	Medical Document Binding to XD*	Content Creator	R
		Content Consumer	R

Table 3.3-5 BPPC Bindings

3.3.9 Consent Content Module

A consent document is a kind of medical document, and shall conform to the requirements of the Consent content module specified in this profile. The content of a consent document shall include the effective time of the consent and coded vocabulary identifying the policies consented to (OID). The content of the consent document may include a text description of what the patient has consented to, and either a facsimile of a wet signature, or a digital signature by the patient (or legal representative). The consent if signed shall use the IHE ITI DSG profile.

3.3.10 BPPC Process Flow

The BPPC profile uses the normal process flow of the XD* profiles, depending upon which bindings have been declared.

1. Administrative tasks prior to BPPC use
    1. The Affinity Domain will write and agree to the Affinity Domain Policy (lots of lawyers involved).
    2. The Affinity Domain Policy will include a small set of Privacy Consent Policies (more lawyers). These are text documents very similar to the privacy consent documents used today.
    3. Each Privacy Consent Policy will be given an XDS Affinity Domain unique identifier (OID)
    4. The Affinity Domain Policy and all of the Privacy Consent Policies will be published in a way consistent with the Affinity Domain's Policy. It is expected that this will be sufficiently public to support local regulation.

2. Patient consents to a policy
    1. The Patient will be presented with the Affinity Domain – Patient Privacy Consent Policies.
    2. The Patient will agree to one or more of the Privacy Consent Policies. In most regions the patient must be fully informed and acknowledge the privacy consent. In some regions there is implied consent, and thus there is no need to capture a patient's consent.
    3. A system that captures patient privacy consents will capture this act in a BPPC Patient Privacy Consent Document.
        1. XDS Metadata
            1. authorPerson is the patient or legal guardian that is agreeing to the consent.
            2. classCode indicates this is a consent document
            3. confidentialityCode may indicate other consent OIDS that control this consent document
            4. eventCodeList indicates the Privacy Consent Policy identifier (OID)
            5. legalAuthenticator would be the digital signer if used, or the identity of the Affinity Domain representative that is confirming that the patient is agreeing.
            6. serviceStartTime and serviceStopTime indicate when this consent is effective.
        2. Patient Privacy Consent Document
            1. template ID = "1.3.6.1.4.1.19376.1.5.3.1.1.7 "
            2. The patient or legal guardian that is agreeing to the consent is identified as the author of the consent document.
            3. Any witness to this consent may be captured (i.e. participant typeCode='WIT')
            4. authorization indicates that this is a consent act
            5. Effective time is set
                1. When the privacy consent is first effective. This effective date may be retroactive based on the XDS Affinity Domain Policy.
                2. If necessary, when the privacy consent is expected to elapse

1. If wet signature is used, the XDS-SD profile will be used to scan the paper and encode it into the consent document
    1. the XDS-SD CDA attributes are combined with the BPPC CDA attributes.
2. If digital signature is used the DSG profile will be used to sign the consent document. This is an additional document that is published. This may be published in the same submission set, or may come after based on workflow.

3. System checking on a patient's consent status
    1. When a system/individual wants to know if a specific patient has consented it can do a query for consent documents on that patient.
    2. Note if the local regulations allow, some XDS Affinity Domains may not publish the consent documents, so systems should be able to handle these configurations.
    3. Note if the local regulations allow, some patients may have documents shared before informed consent can be captured.
4. Clinical documents are published into XDS Affinity Domain
    1. When clinical documents are published into XDS an assessment must be done to determine which of the XDS Affinity Domain – Privacy Consent Policies would allow the documents to be published.
        1. In some XDS Affinity domains this may require that the system check that a patient has indeed consented to the specific policy (see 3)
        2. This is likely based on human configuration of the document source system.
    2. The XDS Metadata – confidentialityCode - will include the OIDS of the appropriate (determined by the XDS Affinity Domain Policy) Privacy Consent Policy identifier (OID)
    3. The XDS Registry will validate that the confidentialityCode is one approved for use within the XDS Affinity Domain.
5. Clinical documents are used from the XDS Affinity Domain
    1. When a system queries the XDS Affinity Domain it should utilize the confidentialityCode in the queries to restrict the documents returned to those that the system can utilize
        1. For Example: If the system is a research application, then it should set the confidentialityCode in the query to the list of XDS Affinity Domain

Policy identifiers (OIDs) that would allow for the documents to be used for the research.

2. Even if the confidentialityCode is not specified, the system implementing the Document Consumer actor is still bound to enforce the XDS Affinity Domain Policies.
3. The consumer system will enforce access controls based the returned metadata-confidentialityCode, system type, user, context, and any number of other factors that the system is capable of enforcing.

3.3.11 Grouping with Other Profile Actors

The capturing of the patient consenting could be futher covered by use of the IHE Digital Signature content profile (DSG). Systems should be prepared to see DSG related content associated with the Patient Privacy Consent document.

3.3.12 Security Considerations

Consents stored in an XDS affinity domain are also governed by privacy policies. The content of a Privacy Consent may itself contain sensitive information. For example, a terminally ill patient may decide that his prognosis should not be shared with his family members, but that other information may be. Sharing the Privacy Consent Act with family members would potentially inform them of a negative prognosis.

However, Privacy Consent Acts stored in the clear on media (XDM), or otherwise transmitted through XDR should not contain sensitive information. The rationale is that the receiver of the information must be able to read the consent that was used to share this information in order to understand how they must treat the information with respect to their own Privacy Consent Policies.

Implementation of Privacy Consent Policies within a healthcare environment has different considerations and risks than implementing similar access control policies within other non-treatment environments. This is for the simple reason that failing to provide access to critical healthcare information has the risk of causing serious injury or death to a patient. This risk must be balanced against the risk of prosecution or lawsuit due to accidental or malicious disclosure of private information. The XDS Affinity Domain should take care in writing their Privacy Consent Policies to avoid this.

One mitigation strategy often adopted in healthcare provides Accountability through Audit Controls. That is to say that healthcare providers are trusted not to abuse their access to private information, but that this is followed up by a policy of monitoring healthcare provider accesses to private information to ensure that abuse does not occur. This strategy reduces the risk of serious death or injury due to lack of access to critical healthcare information, at the increased risk of disclosure of private information. This is why the ITI Technical Committee created the Audit Trail and Node Authentication

(ATNA) Integration profile, and furthermore, why that profile is a requirement of XDS and related profiles.

Another risk that must be resolved by an affinity domain is how to address the issues of sharing truly sensitive information in a registry (e.g., for VIP patients, or sensitive data). One strategy that might be recommended is that truly sensitive data not be shared within the XDS Affinity Domain, directed communications using XDR or XDM may be more appropriate.

3.4 EDR Integration Profile

Physicians frequently determine that patients either onsite, or calling in, should proceed directly to an emergency department for care. The referring physician has valuable data that can inform ED providers, including the history of the current problem, past medical problems, medications, allergies, and frequently a concrete assessment and plan for the patient such as hospital admission. Unfortunately, this information is inconsistently relayed to the ED provider who ultimately cares for the patient. Currently, this transfer of care requires verbal transfer of extensive information. Unfortunately, the ED provider recording the information may not be the person who will ultimately care for the patient, may not document sufficient detail, or may forget to document any information at all.

Loss of this data can lead to costly over-testing in the ED, or worse, an inappropriate disposition for the patient.

Using an EHR, an ED Referral is created; including the nature of the current problem, past medical history, and medications. Upon arrival of the patient to the ED, the patient is identified as a referral, and the transfer document is incorporated into the EDIS.

This profile may be used to cover a wide variety of ED referral situations, for example, primary care provider to ED Referral, Long term care to ED referral, or even ED to ED referral (as in the case of transfer from a level 2 Critical care facility to a level 1 facility).

3.4.1 Actors/Transaction

There are two actors in the EDR profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor. The sharing or transmission of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described in the section on Content Bindings with XDS, XDM and XDR.

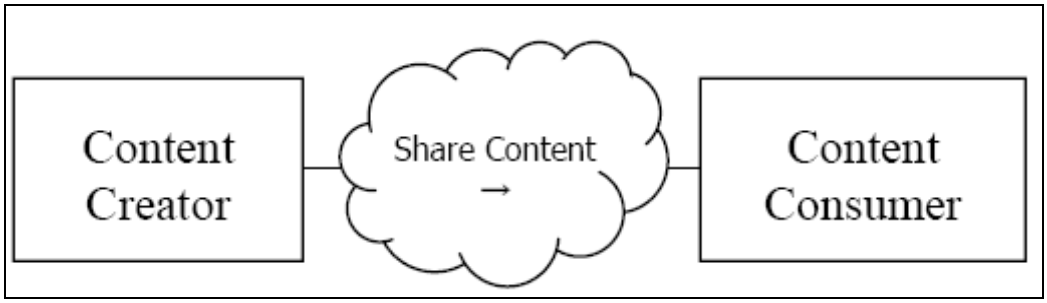


Figure 3.4-1 EDR Actor Diagram

3.4.2 Options

Actor	Option
Content Consumer	View Option (1)
	Document Import Option (1)
	Section Import Option (1)
	Discrete Data Import Option (1)

Table 3.4-1 EDR Options

Note 1: The Actor shall support at least one of these options.

3.4.3 Content Consumer Options

3.4.3.1 View Option

This option defines the processing requirements placed on Content Consumers for providing access, rendering and management of the medical document. See the View Option in PCC TF-2 for more details on this option.

3.4.3.1.1 Display Transform

A Content Creator Actor should provide access to a style sheet that ensures consistent rendering of the medical document content as was displayed by the Content Consumer Actor.

The Content Consumer Actor must be able to present a view of the document using this style sheet if present.

3.4.3.2 Document Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing the entire medical document and managing it as part of

the patient record. See the Document Import Option in PCC TF-2 for more details on this option.

3.4.3.3 Section Import Option

This option defines the processing requirements placed on Content Consumers for providing access to, and importing the selected section of the medical document and managing them as part of the patient record. See the Section Import Option in PCC TF-2 for more details on this option.

3.4.3.4 Discrete Data Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing discrete data from selected sections of the medical document and managing them as part of the patient record. See the Discrete Data Import Option in PCC TF-2 for more details on this option.

3.4.4 Coded Terminologies

This profile supports the capability to record entries beyond the IHE required coding associated with structured data. Content Creators and Content Consumers may choose to utilize coded data, but interoperability at this level requires an agreement between the communicating parties that is beyond the scope of this Profile.

To facilitate this level of interoperability, the applications that implement actors within this profile shall provide a link to their HL7 conformance profile within their IHE Integration statement. The conformance profile describes the structure of the information which they are capable of creating or consuming. The conformance profile shall state which templates are supported by the application (as a Content Creator or Content Consumer), and which vocabularies and/or data types are used within those templates. It should also indicate the optional components of the entry that are supported.

See the HL7 Refinement Constraint and Localization for more details on HL7 conformance profiles.

3.4.5 Content Bindings with XDS, XDM and XDR

It is expected that this profile will be used environment where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross-Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ), and notification of availability of documents (NAV).
- A media-based infrastructure is defined by the IHE Cross-Enterprise Document Media Interchange (XDM) profile.

- A reliable messaging-based infrastructure is defined by the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile.
- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework, found here: http://www.ihe.net/Technical_Framework/.

Such an infrastructure is assumed by the use cases that focus on the context for defining the specific clinical information content for this profile.

A content binding describe how the payloads used in IHE transactions are related to and/or constrained by the data elements contained within the content sent or received in those transactions. This section is where any specific dependencies between the content and transaction are defined. The Patient Care Coordination Technical Framework defines a binding to use when grouping the Content Creator of this Profile with the IHE ITI XDS, XDM or XDR Integration Profiles.

Content	Binding	Actor	Optionality
ED Referral	Medical Document Binding to XDS, XDM and XDR	Content Creator	R
		Content Consumer	R

Table 3.4-2 EDR Content Binding

3.4.6 ED Referral Document Content Module

An ED Referral content document is a type of referral summary, and also incorporates the constraints defined for referral summaries found in a Referral Summary as described in PCC TF-2. In addition, the ED Referral content profile includes additional information to support recording the mode of transportation, estimated time of arrival, and proposed disposition.

3.4.7 ED Referral Process Flow

3.4.7.1 Use Case 1: Provider to Emergency Department Referral

This use case involves a "collaborative" transfer of care for the referral of a patient from a care provider to the emergency department. This use case is a central component of an "e-referral" process, which typically requires an appropriate level of agreement and collaboration between the two parties prior to the actual transfer of clinical information being initiated.

Preconditions: The referring provider has an EMR system with capability to write notes and manage data elements, and share information. The specific data elements managed by the providers EMR are expected to be the source for the information used in creating

the medical summary document related to this transfer of care. A variety of EMR implementations and usage by clinicians may result in some variability in the content of the medical summary. The receiving ED provider has an EDIS system with the capability to share information.

