Integrating the Healthcare Enterprise



IHE Patient Care Coordination (PCC)

Technical Framework Volume I Revision 5.0

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Foreward

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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 Healthcare Information and Management Systems Society (<u>HIMSS</u>) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE

- Radiological Society of North America (<u>RSNA</u>). <u>IHE Canada</u> has also been formed. IHI Europe (<u>IHE-EUR</u>) is supported by a large coalition of organizations including the European Association of Radiology (<u>EAR</u>) and European Congress of Radiologists (<u>ECR</u>), the Coordination Committee of the Radiological and Electromedical Industries (<u>COCIR</u>), Deutsche Röntgengesellschaft (<u>DRG</u>), the <u>EuroPACS Association</u>,
- Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH),
 Société Française 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
- Association of Radiological Systems (<u>JIRA</u>), the Japan Association of Healthcare Information Systems Industry (<u>JAHIS</u>), Japan Radiological Society (<u>JRS</u>), Japan Society of Radiological Technology (<u>JSRT</u>), and the Japan Association of Medical Informatics (<u>JAMI</u>). 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.

145 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.

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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1.1 Preface to Volume 1 of the PCC Technical Framework

170 1.1.1 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

1.1.2 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 http://www.ihe.net/Technical_Framework/index.cfm)
- HL7 Clinical Document Architecture Release 2: Section 1, CDA Overview.
- Care Record Summary Implementation Guide for CDA Release 2 (US Realm): Section 1
- Presentations from IHE Workshop: Effective Integration of the Enterprise and the Health System - June 28–29, 2005: http://www.ihe.net/Participation/workshop 2005.cfm, June 2005:
- For a RHIO-3.ppt Leveraging IHE to Build RHIO Interoperability
- Cross-Enterprise Document Sharing (XDS)
- Notification of Document Availability (NAV)
- Use Cases for Medical Summaries
- Ovrw.ppt Patient Care Coordination Overview of Profiles

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.

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205 1.1.4 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.

1.1.4.1 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:

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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.

1.1.4.2 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 Audit Trail and Node Authentication (ATNA). These dependencies can be found by locating the desired profile in the dependencies section of this document 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.

245 **1.1.4.3 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.

1.1.5 Copyright Permissions

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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.

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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:

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- 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.
 - 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 Connectations
 - The Committee regularly considers change proposals to the Trial Implementation version of the Technical Framework, including those from implementers who participate in the Connectation. After resolution of all change proposals received within 60 days of the Connectation, 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 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.

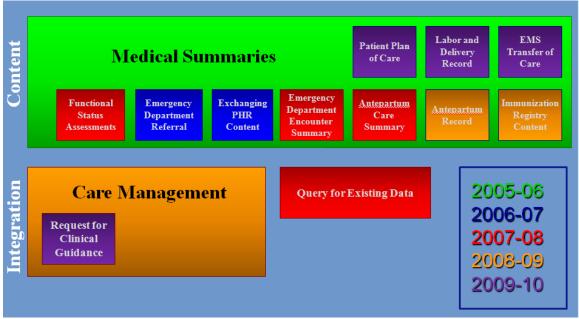


Figure 2.4-1 IHE Patient Care Coordination Content Integration Profiles

2.5 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 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.

Integration Profile	Depends on	Dependency Type	Purpose
All PCC Content Profiles	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.

Table 2.5-1 PCC Profile 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.

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2.6 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.
- The content of the IHE transactions

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.

The content of the transactions are presented as Content Integration Profiles. These are specification of the content to be exchange, along with explanations (called bindings) of how the content affects the transactions in which it is exchanged. It is expected that Content Integration Profiles will be used environments 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 & PDO), 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/.

435 Such an infrastructure is assumed by the use cases that focus on the context for defining the specific clinical information content for this profile. These content integration profiles use similar transactions and differ only in the content exchanged. A process flow for these use cases using Cross Enterprise Document Sharing (XDS) and Notification of Document Availability (NAV) is shown in the figure below. Other process flows are possible using XDM and/or XDR.