Events: A provider sees a patient, or has spoken with the patient or a family member, and has decided to refer the patient to an ED. The provider creates an ED Referral summary document, and shares it. The detailed content of the medical summary to support this use case is detailed as part of the document content profile specification.

Post conditions: The ED specialist physician retrieve the Documents and views them, optionally importing data. Import assumes the specialist has an EDIS system with the capability for managing those discrete data elements.

Steps to identify the ED and obtain insurance preauthorization have been placed out of scope for this Integration Profile.

3.5 PPHP Integration Profile

The PPHP Profile is not being released for public comment this cycle. Compents of this profile have been incorporated into the technical framework for use with other content profiles, and these remain in Volume II.

3.6 Antepartum Summary (APS)

Obstetric patients in labor and admitted to Labor and Delivery must have a complete summary of their antepartum ambulatory care available at the time of admission to evaluate and / or ameliorate risk. This same data is required at any visit to Labor and Delivery for any other problems or special needs a patient may require.

As the patient is seen over a finite period in the office, aggregation of specific relevant data is important to the evaluation of the obstetric patient upon presentation to Labor and Delivery. During the 40 weeks of a typical pregnancy duration, the patient will have an initial History and Physical Examination, followed by repetitive office visits with multiple laboratory studies, imaging (usually ultrasound) studies, and serial physical examinations with recordings of vital signs, fundal height, and the fetal heart rate. The original New OB History & Physical, ongoing Medical Diagnoses, the Estimated Due Date, outcomes of any prior pregnancies, serial visit data on the appropriate growth of the uterus and assessments of fetal well being, authorizations, laboratory and imaging studies must all be presented and evaluated upon entry to the Labor and Delivery Suite to ensure optimal care for the patient and the fetus.

Although the patient and her care provider may plan for a vaginal (natural) method of delivery, there is a substantive chance the delivery route may be surgical, requiring anesthesia and post-surgical care.

Current practice is to copy the patient's (paper) chart at various times during the pregnancy (as at 28 weeks and at 36 weeks of completed gestation), and transport the copies of the chart to the hospital the patient intends to use for delivery. Should the patient arrive prior to the chart copy arriving, or if the chart (or information within the chart) is missing on presentation of the patient to Labor and Delivery (a frequent occurrence), often the staff or clinicians repeat laboratory or imaging studies. This results in unwarranted and duplicative tests, is wasteful of time and resources, and leads to dissatisfied patients.

Further, missing or incomplete information about the patient's clinical status may create a situation where critical information is unavailable to clinicians, which may ultimately result in an injury, inadequate aftercare or other undesirable outcome.

Significantly, a large portion of patients arrive in L&D without complete documentation. In one recent U.S. study , ~70% of patients (with paper charts) arrived in L&D without their current medical record being available. While in this study, only one hospital was involved, one can see the extent of the issue, with pregnant patients possibly going to a different hospital than planned (preterm labor, rapid labor and unable to make it to the planned delivery hospital, or visiting a distant city), moving mid-care, or with a covering physician (rather than the primary obstetrician) on call.

In a Swedish study done in the 1990's, critical data on paper records were incomplete from 45 to 87.5% of the time. Thus, availability of current medical records remains a significant problem for most hospital Labor and Delivery units; availability of key information electronically will significantly enhance patient safety.

3.6.1 Technical Approach

The Antepartum Summary is a folder in XDS that defines a collection of documents. Several content profiles must be completed for the various kinds of documents that might be found in the Pre-Procedure Folder. These content profiles would include (existing and new):

- Pre-procedure patient questionnaire
- Pre-procedure H&P (including surgical and relevant social history)
- Summary of OB-specific Ambulatory Visit Data
- Laboratory Reports
- Imaging Reports
- Consultation Reports
- Diagnostic Imaging (Ultrasound) Images
- Non Stress Test (NST) Reports
- NST Waveforms (may be covered by DICOM)
- Patient Consent Forms for Performance of Procedures

- Payer Authorization Forms

Although the scope of this content profile is limited to the Antepartum Ambulatory Prenatal Care, this discussion illustrates the need to view the aggregation of documents for L&D as the center of multiple related documents and to include in the content profile the mechanisms for specifically referencing these document types.

3.6.2 Stakeholders

The stakeholders who use this document for decision making in the course of patient care include:

- Obstetrician
- Perinatologist
- Certified Nurse Midwives
- Anesthesiologist
- Labor and Delivery and Peri-operative personnel (L&D staff, surgical coordinator, scheduling, surgical nursing)
- Post-op and Post-Partum Nursing
- Social Work (discharge planning)
- Obstetrician (after discharge)

3.6.3 Use Cases

3.6.3.1 Use Case: Antepartum Care Delivery

Pre-condition

The patient's obstetrician sees the patient for her pregnancy in the ambulatory (office) setting. During the pregnancy, the patient is noted to have a medical problem requiring consultation with a Maternal-Fetal Medicine specialist (perinatologist). The office obtains pre-authorization from the insurance payer for the consult, and for the intended or anticipated route of delivery, and transmits that information to both the consultant and to the hospital.

Events

The patient is seen in the obstetrician's office where a complete medical and relevant social history are taken by the nurse and recorded in the office EHR, incorporating data from the perinatologist's consultation report as appropriate. Laboratory and imaging reports ordered by the perinatologist as well as the perinatologist's consultation report are displayed electronically to the obstetrician. The obstetrician reviews the consultation report from the perinatologist's office and imaging studies ordered by the perinatologist along with data recorded by the nurse. Physical exam

reveals some abnormalities. The obstetrician orders additional laboratory studies, and sends the patient to the hospital to Labor and Delivery.

When the laboratory results return, the physician completes the admission H&P, Allergies, Medications, includes the data prepared or ordered by the perinatologist, and makes it available to L&D. This data includes an assessment of the patient's health status, and the requisite data summarized from the antepartum care given. The charge nurse for L&D documents that the complete collection of documents needed is available. The Post-Partum discharge planning is notified and assures that there is a suitable environment with appropriate support for post-delivery after-care.

Post-condition

The Pre-delivery H&P and Antepartum Summary with appropriate relationships to the Perinatologist Consultation, and all the antepartum laboratory and imaging studies are available to the obstetrician and the birthing center personnel for incorporation into their respective EHRs. The H&P is also available to the patient for viewing and incorporation into the patient's PHR, and into the newborn baby's PHR.

3.6.4 Actors/Transaction

There are two actors in the APS profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor. The sharing or transmission of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described in the section on Content Bindings with XDS, XDM and XDR.

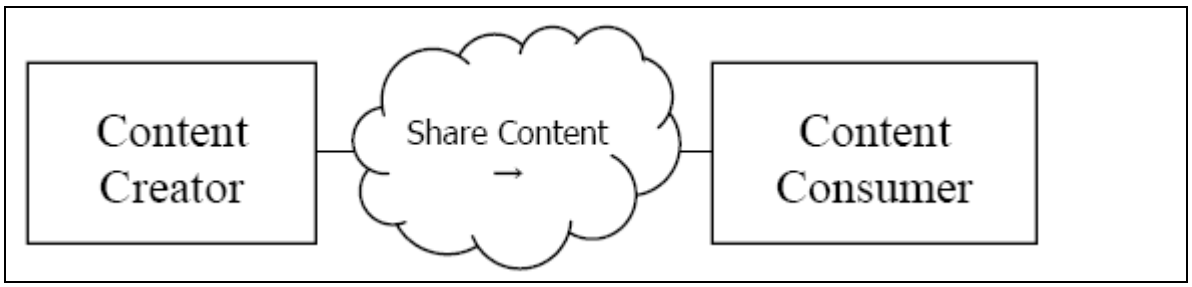


Figure 3.6-1 APS Actor Diagram

3.6.5 Options

Actor	Option
Content Consumer	View Option (1)

	Document Import Option (1)
	Section Import Option (1)
	Discrete Data Import Option (1)

Table 3.6-1 APS Options

Note 1: The Actor shall support at least one of these options.

3.6.6 Content Consumer Options

3.6.6.1 View Option

This option defines the processing requirements placed on Content Consumers for providing access, rendering and management of the medical document. See the View Option in PCC TF-2 for more details on this option.

3.6.6.1.1 Display Transform

A Content Creator Actor should provide access to a style sheet that ensures consistent rendering of the medical document content as was displayed by the Content Consumer Actor.

The Content Consumer Actor must be able to present a view of the document using this style sheet if present.

3.6.6.2 Document Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing the entire medical document and managing it as part of the patient record. See the Document Import Option in PCC TF-2 for more details on this option.

3.6.6.3 Section Import Option

This option defines the processing requirements placed on Content Consumers for providing access to, and importing the selected section of the medical document and managing them as part of the patient record. See the Section Import Option in PCC TF-2 for more details on this option.

3.6.6.4 Discrete Data Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing discrete data from selected sections of the medical document and managing them as part of the patient record. See the Discrete Data Import Option in PCC TF-2 for more details on this option.

3.6.7 Coded Terminologies

This profile supports the capability to record entries beyond the IHE required coding associated with structured data. Content Creators and Content Consumers may choose to utilize coded data, but interoperability at this level requires an agreement between the communicating parties that is beyond the scope of this Profile.

To facilitate this level of interoperability, the applications that implement actors within this profile shall provide a link to their HL7 conformance profile within their IHE Integration statement. The conformance profile describes the structure of the information which they are capable of creating or consuming. The conformance profile shall state which templates are supported by the application (as a Content Creator or Content Consumer), and which vocabularies and/or data types are used within those templates. It should also indicate the optional components of the entry that are supported.

See the HL7 Refinement Constraint and Localization for more details on HL7 conformance profiles.

3.6.8 Content Bindings with XDS, XDM and XDR

It is expected that this profile will be used environment where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross-Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ), and notification of availability of documents (NAV).
- A media-based infrastructure is defined by the IHE Cross-Enterprise Document Media Interchange (XDM) profile.
- A reliable messaging-based infrastructure is defined by the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile.
- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework, found here: http://www.ihe.net/Technical_Framework/.

Such an infrastructure is assumed by the use cases that focus on the context for defining the specific clinical information content for this profile.

A content binding describe how the payloads used in IHE transactions are related to and/or constrained by the data elements contained within the content sent or received in those transactions. This section is where any specific dependencies between the content and transaction are defined. The Patient Care Coordination Technical Framework defines a binding to use when grouping the Content Creator of this Profile with the IHE ITI XDS, XDM or XDR Integration Profiles.

Content	Binding	Actor	Optionality
Antepartum Summary Form C & F	Medical Document Binding to XDS, XDM and XDR	Content Creator	R
		Content Consumer	R

Table 3.6-2 APS Bindings

3.6.9 Grouping

3.6.9.1 Cross Enterprise Document Sharing, Media Interchange and Reliable Messages

Actors from the ITI XDS, XDM and XDR profiles embody the Content Creator and Content Consumer sharing function of this profile. A Content Creator or Content Consumer must be grouped with appropriate actors from the XDS, XDM or XDR profiles, and the metadata sent in the document sharing or interchange messages has specific relationships to the content of the clinical document described in the content profile.

3.6.9.2 Notification of Document Availability (NAV)

A Document Source should provide the capability to issue a Send Notification Transaction per the ITI Notification of Document Availability (NAV) Integration Profile in order to notify one or more Document Consumer(s) of the availability of one or more documents for retrieval. One of the Acknowledgement Request options may be used to request from a Document Consumer that an acknowledgement should be returned when it has received and processed the notification. A Document Consumer should provide the capability to receive a Receive Notification Transaction per the NAV Integration Profile in order to be notified by Document Sources of the availability of one or more documents for retrieval. The Send Acknowledgement option may be used to issue a Send Acknowledgement to a Document Source that the notification was received and processed.

3.6.9.3 Document Digital Signature (DSG)

When a Content Creator Actor needs to digitally sign a document in a submission set, it may support the Digital Signature (DSG) Content Profile as a Document Source. When a Content Consumer Actor needs to verify a Digital Signature, it may retrieve the digital signature document and may perform the verification against the signed document content.

3.7 Emergency Department Encounter Record (EDER)

An Emergency Department "chart" is the entire collection of (multi-authored) documents and reports recording the assessments and care delivered by the entire ED team (including physicians, nurses, technologists and other providers) in response to an ED visit.

For the purposes of this integration profile, we define the Emergency Department Encounter Record (EDER) as a summary of the patient's current health status and care rendered in the ED between arrival and ED departure. The EDER is not intended to replace the ED Chart as a complete, legal document of care, but is a collection of medical summaries with focused scope that are produced to fulfill a number of collaborative transfers of care.