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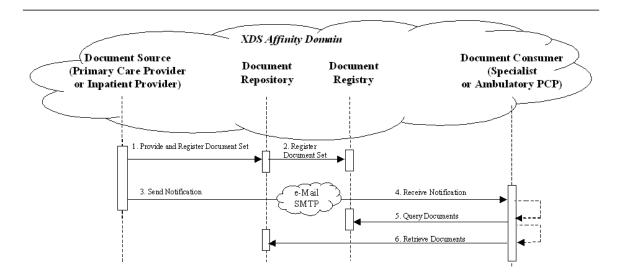


Figure 2.6-1 Use Case Process Flow Diagram

These steps are:

- 1. Extract/capture a collection of records into a set of documents packaged as an XDS Submission Set. This submission contains at least one clinical document, and may contain a number of other related clinical documents. For example, Medical Summaries are clinical documents (already known in the paper world), which often serve the dual purpose of documenting an encounter and 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).
 - 2. 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).
- 455 3. 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.
 - 4. The e-mail notification that contains no patient identified information is received by the specialist EMR system.
- The receiving provider can then utilize existing query transactions from the XDS profile to find the URL of the Documents.
 - 6. Finally, the receiving provider may choose to display the document, or import relevant information from these records into their own EMR system.

2.6.1 Unplanned Access to past Content

In many cases, a provider may need to assess information from the patient care history, and patients may have content 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.

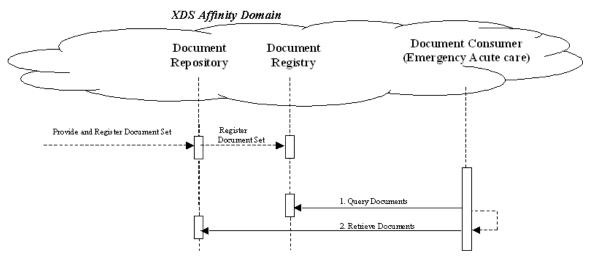


Figure 2.6-2 Unplanned Access Process Flow Diagram

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 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

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other healthcare providers to enable better interoperability between these systems. 500 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. 505 Please Note: This profile was transferred to the ITI Domain in the Fall of 2007, and can be found here http://www.ihe.net/Technical_Framework/index.cfm#IT **Pre-procedure History and Physical Content Profile (PPHP)** – supports the exchange of information allowing for the assessment and amelioration of 510 risks related to a procedure. Please Note: This profile has been withdrawn. **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 515 integration profiles were added as supplements to the technical framework. **Antepartum Care Summary (APS)** - describes the content and format of summary documents used during Antepartum care. **Emergency Department Encounter Summary (EDES)** - describes the content and format of records created during an emergency department visit. 520 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 525 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. [Please Note: This profile has been subsequently moved to the XD-LAB specification, and 530 van be found here http://www.ihe.net/Technical Framework/index.cfm#LAB] In addition, all content within the technical framework was revised in the 2007-2008

cycle to encourage compatibility with the ASTM/HL7 Continuity of Care Document Implementation Guide.

In the 2008-2009 cycle of the IHE Patient Care Coordination initiative, the following 535 integration profiles were added as supplements to the technical framework.

- **Antepartum Record (APR)** describes the content and format of summary documents used during Antepartum care.
- Care Management (CM) describes the content and format of summary documents used during Antepartum care.

• Immunization Content (IC) - describes the content and format of summary documents used during Antepartum care.

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:

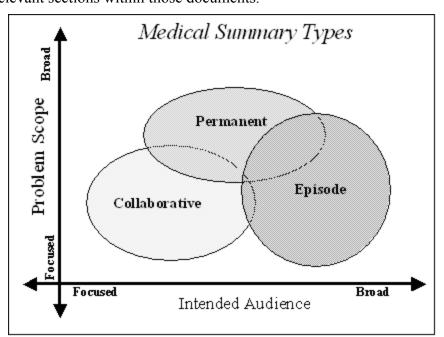
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- For a system, select which actors it will incorporate (multiple actors per system are acceptable).
- For each actor, select the integration profiles in which it will participate.
- For each actor and profile, select which options will be implemented.
- 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
- 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 Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile

575 **3.1 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.



3.1-1 Medical Summary Types

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

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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.

620 3.2 Process Flow

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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.

3.2.1 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
- 640 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.
- 645 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.
- 650 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.

3.2.2 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 655 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. 660
 - 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.
- 665 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).

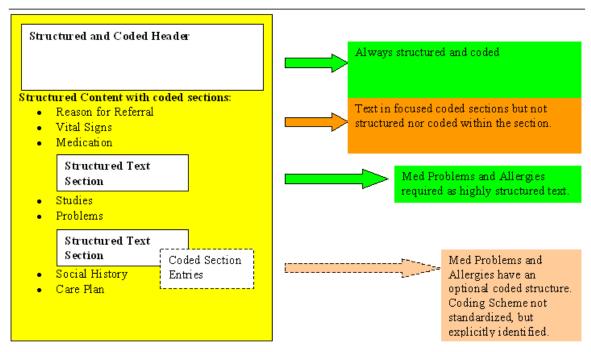
3.2.3 Content Interoperability Levels

- The use cases described above imply different levels of interoperability. At the lowest 670 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 675 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.



3.2.3-1 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.

715 3.2.4 Use Case Conclusion

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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.

3.3 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. in PCC
TF 2:4.1



3.3.1-1 XDS-MS Actor Diagram

3.4 Options

Actor	Option
	<u>View Option</u> (1)
Content Consumer	Document Import Option (1)
Content Consumer	Section Import Option (1)
	<u>Discrete Data Import Option</u> (1)
Content Creator	Referral Option (1)
Content Cleator	<u>Discharge Summary Option</u> (1)

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

3.4.1 Content Consumer Options

3.4.1.1 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 2:3.0.1 for more details on this option.

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 shall be able to present a view of the document using this style sheet if present.

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3.4.1.2 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 2:3.0.2 for more details on this option.

3.4.1.3 Section Import Option

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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 2:3.0.3 for more details on this option.

3.4.1.4 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 2:3.0.3 for more details on this option.

3.4.2 Content Creator Options

3.4.2.1 Referral Option

Content Creators implementing this option shall create Referrals that comply with the Referral Content Module in PCC TF 2:6.1.1.3.

775 **3.4.2.2 Discharge Summary Option**

Content Creators implementing this option shall create Discharge Summaries that comply with the Discharge Summary Content Module in PCC TF 2:6.1.1.4.

3.5 Coded Terminologies

This profile supports the capability to record entries beyond the IHE required coding associated with structured data. Actors from this profile 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 implementing the profile Actors, 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.

An Example HL7 Conformance Profile is available to show how to construct such a statement. See the <u>HL7 Refinement Constraint and Localization</u> for more details on HL7 conformance profiles.

3.6 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.

3.6.1 Referral Summary

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All referral summaries shall be structured and coded as required by the <u>Referral Summary Content Module</u> described in PCC TF-2:6.1.1.3. 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.

3.6.2 Discharge Summary

All discharge summaries shall be structured and coded as required by the <u>Discharge Summary Content Module</u> described in PCC TF-2:6.1.1.4. 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.

3.7 Grouping with other Profile Actors

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

3.7.1 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 may be grouped with appropriate actors from the XDS, XDM or XDR profiles to exchange the content described therein. The metadata sent in the document sharing or interchange messages has specific relationships or dependencies (which we call bindings) to the content of the clinical document described in the content profile.

The Patient Care Coordination Technical Framework defines the bindings to use when grouping the Content Creator of this Profile with actors from the IHE ITI XDS, XDM or XDR Integration Profiles.

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Content	Binding	Actor	Optionality
Referral Summary	Medical Document Binding to XDS, XDM and	Content Creator	O (Note 1)
PCC TF-2:6.1.1.3	XDR PCC TF-2:4.1	Content Consumer	R
Discharge	Medical Document Binding to XDS, XDM and	Content Creator	O (Note 1)
Summary PCC TF-2:6.1.1.4	XDR PCC TF-2:4.1	Content Consumer	R

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.

3.7.2 Notification of Document Availability (NAV)

When a Content Creator actor of the XDS-MS Integration Profile needs to notify other systems of documents, it may support the ITI Notification of Document Availability (NAV) Integration Profile. 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. When a Content Consumer wants to provide the capability to receive a Receive Notification Transaction it may support the Document Consumer Actor of the NAV Integration Profile. The Send Acknowledgement option may be used to issue a Send Acknowledgement to a Document Source that the notification was received and processed.

3.7.3 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.

3.8 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.

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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.

875 3.9 Requirements of XDS-MS Actors

This section describes the specific requirements for each Actor defined within this profile. Specific details can be found in Volume 1 and Volume 2 of the technical framework.