3.7.1 Issue Log

3.7.1.1 Open Issues

1. New LOINC codes for data elements
   - ED REFERRAL NOTE
   - PRE-HOSPITAL CARE NOTE (EMS Note)
   - ED TRIAGE NOTE
   - XASSES-X NURSING ASSESSMENTS PANEL
   - NURIN-T NURSING INTERVENTIONS PANEL
   - XIVFLU-X INTRAVENOUS FLUID ADMINISTERED (COMPOSITE)

3.7.1.2 Closed Issues

1. The EDER is a multi-authored (but singly attested?) document. How should this best be implemented/reflected: Document to be attested to by ED attending physician.
2. Patients frequently leave the ED prior to documentation being finalized. Triggers in workflow vary. How should the Draft vs. Final Status be handled: Only final documents will be posted to XDS.
3. Potential for multiple entries: using folders, multiple sections do not occur.
4. Timetable for CCD harmonization: done
5. Target systems discussion: use case defined as EDIS posts to XDS.
6. Use of Co-occurrence Constraint [Conditional Restraint] for Disposition elements: Yes.
7. Snomed vs. DEEDS for Disposition: DEEDS

Glossary

Add the following terms to the Glossary

Acuity Assessment

Also known as triage category, this is the acuity of the patient assigned during the process of ED triage. A number of evidenced based triage scales exist, including the Emergency Severity Index (ESI), Canadian Triage and Acuity Scale (CTAS), the Australasian Triage Scale (ATS), and the Manchester Triage System. In many emergency departments, patients may simply be classified as *emergent*, *urgent* or *non-urgent*.

EDIS

An Emergency Department Information System (EDIS) is an extended EHR system used to manage data in support of Emergency Department patient care and operations. The functions of an EDIS may be provided by a single application or multiple applications.

Mode of Arrival

The method of transportation used to transport the patient to the Emergency Department.

Referral Source

An individual, group, or agency that determined the patient should seek care at the ED. Referral source may be used to determine appropriate discharge referrals and services, or to provide surveillance data for program and service planning, or to examine referral patterns.

3.8 Emergency Department Encounter Record (EDER)

Emergency Department Encounter Record (EDER) as a summary of the patient's current health status and a summary of care rendered in the ED between arrival and ED departure. The EDER is not (yet) intended to replace the ED Chart as a complete, legal document of care, but is intended as a collection of medical summaries with focused scope that can be used to fulfill a number of collaborative transfers of care. The ED encounter record may include links to diagnostic tests performed during the ED encounter, as well as links to an initial ED referral (a 2006 IHE work product), prehospital (EMS) records (IHE roadmap 2008), and the consultations of other providers for patients seen in the ED.

Data released by the Centers for Disease Control and Prevention (CDC) estimates that there were over 110 million emergency department visits in 2004, making the emergency department (ED) chart (hereafter called encounter record) one of the most common

medical summaries in use today. Currently, the ED encounter record remains largely a paper based artifact, and when produced by an Emergency Department information system (EDIS) is almost exclusively delivered as unstructured or loosely structured text. The ED chart is used to communicate the details of an emergency department visit in a variety of ways. The chart is most frequently faxed or mailed to primary care providers, and is increasingly archived electronically to hospital clinical data repositories. The original (or a copy) must accompany the patient to the ward upon hospital admission where is can be reviewed by hospital providers, or a copy may be sent with the patient on transfer from ED to ED or from ED to other medical treatment facilities. Unfortunately, these frequently become lost or misplaced. ED encounter records have no standardized format, and may be frequently be difficult to read by users unfamiliar with their formatting. None yet carry any semantic meaning that could be consumed by a receiving EHR system (EHR-S).

The production and delivery of the ED encounter record solves a number of problems, including:

- Communication with and transfer of care back to the patient's primary care physician.
- Communication with care providers in the inpatient setting for patients admitted to the hospital from the emergency department.

The ED encounter record could also be employed in:

- Transfer of information to hospital and provider billing systems.
- Transfer of information to regulatory and public health agencies requesting data from emergency department encounters.

3.8.1 Use Case -- Emergency Department Visit

This use case presumes the patient is cared for at a hospital facility with an EDIS as well as a hospital information system. Additionally, the patient's primary care provider is also assumed to posses an interoperable EHR system. This use case begins upon the arrival of the patient to the emergency department. Data including mode of arrival, chief complaint, and other arrival data are manually entered into the EDIS. Additional data including past medical problems, medications and allergies, are obtained in one of the following ways:

1. Entered manually into the EDIS by the triage nurse
2. Imported from a legacy ED encounter within the EDIS
3. Imported from the hospital information system or CDR, perhaps using Query for Existing Data.
4. Imported from an Emergency Department Referral (IHE 2006-2007)
5. Imported from a prehospital EMS report (Emergency Medical Services (EMS) to Emergency Dept Data Transfer, PCC Roadmap 2008-2009)

The patient undergoes assessments by a triage nurse, is assigned a triage category (i.e. emergent, urgent, non-urgent). The patient is then registered and demographic data is obtained. One taken to the treatment area, the patient undergoes additional assessments by a primary RN, and seen by an ED physician who performs a history and physical, orders various diagnostic tests, determines a course of therapy, orders medications to be administered in the ED and performs procedures on the patient. Upon completion of ED care, the patient is either admitted to the hospital, discharged from the ED, or transferred to another facility. Hence, the use case can take one of three branches:

1. If admitted, the EDER is sent to the hospital information system where it can be viewed by providers, or read by the EHR system so that medical summary data and details of care rendered in the ED available to inpatient providers.
2. If the patient is discharged the EDER is sent to the patients primary care physician as a summary of care rendered during the ED encounter.
3. If the patient is transferred to another facility, the EDER is posted to the RHIO and made available for providers at the receiving facility.

3.8.2 Example

Mr. John Smith, a longstanding patient of Dr. Mark Klein, is 62 year old man with hypertension and diabetes who awoke with acute onset of fever, right-sided chest pain and cough. He presents to the IHE ED via EMS where he is triaged by nurse Karen Ross who collects his past medical history, medications, allergies, mode of arrival, and inputs this data into the EDIS. Mr. Smith is taken directly to the treatment area where he is assigned to nurse Barbara Reiter who obtains vital signs, baseline pulse oximetry, places the patient on oxygen, and obtains IV access. She documents her assessments and interventions in the EDIS. The patient is seen by Dr. William Reed who performs and records a history and physical examination, orders an ECG, chest radiograph, CBC, electrolytes, and blood cultures. The chest radiograph reveals bi-lobar pneumonia and the ECG is slightly abnormal. Ceftriaxone 1gm IV plus Azythromycin 500mg PO are administered. After multiple attempts by Dr. Reed to contact Dr. Klein, Mr. Smith is admitted to a intermediate care bed under the care of Dr. Herman Edwards the IHE hospitalist. Upon hospital admission, Dr. Reed completes the record and, as the responsible attending physician, electronically signs the ED chart authenticating the EDER. The initial ED attending physician to see the patient is by default the legal authenticator, and may only delegate this responsibility to another provider through a formal transfer of care. The EDER is posted to the RHIO and also sent to the hospital information system. Using the HIS, the nurse on the intermediate care ward accesses the record and notes the time and administration of antibiotics. When Dr. Klein reaches the office in the morning, his office EHR-S notifies him that his patient was seen in the IHE ED the previous night, and displays the ED encounter record.

3.8.3 Actors/Transaction

There are two actors in the APS profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor. The sharing or transmission of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described in the section on Content Bindings with XDS, XDM and XDR.

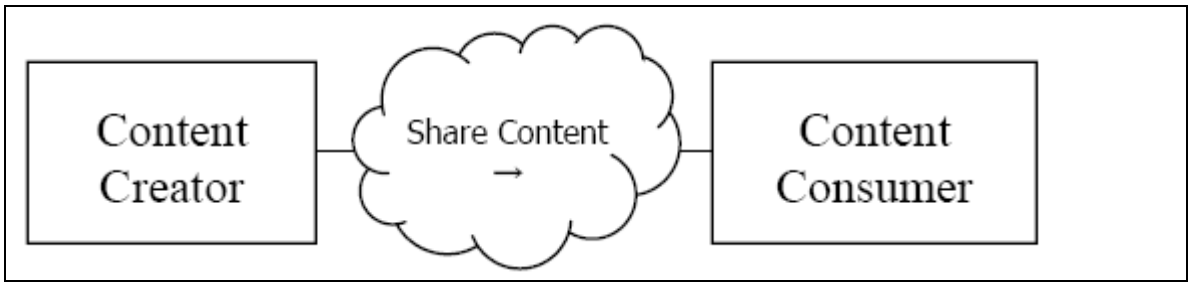


Figure 3.8-1 APS Actor Diagram

3.8.4 Options

Actor	Option
Content Consumer	View Option (1)
	Document Import Option (1)
	Section Import Option (1)
	Discrete Data Import Option (1)

Table 3.8-1 APS Options

Note 1: The Actor shall support at least one of these options.

3.8.5 Content Consumer Options

3.8.5.1 View Option

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A Content Creator Actor should provide access to a style sheet that ensures consistent rendering of the medical document content as was displayed by the Content Consumer Actor.

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3.8.5.3 Section Import Option

This option defines the processing requirements placed on Content Consumers for providing access to, and importing the selected section of the medical document and managing them as part of the patient record. See the Section Import Option in PCC TF-2 for more details on this option.

3.8.5.4 Discrete Data Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing discrete data from selected sections of the medical document and managing them as part of the patient record. See the Discrete Data Import Option in PCC TF-2 for more details on this option.

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- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework, found here: http://www.ihe.net/Technical_Framework/.

Such an infrastructure is assumed by the use cases that focus on the context for defining the specific clinical information content for this profile.

A content binding describe how the payloads used in IHE transactions are related to and/or constrained by the data elements contained within the content sent or received in those transactions. This section is where any specific dependencies between the content and transaction are defined. The Patient Care Coordination Technical Framework defines a binding to use when grouping the Content Creator of this Profile with the IHE ITI XDS, XDM or XDR Integration Profiles.

Content	Binding	Actor	Optionality
Triage Note	Medical Document Binding to XDS, XDM and XDR	Content Creator	R
		Content Consumer	R
Nursing Note	Medical Document Binding to XDS, XDM and XDR	Content Creator	R
		Content Consumer	R
Composite Triage and Nursing Note	Medical Document Binding to XDS, XDM and XDR	Content Creator	R
		Content Consumer	R
ED Physician Note	Medical Document Binding to XDS, XDM	Content Creator	R

	and XDR	Content Consumer	R

Table 3.8-7 Content Bindings for grouped profiles/actors

3.8.8 Grouping

3.8.8.1 Cross Enterprise Document Sharing, Media Interchange and Reliable Messages

Actors from the ITI XDS, XDM and XDR profiles embody the Content Creator and Content Consumer sharing function of this profile. A Content Creator or Content Consumer must be grouped with appropriate actors from the XDS, XDM or XDR profiles, and the metadata sent in the document sharing or interchange messages has specific relationships to the content of the clinical document described in the content profile.

3.8.8.2 Notification of Document Availability (NAV)

A Document Source should provide the capability to issue a Send Notification Transaction per the ITI Notification of Document Availability (NAV) Integration Profile in order to notify one or more Document Consumer(s) of the availability of one or more documents for retrieval. One of the Acknowledgement Request options may be used to request from a Document Consumer that an acknowledgement should be returned when it has received and processed the notification. A Document Consumer should provide the capability to receive a Receive Notification Transaction per the NAV Integration Profile in order to be notified by Document Sources of the availability of one or more documents for retrieval. The Send Acknowledgement option may be used to issue a Send Acknowledgement to a Document Source that the notification was received and processed.

3.8.8.3 Document Digital Signature (DSG)

When a Content Creator Actor needs to digitally sign a document in a submission set, it may support the Digital Signature (DSG) Content Profile as a Document Source. When a Content Consumer Actor needs to verify a Digital Signature, it may retrieve the digital signature document and may perform the verification against the signed document content.

3.9 Functional Status Assessment (FSA) Integration Profile

The Functional Status Assessment Profile (FSA) supports the handoff of assessment information between practictioners during transfers of care by defining the Functional Status Assessment option on the XDS-MS and XPHR profiles.

The Institute of Medicine has determined that the highest risk for medical errors occurs during the handoffs of patient care between practitioners, cross-enterprise or intra-

enterprise. Continuity of care requires provision of assessments to be available to the receiving practitioner for critical decision making. The transfer of physician documentation provides much of the medical/physiologic condition information. Transfer of nursing documentation provides human response (psychological, social, emotional, physiological and spiritual) of patient/family to changing conditions. Both types of documentation support continuity of patient care as each patient moves through the continuum. This profile demonstrates the collection and exchange of standardized assessment information as it is exchanged across a variety of residential and care provision settings.