3.9.1 Content Creator

- 1. A Content Creator shall be able to create either a Referral Summary or a Discharge Summary, or both, according to the specifications for these content profiles found in PCC TF-2: 6.1.1.3 and 6.1.1.4.
 - 2. A Content Creator shall be grouped with the Time Client Actor, and shall synchronize its clock with a Time Server.
 - 3. A Content Creator shall be grouped with the Secure Node or Secure Application Actor of the ATNA profile.
 - 4. All activity initiated by the application implementing the Content Creator shall generate the appropriate audit trail messages as specified by the ATNA Profile. The bare minimum requirements of a Content Creator are that it be able to log creation and export of clinical content.
 - 5. A Content Creator shall use secure communications for any document exchanges, according to the specifications of the ATNA profile.

3.9.2 Content Consumer

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- 6. A Content Consumer shall be able to consume a Referral Summary and a Discharge Summary.
- 7. A Content Consumer shall implement the View Option or Discrete Data import option, or both.
- 8. A Content Consumer that implements the Document Import or Section Import Option shall implement the View Option as well.
- 9. A Content Consumer that implements the View option shall be able to:
 - Demonstrate rendering of the document for display.
 - Print the document.
 - Display the document with its original style sheet.
 - Support traversal of any links contained within the document.
- 905 10. A Content Consumer that implements the Document Import Option shall:
 - 1. Store the document.
 - 2. Demonstrate the ability to access the document again from local storage.
 - 11. A Content Consumer that implements the Section Import Option shall offer a means to import one or more document sections into the patient record as free text.
 - 12. A Content Consumer that implements the Discrete Data Import Option shall offer a means to import structured data from one or more sections of the document.
 - 13. A Content Consumer Actor shall be grouped with the Time Client Actor, and shall synchronize its clock with a Time Server.
 - 14. All activity initiated by the application implementing the Content Consumer shall generate the appropriate audit trail messages as specified by the ATNA Profile. The bare minimum requirements of a Content Consumer are that it be able to log views or imports of clinical content.
- 920 15. A Content Consumer shall log events for any views of stored clinical content.
 - 16. A Content Consumer shall use secure communications for any document exchanges, according to the specifications of the ATNA profile.

4 Exchange of Personal Health Record Content Integration Profile (XPHR)

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.

935 4.1 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.

PHR systems allow patients to manage their healthcare information. EHR and other information systems allow healthcare providers to manage the electronic records they maintain for their patients. 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.

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4.2 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.



4.2-1 XPHR Actor Diagram

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4.3 Options

Actor	Option	
	View Option (1)	
Content Consumer	Document Import Option (1)	
	Section Import Option (1)	
	<u>Discrete Data Import Option</u> (1)	
Content Creator	<u>Update Option</u>	

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

4.3.1 Content Consumer Options

980 **4.3.1.1 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 2:3.0.1 for more details on this option.

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 shall be able to present a view of the document using this style sheet if present.

4.3.1.2 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 2:3.0.2 for more details on this option.

4.3.1.3 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 2:3.0.3for more details on this option.

4.3.1.4 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 2:3.0.4 for more details on this option.

4.3.2 Content Creator Options

1005 **4.3.2.1 Update Option**

Content Creators supporting the update option shall create be able to create a PHR Update Module Content document structured and coded as required by the PHR Update Module Content found in PCC TF 2: 6.1.1.6.

4.4 Coded Terminologies

- This profile supports the capability to record entries beyond the IHE required coding associated with structured data. Actors from this profile 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 implementing the profile Actors, 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.

An Example HL7 Conformance Profile is available to show how to construct such a statement. See the <u>HL7 Refinement Constraint and Localization</u> for more details on HL7 conformance profiles.

4.5 XPHR Content Modules

1025 4.5.1 PHR Extract Module

The content exchanged shall be structured and coded as required by the PHR Extract Module Content defined in PCC TF 2:6.1.1.5. The Content Creator Actor creates a PHR Extract and shares it with the Content Consumer.

4.5.2 PHR Update Module

1030 The content exchanged shall be structured and coded as required by the PHR Update Module Content defined in PCC TF 2:6.1.1.6. 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.

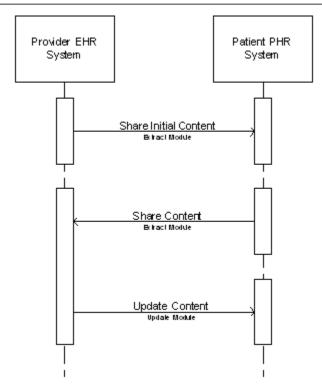
4.6 XPHR Integration Profile Process Flow

One key use scenario has been identified as an example. This use case originated with the Cross-Enterprise Document Sharing on Media (XDM) profile, and is reproduced here.

4.6.1 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).
- 1050 **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.



4.6.1-1 Basic Process Flow in XPHR Profile

4.7 Grouping with Other Actors

4.7.1 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 may be grouped with appropriate actors from the XDS, XDM or XDR profiles
to exchange the content described therein. The metadata sent in the document sharing or
interchange messages has specific relationships or dependencies (which we call bindings)
to the content of the clinical document described in the content profile.

The Patient Care Coordination Technical Framework defines the bindings to use when grouping the Content Creator of this Profile with actors from 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
THE Extract	Medical Bootaliest Bilding to ABB, ABM and ABR	Content Consumer	R
PHR Update	Medical Document Binding to XDS, XDM and XDR	Content Creator	О
Tine opauce	Wedlett Bottanient Bilding to 7855, 785W and 785K	Content Consumer	R

4.7.2 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.

4.8 Requirements of XPHR Actors

This section describes the specific requirements for each Actor defined within this profile. Specific details can be found in Volume 1 and Volume 2 of the technical 1085 framework

4.8.1 Content Creator

- 1 A Content Creator shall be able to create a PHR Extract according to the specification for that content profile found in PCC TF-2:6.1.1.5.
- 1090 2. A Content Creator implementing the Update option shall be able to create a PHR Update according to the specification for that content profile found in PCC TF-2:6.1.1.6.
 - 3. A Content Creator shall be grouped with the Time Client Actor, and shall synchronize its clock with a Time Server.
- 1095 4. A Content Creator shall be grouped with the Secure Node or Secure Application Actor of the ATNA profile.
 - 5. All activity initiated by the application implementing the Content Creator shall generate the appropriate audit trail messages as specified by the ATNA Profile. The bare minimum requirements of a Content Creator are that it be able to log creation and export of clinical content.
 - A Content Creator shall use secure communications for any document exchanges, according to the specifications of the ATNA profile.

4.8.2 Content Consumer

- A Content Consumer shall be able to consume a PHR Extract and a PHR 1 Update.
- 2. A Content Consumer shall implement the View Option or Discrete Data import option, or both.
- 3. A Content Consumer that implements the Document Import or Section Import Option shall implement the View Option as well.
- A Content Consumer that implements the View option shall be able to: 1110 4.
 - Demonstrate rendering of the document for display.
 - Print the document.
 - Display the document with its original stylesheet.

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- Support traversal of any links contained within the document.
- 5. A Content Consumer that implements the Document Import Option shall:
 - Store the document.
 - Demonstrate the ability to access the document again from local storage.
 - 6. A Content Consumer that implements the Section Import Option shall offer a means to import one or more document sections into the patient record as free text.
 - 7. A Content Consumer that implements the Discrete Data Import Option shall offer a means to import structured data from one or more sections of the document.
 - 8. A Content Consumer Actor shall be grouped with the Time Client Actor, and shall synchronize its clock with a Time Server.
 - 9. All activity initiated by the application implementing the Content Consumer shall generate the appropriate audit trail messages as specified by the ATNA Profile. The bare minimum requirements of a Content Consumer are that it be able to log views or imports of clinical content.
- 1130 10. A Content Consumer shall log events for any views of stored clinical content.
 - 11. A Content Consumer shall use secure communications for any document exchanges, according to the specifications of the ATNA profile.

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5 Emergency Department Referral (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).

5.1 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 in PCC TF 2:4.1.



5.1-1 EDR Actor Diagram

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5.2 Options

Actor	Option
	<u>View Option</u> (1)
Content Consumer	Document Import Option (1)
Content Consumer	Section Import Option (1)
	<u>Discrete Data Import Option</u> (1)

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

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5.2.1 Content Consumer Options

5.2.1.1 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 2:3.0.1 for more details on this option.

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 shall be able to present a view of the document using this style sheet if present.

5.2.1.2 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 2:3.0.2 for more details on this option.

5.2.1.3 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 2:3.0.3 for more details on this option.

5.2.1.4 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 2:3.0.4 for more details on this option.