Glossary

Add the following terms to the Glossary

IHE Functional Status Assessments Profile Glossary of Terms

IHE Integration Profiles describe the solution to a specific integration problem, and document the system roles, standards and design details for implementors to develop systems that cooperate to address that problem. IHE Profiles are a convenient way for implementors and users to be sure they're talking about the same solution without having to restate the many technical details that ensure actual interoperability.

Continuity of Care Record (CCR): A core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more encounters. The CCR is Designation E2369-05 of the ASTM (American Society for Testing and Materials, International). More information is available from [1].

Continuity of Care Document(CCD): An HL7 Clinical Document Architecture (CDA) implementation alternative to ASTM ADJE2369 for institutions or organizations committed to HL7 standards. This specification was developed as a collaborative effort between ASTM and HL7. More information is available from [2].

Clinical Document Architecture (CDA): A document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. From the perspective of CDA the CCR is a standardized data set that can be used to constrain CDS specifically for summary documents. More information is available from [3].

Logical Observation Identifiers Names and Codes(LOINC®) A database protocol developed by the Regenstrief Institute for Health Care aimed at standardizing laboratory and clinical code for use in clinical care, outcomes management, and research. LOINC® codes (sometimes in combination with SNOMED-CT codes are used to encode functional status assessments to facilitated health information exchange. Additional information found at [4].

Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT®): A comprehensive clinical terminology, originally created by the College of American Pathologists (CAP) and, as of April 2007, owned, maintained, and distributed by the International Health Terminology Standards Development Organisation (IHTSDO), a

non-for-profit association in Denmark. The CAP continues to support SNOMED CT operations under contract to the IHTSDO and provides SNOMED-related products and services as a licensee of the terminology. More information available from [5] or the United States National Library of Medicine at [6]

Add the following bullet to the list of profiles

- **Functional Status Assessment Profile (FSA) -** supports the handoff of assessment information between practitioners during transfers of care by defining the Functional Status Assessment option on the XDS-MS and XPHR profiles.

3.9.1 Dependencies

Add the following row(s) to the list of dependencies

Integration Profile	Dependency	Dependency Type	Purpose
Functional Status Assessment	XDS-MS or XPHR	Content Consumers implementing the Functional Status Assessments profile shall be grouped with either the XDS-MS or XPHR Content Consumer. Content Creators implementing the Functional Status Assessments profile shall be grouped with either the XDS-MS or XPHR Content Creator.	Functional Status Assessments are communicated in medical summaries, thus a Content Creator that is capable of producing a medical summary is needed.

Table 3.99-1 Dependencies

3.10 Functional Status Assessment

The Functional Status Assessment Profile (FSA) supports the handoff of assessment information between practictioners during transfers of care.

In the context of the Continuity of Care Document, the functional status describes the patient's status of normal functioning at the time the document was created.

Functional status includes information concerning:

- Ambulatory ability
- Mental status or competency
- Activities of Daily Living (ADL's) including bathing, dressing, feeding, grooming
- Home/living situation having an effect on the health status of the patient
- Ability to care for self
- Social activity, including issues with social cognition, participation with friends and acquaintances other than family members

- Occupation activity, including activities partly or directly related to working, housework or volunteering, family and home responsibilities or activities related to home and family
- Communication ability, including issues with speech, writing or cognition required for communication
- Perception, including sight, hearing, taste, skin sensation, kinesthetic sense, proprioception, or balance

The Institute of Medicine has determined that the highest risk for medical errors occurs during the handoffs of patient care between practitioners, cross-enterprise or intra-enterprise. Continuity of care requires provision of assessments to be available to the receiving practitioner for critical decision making. The transfer of physician documentation provides much of the medical/physiologic condition information. Transfer of nursing documentation provides human response (psychological, social, emotional, physiological and spiritual) of patient/family to changing conditions. Both types of documentation support continuity of patient care as each patient moves through the continuum.

This profile does not convey the entire functional status, but is an initial interoperabe entry to manage continuity of care with the use of four scales which support assessment comparison related to time/date,informing caregivers for critical decision making. The profile demonstrates the collection and exchange of standardized assessment information as it is exchanged across a variety of residential and care provision settings.

3.10.1 Options

This integration profile supplement adds the following two options to the Cross Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile, and to the Exchange of Personal Health Record Content (XPHR) Integration Profile.

Actor	Option
Content Consumer	Functional Status Option
Content Creator	Functional Status Option

Table 3.10-1 Functional Status Assessment Options

3.10.1.1 Functional Status Option

A Content Consumer Actor implementing the Functional Status Option of this profile supplement shall be able to view and consume coded functional status information sent in the functional status section of a Medical Summary or XPHR Extract. If the Content Consumer implements any of the import options of those profiles, it shall be able to import the coded functional status information.

A Content Creator Actor implementing the Functional Status Option of this profile supplement shall be able to create a coded functional status section that contains at least one of the optional functional status assessments in a Medical Summary or XPHR Extract.

This option has the effect of adding the Functional Assessments data element as a required data element in the XPHR Extract, Referral or Discharge Summary content modules.

For Public Comment	***How should we handle this profile? Should the coded functional status section be added to XDS-MS and XPHR as conditionally required (when the Functional Status Option is declared on the actor), or should this profile be published on its own.***

3.10.2 Coded Terminologies

This profile supports the capability to record entries beyond the IHE required coding associated with structured data. Content Creators and Content Consumers may choose to utilize coded data, but interoperability at this level requires an agreement between the communicating parties that is beyond the scope of this Profile.

To facilitate this level of interoperability, the applications that implement actors within this profile shall provide a link to their HL7 conformance profile within their IHE Integration statement. The conformance profile describes the structure of the information which they are capable of creating or consuming. The conformance profile shall state which templates are supported by the application (as a Content Creator or Content Consumer), and which vocabularies and/or data types are used within those templates. It should also indicate the optional components of the entry that are supported.

See the HL7 Refinement Constraint and Localization for more details on HL7 conformance profiles.

3.10.3 Content Modules

Content modules describe the content of a payload found in an IHE transaction. Content profiles are transaction neutral. They do not have dependencies upon the transaction that they appear in.

3.10.3.1 Coded Functional Status Assessment

The coded functional status assessment section contains one or more subsections that include coded functional status assessment information. This is a section content profile that is intended to be used in Medical Summaries of various type, including those described in the XDS Medical Summaries profile, and the XPHR profile. The subsections that are defined by this content profile are further described below.

3.10.3.1.1 Numeric Pain Scale

Using the Numeric Pain Scale (NRS 11), a Patient rates his/her pain from 0 to 10, with 0 representing no pain and 10 representing the worst possible pain. This scale is used for age 5 years and older and is the preferred pain scale for many older healthy adults. Reliable and valid per Herr & Garland, 2001; Ho et al, 1996; Price et al, 1994.

This content profile describes how a Pain Scale assessment is reported in a CDA Document.

3.10.3.1.2 Braden Scale For Predicting Pressure Sore Risk

The Braden Scale For Predicting Pressure Sore Risk is a summated rating scale made up of six subscales scored from 1-3 or 4, for total scores that range from 6-23. The subscales measure functional capabilities of the patient that contribute to either higher intensity and duration of pressure or lower tissue tolerance for pressure. A lower Braden Scale Score indicates lower levels of functioning and, therefore, higher levers of risk for pressure ulcer development. Reliability and validity research found at [7] Media:braden.pdf

This content profile illustrates how to record the Braden Score within a CDA document.

3.10.3.1.3 Geriatric Depression Scale

While there are many instruments available to measure depression, the Geriatric Depression Scale (GDS), first created by Yesavage et al.,(Stanford University) has been tested and used extensively with the older population. It is a brief questionnaire in which participants are asked to respond to the 30 questions by answering yes or no in reference to how they felt on the day of administration. Scores of 0 - 9 are considered normal, 10 - 19 indicate mild depression and 20 - 30 indicate severe depression. The GDS may be used with healthy, medically ill and mild to moderately cognitively impaired older adults. It has been extensively used in community, acute and long-term care settings. As for evidence-based research the GDS was found to have 92% sensitivity and 89% specificity when evaluated against diagnostic criteria per the Hartford Institute for Geriatric Nursing. The validity and reliability of the tool have been supported through both clinical practice and research. More information is available from [8].

This content profile illustrates how to record the Geriatric Depression Scale within a CDA document.

3.10.3.1.4 Physical Function

The **Minimum Data Set for Long Term Care Version 2.0 (MDS 2.0)** is a federally mandated (in the United States) standard assessment form. This instrument is specified by the Centers for Medicare and Medicaid Services, and requires nursing facilities to conduct a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity. Section G Physical Functioning and Structural Problems are included in this profile. More information is found at[9].

3.10.4 Process Flow

Three use cases are described in futher detail below.

1. Long-Term Care to Acute Care - describes a use case for assessment information during transfers of care from long term to acute care.
2. Home or Ambulatory Care into Acute Care - describes a use case for assessment information during multiple care transfers.
3. Behavioral - describes a use case for assessment information during transfers of care where information about depression in an older patient is used.

Note:	**Italicized text in the use cases below denote information in the use case that provides details regarding patient condition and workflow, but will not be included as part of the content integration profile.**

3.10.4.1 Long-Term Care to Acute Care

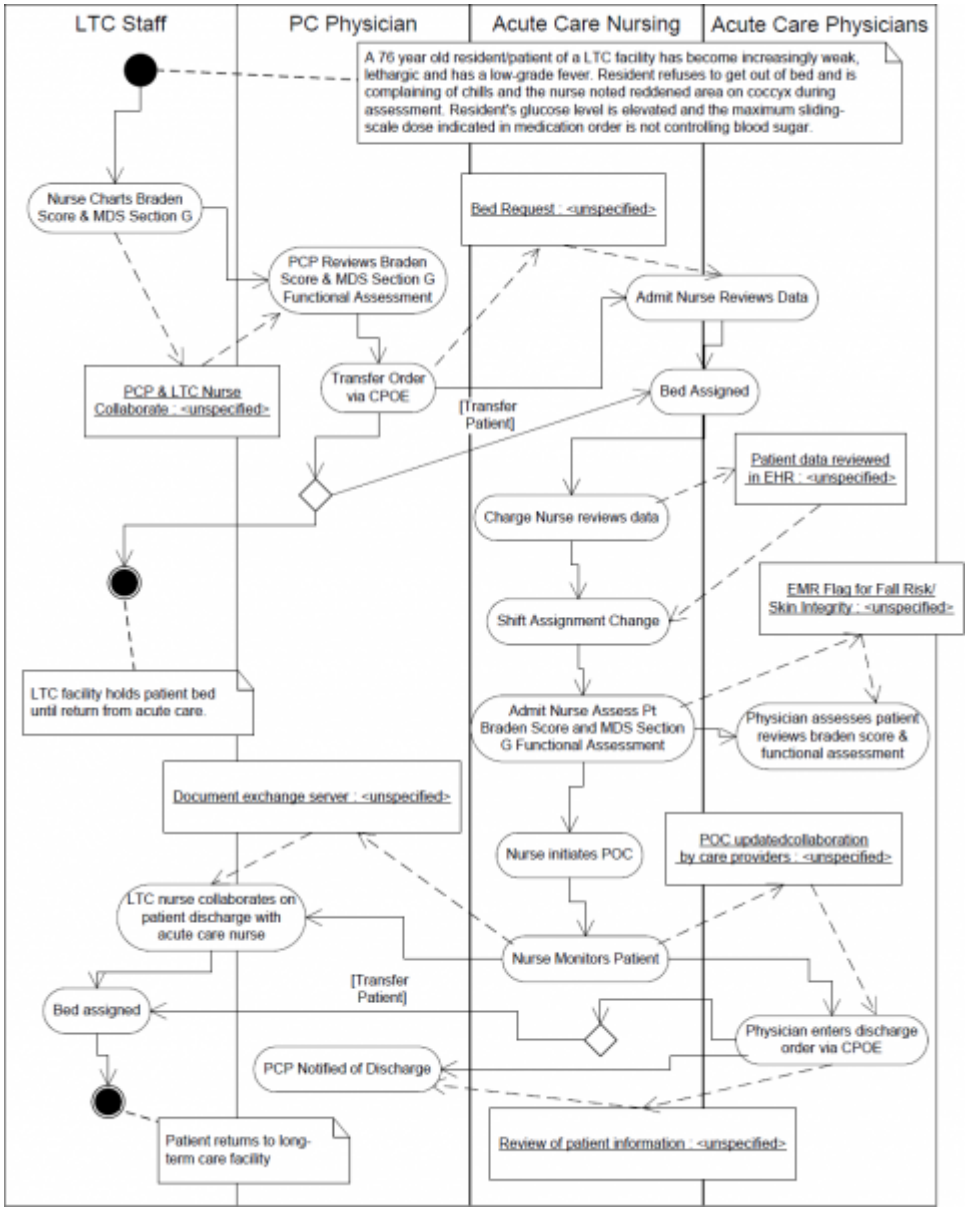

Table 3.10-2 Long Term Care to Acute Care Process Flow

Primary Actor(s): Discharge nurse in LTC facility, Admitting nurse in acute care facility

Stakeholder(s): Primary Care Physician, Hospitalist

Use Case Overview: A diabetic nursing home patient is transferring from the LTC environment to an in-patient acute care hospital based on deteriorating functional status assessments.

Use Case Scenario

1. A 76 year old resident/patient of a LTC facility has become increasingly weak, lethargic and has a low-grade fever. Resident refuses to get out of bed and is complaining of chills and the nurse noted reddened area on coccyx during assessment. Resident's glucose level is elevated and the maximum sliding-scale dose indicated in medication order is not controlling blood sugar.
    1. Nurse documents vital signs.
    2. Nurse documents finger-stick glucose measurement.
    3. Nurse documents current functional assessment.
    4. Nurse documents braden score.
    5. Nurse initiates phone collaboration with Primary Care Provider (PCP).
    6. Primary care provider(PCP)and nurse review patient status information on the electronic health record (EHR). Note: Interdisciplinary collaboration supports evaluation of physiologic changes and critical thinking leading to early intervention.
    7. PCP enters transfer order to acute care facility via computerized physician order entry (CPOE).
2. The patient's baseline and serial functional assessment data is sent to the acute care hospital via a document exchange server.
    1. Nurse admission coordinator reviews transfer documents via the EHR. Note: Early comprehensive patient information availability allows the admission coordinator to assign appropriate unit and adjust staffing based on potential acuity. Appropriate nurse to patient acuity staffing ratios support both staff and patient safety, reducing risk of errors.
    2. Bed is assigned on medical floor at acute care facility, pending admission is sent to charge nurse on the medical floor.
3. Charge nurse reviews the patient's functional status assessment data, *VS, glucose values* and braden score from LTC facility. Note: The charge nurse is provided additional time to reassign other patients and/or allowing the admitting nurse more time to prepare for the patient admission.
    1. Based on the information reviewed, Charge nurse adjusts shift assignment based on patient’s level of care.
4. Patient arrival to medical floor at acute care facility.
    1. Admitting nurse takes patient *VS* and completes admission assessment in EHR. Note: Nurse compares serial EHR preadmission assessments to new admission assessment data. Serial EHR assessments allow nurse to compare

baseline assessment to last assessment at LTC and first hospital assessment supporting critical thinking related to discharge goals.

2. Nurse records admission assessment data in EHR and EHR identifies pressure sore risk due to Braden Score total and *fall risk.*
3. Electronic health record flags need for skin care protocol to clinician. Note: Electronic notifications are an adjunct to support the critical thinking skills of the nurse taking care of the patient and reinforce the proactive monitoring and management of patient's safety needs.
4. An individualized patient plan of care (POC) initiated by nurse in EHR.
5. Skin care protocol and *fall risk protocol* implemented according to facility protocols.
6. Acute care physician assesses patient and reviews serial preadmission and current nurse assessment data in EHR. Physician adds to plan of care. Note: Having one location (EHR) for documentation from all disciplines saves time by reducing time needed to find various documentation paper tools. One EHR also supports communication and collaboration between clinicians, minimizing potential for errors.

5. Patient's medical issues are addressed during course of hospitalization (5 days).
   1. Patient's individualized POC is reviewed and updated daily by each clinician. Note: Clinician is able to review data on-line and quickly update based on availability of previous data. Plan of care and prior knowledge of baseline allow relevant and reachable goals for discharge.
   2. Progress and level of care requirement is continuously monitored by nurse and hospitalist assigned to patient

6. After several days of care, patient ready for discharge as evidenced by *blood sugar levels WNL* and increased functional status (including ambulation with assistance).
   1. Series of functional assessments and overall progress reviewed by care providers.
   2. Patient POC goals met, except level of functional status and unresolved skin risk as noted in EHR.
   3. Acute care physician enters discharge order via CPOE.
   4. PCP notified of transfer back to LTC facility and review of patient status including unresolved issues.

7. Long Term Care/Hospital collaborate on discharge plan/transfer. Note: Multiple series of assessment and POC data can be quickly reviewed and compared to

maximize safety in transfer and supports interdisciplinary decision making to reach patient goals.

2345 1. Patient readied for discharge, EHR documents completed.

2. EHR discharge documents sent to document exchange server; message sent to LTC to download documents.

3. Patient returns to LTC.

3.10.4.2 Home or Ambulatory Care into Acute Care

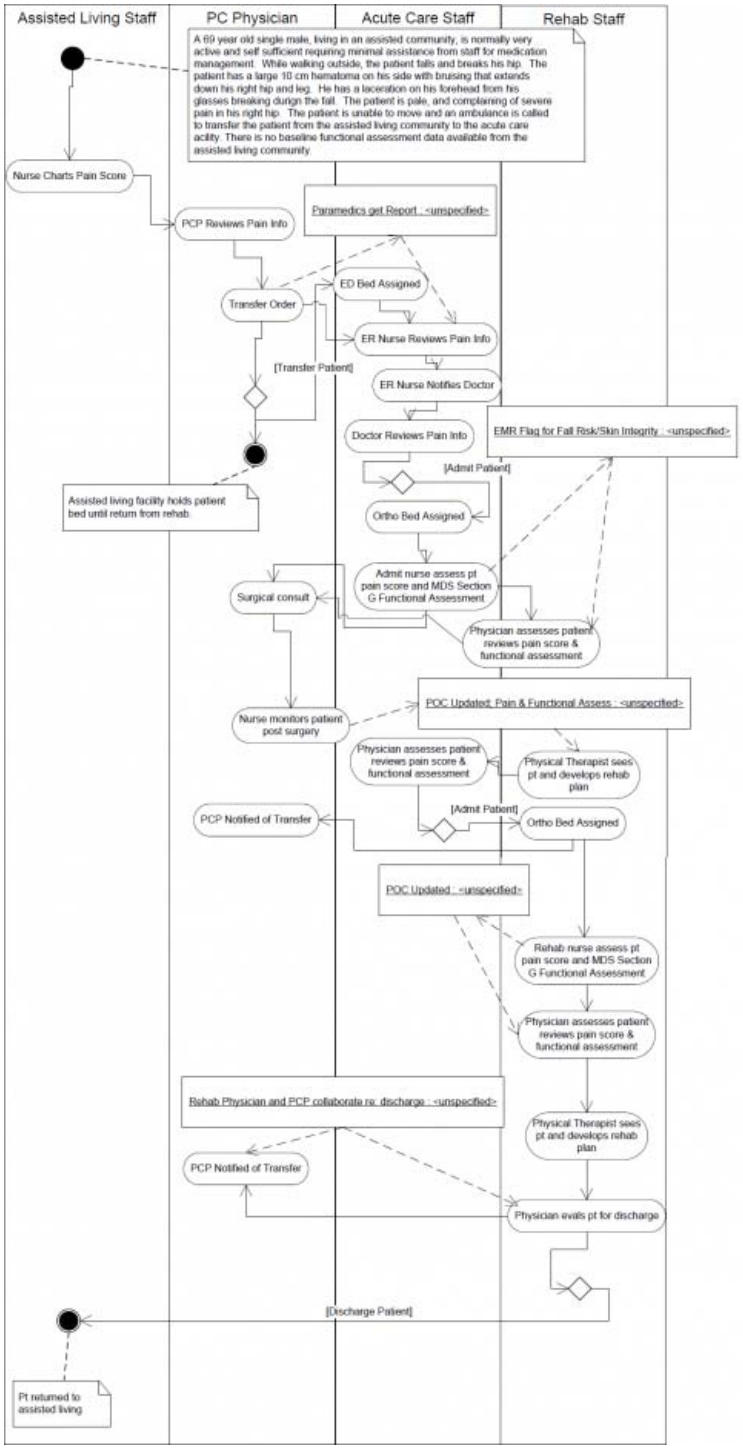

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Figure 3.10-1 Home or Ambulatory Care into Acute Care Process Flow

Primary Actor(s)

ED Nurse, ED Doctor, Surgeon, Orthopedic nurse in acute care facility, Nurse in rehab facility, Clinical staff in assisted living facility

Secondary Actor(s)

Paramedics, Physical Therapist

Stakeholder(s)

Primary Care Physician, Hospitalist

Use Case Overview

A normally active, older adult in an assisted living community has an accidental fall requiring admission to an acute care facility. Alteration in functional status requires the patient discharge to a nursing home for rehabilitation with the long term goal of returning to assisted living.

Use Case Scenario

1. A 69 year old single male, living in an assisted community, is normally very active and self sufficient and requires only minimal assistance from staff for medication management. While walking outside, the patient falls, right lower extremity alignment changes noted. The patient has a large 10 cm hematoma on his side with bruising that extends down his right hip and leg. A laceration on his forehead noted, possibly from his glasses breaking during the fall. The patient is pale, and complaining of severe pain in his right hip. The patient is unable to move and an ambulance is called. Patient is transferred from the assisted living community to the emergency department at an acute care facility. There is no baseline functional assessment data available from the assisted living community. Medical information is maintained on EHR in assisted living.
    1. Nurse charts vital signs
    2. Nurse documents information regarding hematoma, area of bruising on right side and notes alignment changes.
    3. Nurse documents information regarding head laceration and covers wound with 2x2 gauze/tape.
    4. Primary care physician is notified of ambulance transfer to acute care facility
2. The patient's history from the assisted living community is reviewed with the paramedics before the patient is moved to the ambulance prior to transfer to the acute care facility emergency department.
    1. Paramedics are provided with a brief summary of patient including age, date of birth, medical history, medications and allergies.

3. Patient is brought to emergency department of acute care facility and is assessed by clinical staff. Nurse and physician assigned to patient review accident information and patient history via the electronic health record. The nurse performs a thorough assessment of the patient's current condition, x-rays and labs are ordered. Patient is medicated for pain prior to the x-ray.
    1. ED nurse charts vital signs and accident information in electronic health record.
    2. ED nurse assesses patient's level of pain using numeric rating scale in the electronic health record.
    3. ED nurse notifies doctor of pain score.
    4. ED doctor assesses patient and reviews history.
    5. ED doctor orders hip x-ray and pain medication in electronic health record. ED doctor determines patient has hip fracture and recommends patient be transferred to the orthopedic floor with a surgical consult.
    6. ED doctor writes up admission to ortho floor and orders surgical consult in the electronic health record.
4. Patient transferred to orthopedic floor at acute care facility and has surgical consult.
    1. Admitting nurse takes patient *VS* and completes admission assessment including numeric rating scale for pain and Braden scale for pressure risk in the electronic health record.
    2. The electronic health record evaluates admission assessment data entered by the clinician and flags patient for skin integrity problem and fall risk.
    3. Skin care and fall risk protocol implemented in the electronic health record according to facility protocols.
    4. Nurse documents numeric response to pain medication.
    5. Surgeon assesses patient condition and recommends total hip replacement surgery.
5. Patient has surgery and returns to orthopedic floor. Nurses continue to monitor patient, provide interventions and assess pain level and medicate as needed. Patient begins physical therapy 1st day post-op.
    1. Individualized patient plan of care initiated in electronic health record.
        - Patient's individualized POC is reviewed and updated daily by each clinician. Note: Clinician is able to review data on-line and quickly update based on availability of previous data. Plan of care and prior knowledge of baseline allow relevant and reachable goals for discharge.

2. Patient's pain level is assessed pre and post medication using numeric rating scale and documented in electronic health record.
3. Progress and level of care requirement is continuously monitored by nurse, surgeon and physical therapist assigned to patient.
4. Physical therapist establishes rehabilitation plan and goals post total hip surgery and documents progress in electronic health record, adding rehabilitation goals to POC. Note: Interdisciplinary care planning and documentation on single EHR minimizes time spent documenting by eliminating repetition and redundancy while focusing on patient goals. Patient focus by interdisciplinary team reduces length of stay.