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5.3 Coded Terminologies

This profile supports the capability to record entries beyond the IHE required coding associated with structured data. Actors from this profile 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 implementing the profile Actors, 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.

An Example HL7 Conformance Profile is available to show how to construct such a statement. See the <u>HL7 Refinement Constraint and Localization</u> for more details on HL7 conformance profiles.

5.4 ED Referral Document Content Module

The ED Referral content document module is defined in PCC TF 2: :6.1.1.7. This is a type of referral summary, and incorporates the constraints defined for referral summaries found in Referral Summary defined in PCC TF 2: 6.1.1.3. In addition, the ED Referral content profile includes additional information to support recording the mode of transportation, estimated time of arrival, and proposed disposition.

5.5 ED Referral Process Flow

5.5.1 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. 1240

5.6 Grouping with other Profiles

5.6.1 Cross Enterprise Document Sharing, Media Interchange and Reliable Messages

- Actors from the ITI XDS, XDM and XDR profiles embody the Content Creator and 1245 Content Consumer sharing function of this profile. A Content Creator or Content Consumer may be grouped with appropriate actors from the XDS, XDM or XDR profiles to exchange the content described therein. The metadata sent in the document sharing or interchange messages has specific relationships or dependencies (which we call bindings) to the content of the clinical document described in the content profile.
- 1250 The Patient Care Coordination Technical Framework defines the bindings to use when grouping the Content Creator of this Profile with actors from the IHE ITI XDS, XDM or XDR Integration Profiles.

Content	Binding	Actor	Optionality
ED Referral	Medical Document Binding to XDS, XDM and XDR PCC TF-2:4.1	Content Creator	R
PCC TF-2:6.1.1.6		Content Consumer	R

5.7 Requirements of EDR Actors

This section describes the specific requirements for each Actor defined within this profile. Specific details can be found in Volume 1 and Volume 2 of the technical 1255 framework.

5.7.1 Content Creator

- A Content Creator shall be able to create an ED Referral according to the 1. specification for that content profile found in PCC TF-2:6.1.1.7.
- A Content Creator shall be grouped with the Time Client Actor, and shall 1260 2. synchronize its clock with a Time Server.
 - 3. A Content Creator shall be grouped with the Secure Node or Secure Application Actor of the ATNA profile.
- 4. All activity initiated by the application implementing the Content Creator shall 1265 generate the appropriate audit trail messages as specified by the ATNA Profile. The bare minimum requirements of a Content Creator are that it be able to log creation and export of clinical content.

5. A Content Creator shall use secure communications for any document exchanges, according to the specifications of the ATNA profile.

1270 **5.7.2 Content Consumer**

- 1. A Content Consumer shall implement the View Option or Discrete Data import option, or both.
- 2. A Content Consumer that implements the Document Import or Section Import Option shall implement the View Option as well.
- 1275 3. A Content Consumer that implements the View option shall be able to:
 - Demonstrate rendering of the document for display.
 - Print the document.
 - Display the document with its original stylesheet.
 - Support traversal of any links contained within the document.
- 4. A Content Consumer that implements the Document Import Option shall:
 - Store the document.
 - Demonstrate the ability to access the document again from local storage.
 - 5. A Content Consumer that implements the Section Import Option shall offer a means to import one or more document sections into the patient record as free text.
 - 6. A Content Consumer that implements the Discrete Data Import Option shall offer a means to import structured data from one or more sections of the document.
 - 7. A Content Consumer Actor shall be grouped with the Time Client Actor, and shall synchronize its clock with a Time Server.
 - 8. All activity initiated by the application implementing the Content Consumer shall generate the appropriate audit trail messages as specified by the ATNA Profile. The bare minimum requirements of a Content Consumer are that it be able to log views or imports of clinical content.
- 1295 9. A Content Consumer shall log events for any views of stored clinical content.
 - 10. A Content Consumer shall use secure communications for any document exchanges, according to the specifications of the ATNA profile.

Actor Definitions

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.

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Content Consumer

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

Transaction Definitions

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.1 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 1355 transactions for an actor as well as selected options.

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

- Specific internet address (or universal resource locator [URL]) where the 1. vendor's Integration Statements are posted
- 1360 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.
 - URL of the IHE Initiative's web page for general IHE information 3. 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. 1365

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A.2 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.

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.het	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.