6. Patient regains strength and is able to transfer and toilet with assistance. Staples have been removed from hip incision and bruising is resolving. Patients level of pain has dropped significantly since admission and is requiring less pain medication.
    1. Skin care protocol is suspended.
    2. Patient plan of care updated to reflect level of care patient requires.
7. After several days of care post total hip surgery, the patient is progressing, but still not able to function independently (at previous baseline). The surgeon recommends the patient be transferred to a rehabilitation facility for more intense therapy.
    1. Series of functional assessments and overall progress reviewed by interdisciplinary team.
    2. Plan of care is updated in the electronic health record.
    3. Primary care physician is notified of plan to transfer.
    4. Patient is prepared for discharge to rehabilitation facility with final assessment completed.
8. The patient's baseline and recent functional status assessments are sent to the rehabilitation facility via a document exchange server.
    1. Rehabilitation facility nurse admission coordinator reviews transfer documents.
    2. Bed is assigned on orthopedic floor at rehabilitation facility.
    3. Notification of pending admission is sent to charge nurse on the floor at the rehabilitation facility.
9. Charge nurse reviews patient accident history, functional assessment data, and patient progress from acute care facility. Based on the information reviewed,

nurse determines that patient will require assistance transferring, toileting and ambulation and will be at risk for falls.

1. Rehab facility charge nurse adjusts shift assignment based on patient's level of care. # Patient regains strength and is able to transfer, toilet and ambulate with minimal assistance after one week and has not required pain medicine the last 3 days. Surgeon recommends patient for transfer back to assisted living facility.
2. Series of functional assessments and overall progress reviewed by care providers.
3. Plan of care is updated in EMR system.
4. Primary care physician is notified of plan to transfer patient back to assisted living facility.
5. Patient is prepared for discharge to assisted living facility with final assessment completed.

10. The patient's baseline and recent functional status assessments are sent to the assisted living facility via a document exchange server. Note: Early transfer of health information and plan of care facilitates maximum planning for safety and patient's arrival.
    1. Series of functional assessments and overall progress from rehabilitation center is reviewed by assisted living care providers.
11. Assisted living clinical staff review patients hospitalization and rehab history, functional assessment data, and patient progress. Based on the information reviewed, nurse determines that patient will require assistance transferring, toileting and ambulation and will be at risk for falls.
    1. Series of functional assessments and overall progress reviewed by interdisciplinary care team.
    2. Patient's assisted living needs have been updated to reflect fall risk and assistance with ambulation, toileting and transfer in the electronic health record.

3.10.4.3 Behavioral

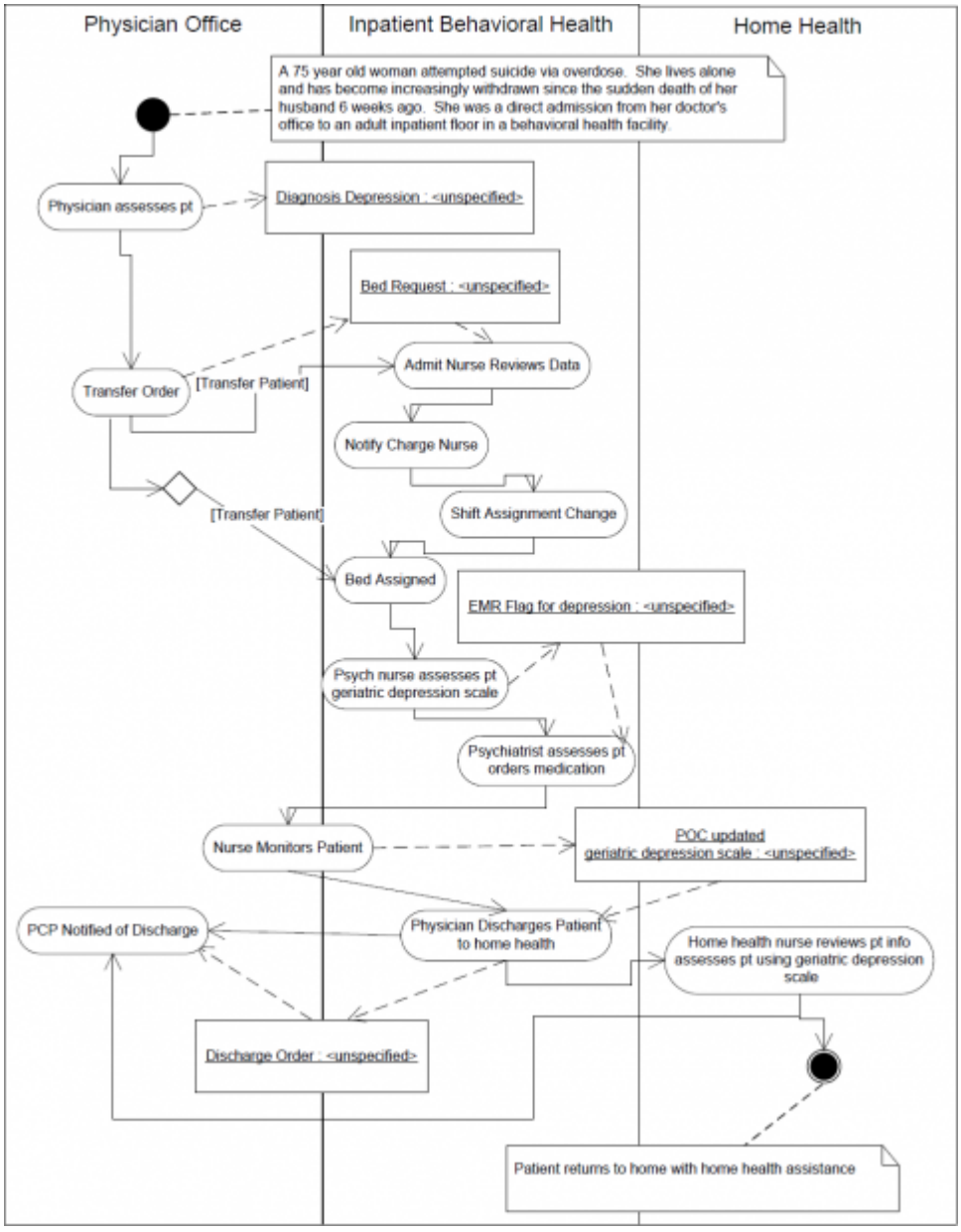

Figure 3.10-2 Behavioral Use Case Process Flow

2490 Primary Actor(s)

Psychiatric nurse, Attending physician/hospitalist, Home health nurse

Stakeholder(s)

Primary Care Physician, Outpatient psychiatrist

Use Case Overview

A recently widowed 75 year old woman is admitted to an adult inpatient floor of a behavior health hospital for depression post suicide attempt

1. A 75 year old woman who lives alone and has become increasingly withdrawn since the sudden death of her husband 6 weeks ago took several days worth of medication at one time from her pill pack. A neighbor found the confused elderly woman in the woman's home, and immediately took her to her psychiatrists office. Patient was diagnosed as depressed by her psychiatrist, and was a direct admission from her doctor's office to an adult inpatient floor in a behavioral health facility.
2. Psychiatrist notes patient issue regarding depression into electonic health record notes.
3. Patient screened by adult inpatient admission nurse using the geriatric depression scale. Her initial score was 26, indicating severe depression. Patient information was entered into the electronic health record. Patient states that she has a hard time getting going each day and is afraid of how she will survive without her husband. She has lost her appetite and is unhappy with her life without her husband.
    1. Nurse documents geriatric depression scale results in the electronic health record.
    2. Nurse documents patient's feelings and concerns in progress notes in the electronic health record.
    3. Nurse initiates plan of care for management of depression.
4. Psychiatrist reviews the patient's progress and visits patient. Psychiatrist orders anti-depressant and mood stabilizer medications via CPOE.
5. Social work evaluates the patient for her social support and financial status. The patient has no limitations in activity of daily living. She has a housekeeper come in monthly to clean and does her own grocery shopping and laundry weekly. Her nearest relative is over 1,000 miles away and her only support network are friends and neighbors that are also frail and elderly. The social worker also collaborates with the nurse regarding the signs of depression and the geriatric depression scale score. The plan of care is updated by the social worker and discharge planning begins.
6. Daily, nursing gives patient medication and assesses the patient's depression status using the geriatric depression scale. Interventional therapy sessions provided to patient to improve mood and outlook for the future.
    1. Nurse documents administration of medication.

2. Nurse documents depression assessment.
3. Nurse documents patient's response to therapies.
4. Nurse documents update to the plan of care.

7. After 5 days, patient is progressing well and responding to therapy. Most recent geriatric depression scale score documented in the electronic health record is 15, indicating mild depression.
    1. Nurse documents administration of medication.
    2. Nurse documents depression assessment.
    3. Nurse documents patient's response to therapies.
    4. Plan of care updated by nurse and social worker.
8. Patient care conference is done with patient, nurse, social worker and physician. Based on progress, patient will be discharged to home with home health visits.
    1. Patient's plan of care is updated and unresolved issues to be managed by home health services.
    2. Physician enters discharge to home order with home health services into the electronic health record.
9. Patient is discharged home with home health referral.
10. Home health nurse reviews patient status electronically and prepares for visit to patient home.
    1. Home health nurse reviews geriatric depression scale ratings from hospital and history of patient stay and underlying issues. Note: Communication of needs and depression status support early intervention by home health staff, minimizing length of time in care.
11. Home health nurse visits patient at home.
    1. Nurse assesses patient using the geriatric depression scale and enters into the electronic health record.
    2. Nurse assesses patient using oasis and enters into the electronic health record.
12. Outpatient psychiatrist reviews patient's progress from home health and follows up with patient. Note: Availability of EHR documentation to all providers of care to this patient supports continuity of care.
    1. Psychiatrist reviews continuing progress of geriatric depression scale rating since in electronic health record.
    2. Psychiatrist reviews home health Oasis assessment information in electronic health record.

3. Outpatient psychiatric appointment made by home health nurse for continuity of care. Note: Interoperable patient information available to provider at the point of care reduces redundant provision of care, thereby reducing cost, but protects patient safety during the transitions.

3.11 Query for Existing Data Profile (QED)

The Query for Existing Data Profile (QED) supports dynamic queries for clinical data. A wide variety of systems often need access to dynamic clinical information stored and maintained in an EMR system or other clinical data repository. This profile makes the information widely available to other systems within and across enterprises to support provision of better clinical care. The information made available by this profile can be used to support clinical care, quality reporting, financial transactions, public health reporting, clinical trials, drug interaction checking, and patient qualification for various protocols.

Add the following bullet to the list of profiles

- Query for Existing Data - This profile (QED) supports dynamic queries for Clinical Data. A wide variety of systems often need access to dynamic clinical information stored and maintained in an EMR system or other clinical data repository. This profile makes the information widely available to other systems within and across enterprises to support provision of better clinical care. The information made available by this profile can be used to support clinical care, quality reporting, financial transactions, public health reporting, clinical trials, drug interaction checking, and patient qualification for various protocols.

3.11.1 Dependencies

Add the following row(s) to the list of dependencies

Integration Profile	Dependency	Dependency Type	Purpose
Query for Existing Data	Audit Trail and Node Authentication	Each actor in this profile shall be grouped with the ATNA Secure Node or Secure Application actor.	Required to manage audit trail of exported PHI, node authentication, and transport encryption.
Query for Existing Data	Consistent Time	Each actor in this profile shall be grouped with the Time Client Actor	Required to manage and resolve conflicts in multiple updates.

3.11.2 Classification of Information

The QED profile classifies information into six different categories for the purpose of determining where it might be found.

Common Observations

These are a collection of simple measurements or reported values that can be determined using simple measuring devices (e.g., Height, Weight), or which can be reported by the patient (date of last menstrual period). These measurements do NOT include anything that might be recorded as a problem, allergy, risk, or which requires interpretation, clinical decision making, or diagnostic quality equipment or procedures for performing the measurement.

Diagnostic Results

These are a collection of observations made or performed using laboratory testing equipment, imaging procedures, vision examinations, et cetera.

Problems and Allergies

These are a collection of diagnoses, clinical findings, allergies, or other risk factors that are recorded for the patient. The information may be obtained from patient reports, or through clinical decision making. It includes such information as would be found in social and family history sections of clinical reports. This classfication can be further subdivided into three groups.

Conditions

This is a collection of disease conditions for the patient.

Intolerances

This is a collection of the patient's allergies and other intolerances.

Risk Factors

This is a collection of the patients significant risk factors, as might be established based on a review of family history, social history, occupational exposures, et cetera. By themselves, they may not be indicitave of a disease condition, but could contribute to one.

Medications

This is a collection of the medications that a patient is or has been taking for treatment of one or more conditions.

Immunizations

This is a collection of immunizations that have been given, or which are planned to be given to the patient.

Professional Services

This is a collection of procedures and/or encounters which the patient has participated in, or is expected to participate in.

Each of these major classifications of information can often be found in distinct repositories of information. For example, patient vital signs, problems and allergies may

be recorded in simple EHR sytem; diagnostic results in a laboratory or radiology information system; medications in a pharmacy information system, immunizations in an immunization registry, and professional services in a practice management system.

3.11.3 Actors/Transaction

There are six actors in this profile, the Clinical Data Consumer, and five different repositories of clinical data, including vitals, problems and allergies, diagnostic results, medications, and immunizations.

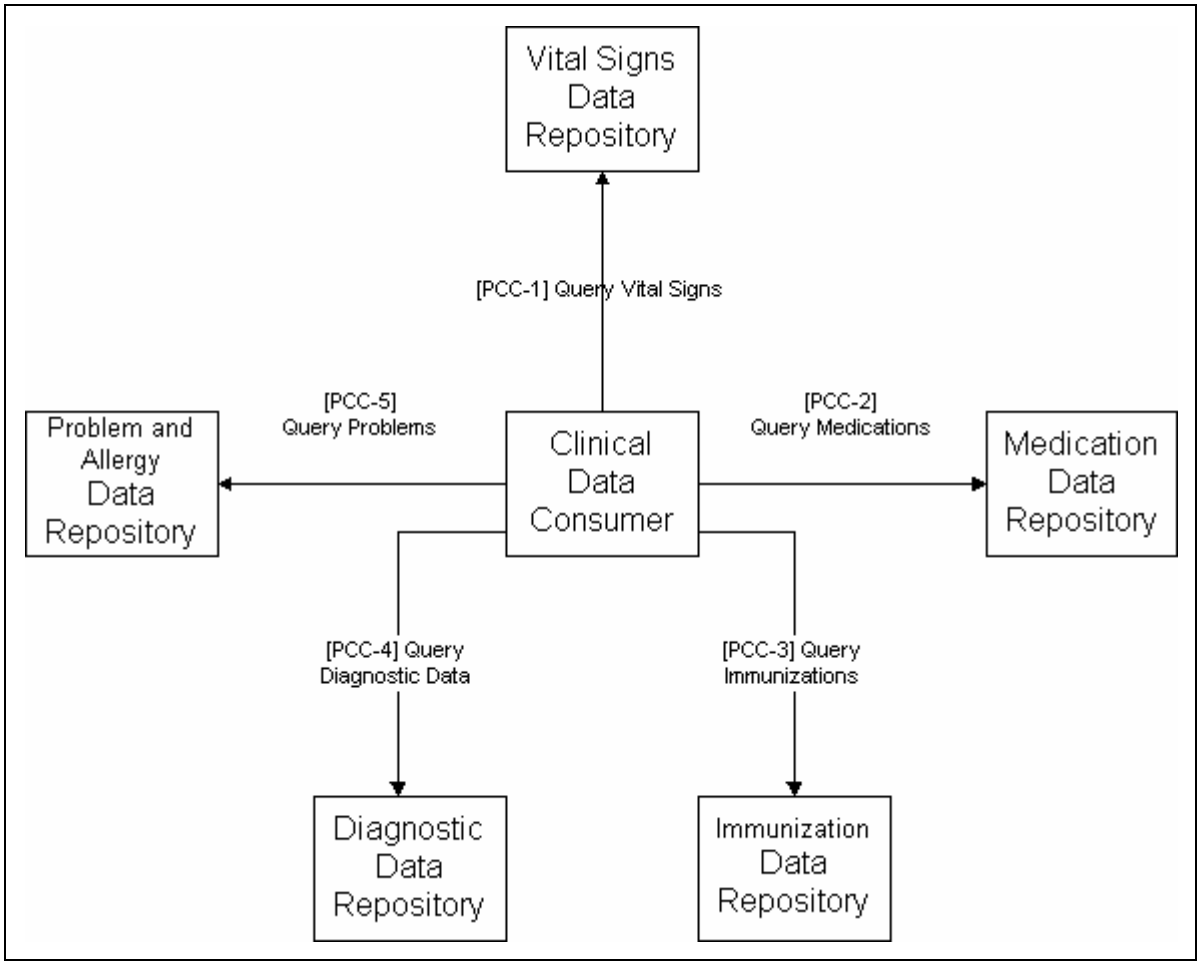

Figure 3.11-1 Query for Existing Data Actor Diagram

For Public Comment	***The Vital Signs Data Repository should probably become the Common Observations Data Repository, because it should be able to contain more than just vital signs measurements.***

The table below lists the transactions for each actor directly involved in the Query for Existing Data Profile. In order to claim support of this Integration Profile, an

implementation must perform the required transactions (labeled 'R'). Transactions labeled 'O' are optional. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed below under Options.

Actor	Name	Optionality	Transaction
Clinical Data Consumer	Query Vital Signs	O1	PCC-1
	Query Problems and Allergies	O1	PCC-2
	Query Diagnostic Data	O1	PCC-3
	Query Medications	O1	PCC-4
	Query Immunizations	O1	PCC-5
Vital Signs Data Repository	Query Vital Signs	R	PCC-1
Problems and Allergies Repository	Query Problems and Allergies	R	PCC-2
Diagnostic Data Repository	Query Diagnosic Data	R	PCC-3
Medications Repository	Query Medications	R	PCC-4
Immunizations Repository	Query Immunizations	R	PCC-5

Table 3.11-1 Query for Existing Data Actors and Transactions

Note [1]: The Actor shall support at least one of these transactions.

3.11.4 Options

Actor	Option
Vital Signs Data Repository	None Defined
Problems and Allergies Data Repository	
Diagnostic Data Repository	
Medications Data Repository	
Immunizations Data Repository	
Clinical Data Consumer	Vital Signs Option (1)
	Problems and Allergies Option (1)
	Diagnostic Data Option (1)
	Medications Option (1)
	Immunizations Option (1)

Table 3.11-2 Query for Existing Data Options

(1) At least one of these options shall be supported by a Clinical Data Consumer Actor

3.11.4.1 Vital Signs Option

A Clinical Data Consumer that implements the Vital Signs Option implements the Query Vital Signs transaction.

3.11.4.2 Problems and Allergies Option

A Clinical Data Consumer that implements the Problems and Allergies Option implements the Query Problems and Allergies transaction.

3.11.4.3 Diagnostic Data Option

A Clinical Data Consumer that implements the Diagnostic Data Option implements the Query Diagnostic Data transaction.

3.11.4.4 Medications Option

A Clinical Data Consumer that implements the Medications Option implements the Query Medications transaction.

3.11.4.5 Immunizations Option

A Clinical Data Consumer that implements the Immunizations Option implements the Query Immunizations transaction.

3.11.5 Grouping

3.11.5.1 Clinical Data Repositories

Any of the repository actors of this profile can be grouped with other repository actors. For example, an EMR might implement all of the repository actors of this profile, while a pharmacy system might implement only the Immunizations and Medications Repository actors.

When actors are grouped in this fashion, it is expected that they will provide appropriate **join** fields to show relationships between different records. For example, when a EMR groups together the Medication Data Repository and Problems and Allergies Data Repository, and recieves a request for Medications, it should also return the Problems, and internal references to those problems that are the reason for prescribing the medication.

3.11.5.2 Audit Trail and Node Authentication and Consistent Time

All actors of this profile shall be grouped with either the Secure Node or the Secure Application actor, to ensure the security of the information being exchanged. These actors shall also implement Time Client to ensure that consistent time is maintained across systems.

TBD -- what specifically are the logging requirements under this profile

- Login/Logout
- Actor Start/Stop
- Query
- Import (if the receiver imports the queried data)
- Export

3.11.5.3 Retrieve Form for Data Capture

A Clinical Data Consumer actor may be grouped with an Form Filler or Form Manager actor to appropriately populate forms with recently gathered clinical data.

3.11.5.4 Cross Enterprise Document Sharing

A Repository actor may be grouped with a Cross Enterprise Document Repository actor. Data gathered from clinical documents submitted to the Document Repository can be a source of information returned by the Repository actor. Information returned by the Repository shall include references to all documents used in generating the results.

3.11.5.5 Content Integration Profiles

A Content Creator may be grouped with a Clinical Data Consumer to obtain some or all of the information necessary to create a Medical Summary based on information found in a Repository.

A Content Creator may be grouped with a Data Repository. When grouped with a Data Repository, the Data Repository Actor shall respond to queries containing the relevant vocabulary codes used by the Content Creator.

For Public Comment	***The assumption is that if a system can create content using a particular code, then it should also be able to respond to queries using that same code.***

3.11.5.6 Patient Identity Cross Referencing and Patient Demographics Query

A clinical data consumer may be grouped with a Patient Identifier Cross-reference Consumer or a Patient Demographics Consumer actor to resolve patient identifiers prior to submitting queries to a Repository.

Within an enterprise, the need to cross-reference patient identifiers may not be necessary. However, once enterprise boundaries are crossed, these identifiers will need to be resolved. In that case either PIX or PDQ shall be used.

3.11.6 Process Flow

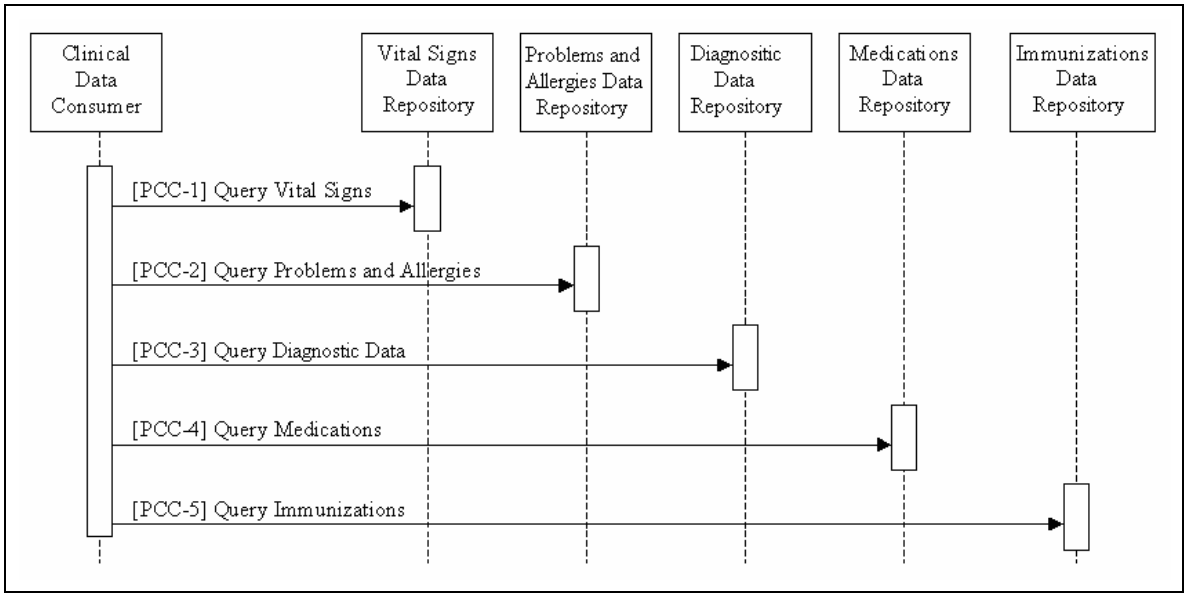

Figure 3.11-2 Query for Existing Data Process Flow

3.11.6.1 Clinical Trials

A patient participating in a clinical trial arrives for a trial-related visit to a physician office. The physician completes a report in his/her EMR gathering information relevant to the trial. Upon completion of the visit, a research assistant gathers the data relevant to the trial and submits it to the clinical trial information system. Among the data needed to gather are the patient's current medications.

The research assistant logs into the clinical trial information system, and enters data about the patient visit pertinent to the trial. The clinical trial information system performs a query of the EMR using [PCC-4] where the patient data is stored, and obtains the list of the patient's current medications.

3.11.6.2 Claims

A claims administrator begins a claim for treatment of a patient who is pregnant. They log into their practice management system to begin processing the claim. Since this claim is for services provided during pregnancy, a patient measurement is needed to complete the claim. The practice management / billing system queries the EMR for the date of last menstruation for the patient using [PCC-1], and completes the claim.

3.11.6.3 Drug Safety

Medication is about to be administered at a modality. Prior to administration, the modality queries the EMR for current problems and allergies and medications using

PCC-3 and PCC-4 to enable display of this information to the operator, or to send to a decision support system to determine if this medication is OK to administer.

A CPOE system needs to generate a medication order for a patient for a medication whose dosage is based on weight. Prior to generating the order, the system will query the EMR for the most recent weight measurements of the patient to determine the correct dose using [PCC-1]. The system also request information about the patient's current problems and allergies using [PCC-3], and medications using [PCC-4] to perform drug interaction checking before completing the order.

3.11.6.4 Public Health, Biosurveillance, and Disease Registries

During a routine pediatric visit, an EMR queries an immunization registry for the immunization history for the patient using [PCC-5]. Upon review of the information, it appears that on a recent visit, the patient was scheduled for immunization, but the immunization was not given due to a current fever. The fever ius not longer present, so the immunization is given to the patient.

Upon completion of the visit, a reporting application is notified. The reporting application queries the EMR visit data to see if any immunizations were given during the just completed visit using [PCC-5]. If an immunization was given during the visit, the reporting application collects the appropriate data and submits it to an immunization registry.

3.11.6.5 Identifying Qualifying Patients

Decision support systems can query the EMR to obtain specific data elements for a patient, and use that information to determine if the patient qualifies for a clinical trial, or if the visit is one that requires additional reporting.

Upon completion of a visit, the EMR activates a decision support system. The decision support system queries the EMR for patient diagnoses using PCC-3. Upon determining that the patient has been diagnosed with Diabetes, the decision support system notifies the EMR that it needs to activate protocols for diabetic care. This use case could be continued as described in the section below.

3.11.6.6 Quality Reports and Disease Management

Upon completion of a visit, certain quality measures need to be gathered in order to produce an aggregate measure. A quality system can query the EMR to determine for each patient the values that need to be measured.

A diabetic patient completes a routine visit. The EMR queries a Lab Result Repository using PCC-2 to determine if a recent HgA1C result is available from the last six months using [PCC-2]. Upon failing to find one the EMR system notifies the physician that an updated HgA1C test is required.

3.11.6.7 Disease Management

A physician wants to monitor a patient's blood sugar levels and body mass index. She requests a graph of the patient's blood sugar lab results (lab) and BMI (vital signs) for the past 9 months from a desktop application. The desktop application queries the EMR for the selected vital signs for the indicated time period using PCC-1, and graphs the data appropriately.

Appendix A - Actor Descriptions

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise.

Content Creator

The Content Creator Actor is responsible for the creation of content and transmission to a Content Consumer.

Content Consumer

A Content Consumer Actor is responsible for viewing, import, or other processing of content created by a Content Creator Actor.

Clinical Data Consumer

A clinical data consumer makes use of clinical patient data.

Vital Signs Data Repository

A Vital Signs Data Repository maintains patient vital signs data.

Problems and Allergies Repository

A Problems and Allergies Repository maintains patient problem and allergy data.

Diagnostic Data Repository

A Diagnostic Data Repository Repository maintains results from diagnostic tests (e.g., Lab, Imaging, or other test results).

Medications Data Repository

A Medications Data Repository maintains patient medication data.

Immunizations Data Repository

An Immunizations Data Repository maintains patient immunization data.

Transaction Descriptions

Transactions are interactions between actors that transfer the required information through standards-based messages.

Query Vital Signs

Request information about recent patient measurements, usually used to obtain vital signs measurements. The query may request all measurements, or those taken for a specific encounter, or date range, or may be for a specific set of measurements.

Query Problems and Allergies

Request information about problems or allergies known for a patient, usually to determine the patients current problems and allergies. The query may request information about all problems, all allergies, or may request information on a specific problem or allergy entry, entered during a specific encounter or date range.

Query Diagnostic Data

Request information about diagnostic results known for a patient. The query may request information about all diagnostic results, or may request information on a specific diagnostic result entry, or one entered for a specific encounter or date range.

Query Medications

Request information about medications given to, or being taken by a patient. The query may request information about all medications or may request information on a specific kind of medication or immunization, or one entered for a specific encounter or date range.

Query Immunizations

Request information about immunizations given to a patient. The query may request information about all immunizations, all immunizations or may request information on a specific kind of medication or immunization, or one entered for a specific encounter or date range.

Appendix B – IHE Integration Statements

A.1 How to Prepare an IHE Integration Statement

IHE Integration Statements are documents prepared and published by vendors to describe the conformance of their products with the IHE Technical Framework. They identify the specific IHE capabilities a given product supports in terms of IHE actors and integration profiles described in the technical frameworks of each domain.

Users familiar with these concepts can use Integration Statements to determine what level of integration a vendor asserts a product supports with complementary systems and what clinical and operational benefits such integration might provide. Integration Statements are intended to be used in conjunction with statements of conformance to specific standards (e.g. HL7, IETF, DICOM, W3C, etc.).

IHE provides a process for vendors to test their implementations of IHE actors and integration profiles. The IHE testing process, culminating in a multi-party interactive testing event called the Connect-a-thon, provides vendors with valuable feedback and provides a baseline indication of the conformance of their implementations. The process is not intended to independently evaluate, or ensure, product compliance. In publishing the results of the Connect-a-thon and facilitating access to vendors' IHE Integration Statements, IHE and its sponsoring organizations are in no way attesting to the accuracy or validity of any vendor's IHE Integration Statements or any other claims by vendors regarding their products.

IMPORTANT -- PLEASE NOTE: Vendors have sole responsibility for the accuracy and validity of their IHE Integration Statements. Vendors' Integration Statements are made available through IHE simply for consideration by parties seeking information about the integration capabilities of particular products. IHE and its sponsoring organizations have not evaluated or approved any IHE Integration Statement or any related product, and IHE and its sponsoring organizations shall have no liability or responsibility to any party for any claims or damages, whether direct, indirect, incidental or consequential, including but not limited to business interruption and loss of revenue, arising from any use of, or reliance upon, any IHE Integration Statement.

A.2 Structure and Content of an IHE Integration Statement

An IHE Integration Statement for a product shall include:

1. The Vendor Name
2. The Product Name (as used in the commercial context) to which the IHE Integration Statement applies.
3. The Product Version to which the IHE Integration Statement applies.

4. A publication date and optionally a revision designation for the IHE Integration Statement.
5. The following statement: "This product implements all transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors and Options listed below:"
6. A list of IHE Integration Profiles supported by the product and, for each Integration Profile, a list of IHE Actors supported. For each integration profile/actor combination, one or more of the options defined in the IHE Technical Framework may also be stated. Profiles, Actors and Options shall use the names defined by the IHE Technical Framework Volume I. (Note: The vendor may also elect to indicate the version number of the Technical Framework referenced for each Integration Profile.)

Note that implementation of the integration profile implies implementation of all required transactions for an actor as well as selected options.

The statement shall also include references and/or internet links to the following information:

1. Specific internet address (or universal resource locator [URL]) where the vendor's Integration Statements are posted
2. URL where the vendor's standards conformance statements (e.g., HL7, DICOM, etc.) relevant to the IHE transactions implemented by the product are posted.
3. URL of the IHE Initiative's web page for general IHE information www.himss.org/ihe.

An IHE Integration Statement is not intended to promote or advertise aspects of a product not directly related to its implementation of IHE capabilities.

A.3 Format of an IHE Integration Statement

Each Integration Statement shall follow the format shown below. Vendors may add a cover page and any necessary additional information in accordance with their product documentation policies.

2885

IHE Integration Statement	Date	12 Oct 2005
Vendor	**Product Name**	**Version**
Any Medical Systems Co.	IntegrateRecord	V2.3
This product implements all transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors and Options listed below:		
Integration Profiles Implemented	**Actors Implemented**	**Options Implemented**
Cross-Enterprise Sharing of Medical Summaries	Document Consumer	View Option
Audit Trail and Node Authentication	Secure Node	none
Patient Identity Cross-referencing	Patient Identifier Cross-reference Consumer	PIX Update Notification
Internet address for vendor's IHE information: www.anymedicalsystemsco.com/ihe		
Links to Standards Conformance Statements for the Implementation		
HL7	www.anymedicalsystemsco.com/hl7	
Links to general information on IHE		
In North America: www.ihe.net	In Europe: www.ihe-europe.org	In Japan: www.jira-net.or.jp/ihe-j

The assumption of an integration statement is that all actors listed are functionally grouped and conform to any profile specifications for such groupings. In case of exceptions the vendor must explicitly describe the functional groupings.

Glossary

The following terms are used in various places within this technical framework, and are defined below. The complete IHE Glossary is available on the IHE Wiki at http://wiki.ihe.net/index.php/IHE_Glossary .

Actor

An entity within a use case diagram that can perform an action within a use case diagram. Possible actions are creation or consumption of a message

ADT

Admit, Discharge & Transfer.

Affinity Domain Policy

Affinity Domain Policy that clearly defines the appropriate uses of the XDS Affinity Domain. Within this policy is a defined set of acceptable use Privacy Consent Policies that are published and understood.

ASTM

Formerly the American Society of Testing and Materials, now ASTM International. An SDO that develops a number of standards across a wide variety of industries, including healthcare.

ATNA

Audit Trail and Node Authentication. An IHE ITI profile.

Care Context

The participations surrounding the care provision act, and the attributes of that act. Everything in the document header. Data history, links to clinical reasoning.

CDA

Clinical Document Architecture. An HL7 standard for the exchange for clinical documents.

Content Binding

A content binding describe how the payload used in an IHE transaction is related to and/or constrained by the data elements contained within the content sent or received in those transactions.

CRS

Care Record Summary. An implementation guide that constrains CDA Release 2 for Care Record Summary documents.

CT

Consistent Time Integration Profile.

DICOM

Digital Imaging and Communication in Medicine

DSG

Digital Signatures. An IHE ITI Profile.

EDIS

Emergency Department Information System.

eMPI

Enterprise Master Patient Index.

EMR

Electronic Medical Record, an Electronic Health Record system used within an enterprise to deliver care (also called EHR-CR by IHE-XDS).

Estimated Time of Arrival

the time the patient being referred can be expected to arrive in the emergency department.

EUA

Enterprise User Authentication Integration Profile.

Expected Actions

Actions which should occur as the result of a trigger event.

Functional Role

Role an individual is acting under when they are executing a function. See ISO 21298

HIMSS

Healthcare Information and Management Systems Society.

HL7

Health Level Seven

HIS

Hospital Information System.

IHE

Integrating the Healthcare Enterprise.

Interaction Diagram

A diagram that depicts data flow and sequencing of events.

IT

Information Technology.

MPI

Master Patient Index.

MRN

Medical Record Number.

NAV

Notification of Document Availability

OID

Object Identifier. (See also 'Globally Unique Identifier').

Patient Privacy Consent

The act of a patient consenting to a specific Privacy Consent Policy.

Patient Privacy Consent Document

A document that follows the BPPC profile and captures the act of the patient consenting to a specific XDS Affinity Domain defined Privacy Consent Policy.

Patient Identifier Cross-reference Domain

Consists of a set of Patient Identifier Domains known and managed by a Patient Identifier Cross-reference Manager Actor. The Patient Identifier Cross-reference Manager Actor is responsible for providing lists of "alias" identifiers from different Patient Identifier Domains.

Patient Identifier Domain

A single system or a set of interconnected systems that all share a common identification scheme for patients. Such a scheme includes: (1) a single identifier-issuing authority, (2) an assignment process of an identifier to a patient, (3) a permanent record of issued patient identifiers with associated traits, and (4) a maintenance process over time. The goal of Patient Identification is to reduce errors.

PDF

Portable Document Format.

PIX

Patient Identifier Cross Referencing. An IHE ITI Profile.

PDQ

Patient Demographics Query. An IHE ITI Profile.

PHR

Personal Health Record

Privacy Consent Policy

One of the acceptable-use Privacy Consent Policies that are agreed to and understood in the Affinity Domain.

Privacy Consent Policy Act Identifier

An Affinity Domain assigned identifier that uniquely defines the act of a patient consenting to a specific Affinity Domain: Privacy Consent Policy.

Privacy Consent Policy Identifier

An Affinity Domain assigned identifier (OID) that uniquely identifies the Affinity Domain: Privacy Consent Policy. There is one unique identifier (OID) for each Privacy Consent Policy within the Affinity Domain.

Procedure

In the context of a "Pre-procedure History and Physical," the "procedure" is a surgery or an invasive examination of a patient that is required by quality review organizations to be preceded by a pre-procedure assessment of procedure risk and anesthesia risk. This assessment is typically referred to as a "Pre-operative" or "Pre-procedure History and Physical."

Process Flow Diagram

A graphical illustration of the flow of processes and interactions among the actors involved in a particular example.

Proposed disposition

the intended disposition (i.e. admission to ICU, discharge to home, transfer to psychiatric hospital), if known, that the referring provider expects the patient will end up after the emergency department intervention.

Role

The actions of an actor in a use case.

RSNA

Radiological Society of North America.

sig.

A Latin abbreviation for signetur used to represent the instruction following the medication name.

Scope

A brief description of the transaction.

Structural Role

Role of an individual within an organization. See ISO 21298

Transport Mode

the method the patient employs, or is provided to get to the emergency department.

Trigger Event

An event such as the reception of a message or completion of a process, which causes another action to occur.

UID

Unique Identifier (See also Globally Unique Identifier).

Universal ID

Unique identifier over time within the UID type. Each UID must belong to one of specifically enumerated species. Universal ID must follow syntactic rules of its scheme.

Use Case

A graphical depiction of the actors and operation of a system.

Wet Signature

Ink on paper signature.

XUA

Cross Enterprise User Authentication

XDS

Cross Enterprise Document Sharing

