

Integrating the Healthcare Enterprise



5 **IHE Patient Care Coordination (PCC)
Technical Framework**

10 **Volume 1
IHE PCC TF-1
Integration Profiles**

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**Revision 10.0 - Final Text
November 4, 2014**

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Foreword

30 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.

35 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.

40 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 ([HIMSS](#)) and the Radiological Society of North America ([RSNA](#)). [IHE Canada](#) has also been formed. IHE Europe ([IHE-EUR](#)) is supported by a large coalition of organizations including the European Association of Radiology ([EAR](#)) and European Congress of Radiologists ([ECR](#)), the Coordination Committee of the Radiological and Electromedical Industries ([COCIR](#)), Deutsche Röntgengesellschaft ([DRG](#)), the [EuroPACS Association](#), Groupement pour la Modernisation du Système d'Information Hospitalier ([GMSIH](#)), Société 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 Information Systems Industry ([JAHIS](#)), Japan Radiological Society ([JRS](#)), Japan Society of Radiological Technology ([JSRT](#)), and the Japan Association of Medical Informatics ([JAMI](#)). Other organizations representing healthcare professionals are actively involved and others are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

50 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.

55 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 1 provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. Subsequent volumes provide detailed technical descriptions of each IHE transaction.

Content of the Technical Framework

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

Volume 1 – Integration Profiles

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 International welcomes comments on this document and the IHE initiative. They can be submitted using the Web-based comment form at http://www.ihe.net/PCC_Public_Comments or by sending an email to the co-chairs and secretary of the Patient Care Coordination committees at pcc@ihe.net.

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1 Preface

215 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
- 220 • Experts involved in standards development
- Those interested in integrating healthcare information systems and workflows

1.2 Related Information for the Reader

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

- 225 • 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 at
- 230 http://www.ihe.net/Resources/Technical_Frameworks/
- HL7 Clinical Document Architecture Release 2: Section 1, CDA Overview.
- Care Record Summary – Implementation Guide for CDA Release 2 (US Realm): Section 1

1.3 How this Volume is Organized

235 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.

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

1.4 Conventions Used in this Document

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

1.4.1 Technical Framework Cross-references

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

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

where:

<domain designator>

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

255 <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.

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

1.4.2 IHE Actor and Transaction Diagrams and Tables

265 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.

270 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.

275 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.

280 **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.

285 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.

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

1.5 Copyright Permissions

295 Health Level Seven, Inc., has granted permission to the IHE to reproduce tables from the HL7 standard. The HL7 tables in this document are copyrighted by Health Level Seven, Inc. All rights reserved. Material drawn from these documents is credited where used.

1.6 Introduction

300 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/Resources/Technical_Frameworks, where the technical framework volumes specific to the various healthcare domains addressed by IHE may be found.

305 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. A complete listing of the other IHE domains and their Technical Frameworks is available at http://www.ihe.net/Resources/Technical_Frameworks. An example of some of the IHE Technical Framework(s) that are available:

- IHE IT Infrastructure Technical Framework
- 315 • 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
320 referencing other frameworks, see the [Preface](#) of this volume.

1.6.1 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
325 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
330 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
335 them to the appropriate standards bodies for resolution within their conformance and standards
evolution strategy.

IHE is therefore an implementation framework, not a standard. Conformance claims for products
must still be made in direct reference to specific standards. In addition, vendors who have
implemented IHE integration capabilities in their products may publish IHE Integration
340 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 IHE PCC TF-1:
Appendix C for the format of IHE Integration Statements.

345 1.6.2 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

350 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
355 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
360 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.

1.6.3 Framework Development and Maintenance

365 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.

370 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:

- 375 • 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.
- 380 • The Committee addresses all comments received during the public comment period and
publishes an updated version of the Technical Framework for “Trial Implementation.”
This version contains both the stable body of the Technical Framework from the
preceding cycle and the newly developed supplements. It is this version of the Technical
Framework that is used by vendors in developing trial implementation software for the
IHE Connectathons.
- 385 • The Committee regularly considers change proposals to the Trial Implementation version
of the Technical Framework, including those from implementers who participate in the
Connectathon. After resolution of all change proposals received within 60 days of the
Connectathon, the Technical Framework version is published as “Final Text”.

As part of the Technical Framework maintenance the Committee will consider change proposals
received after the publication to the “Final Text”.

2 Profiles

390 2.1 Overview

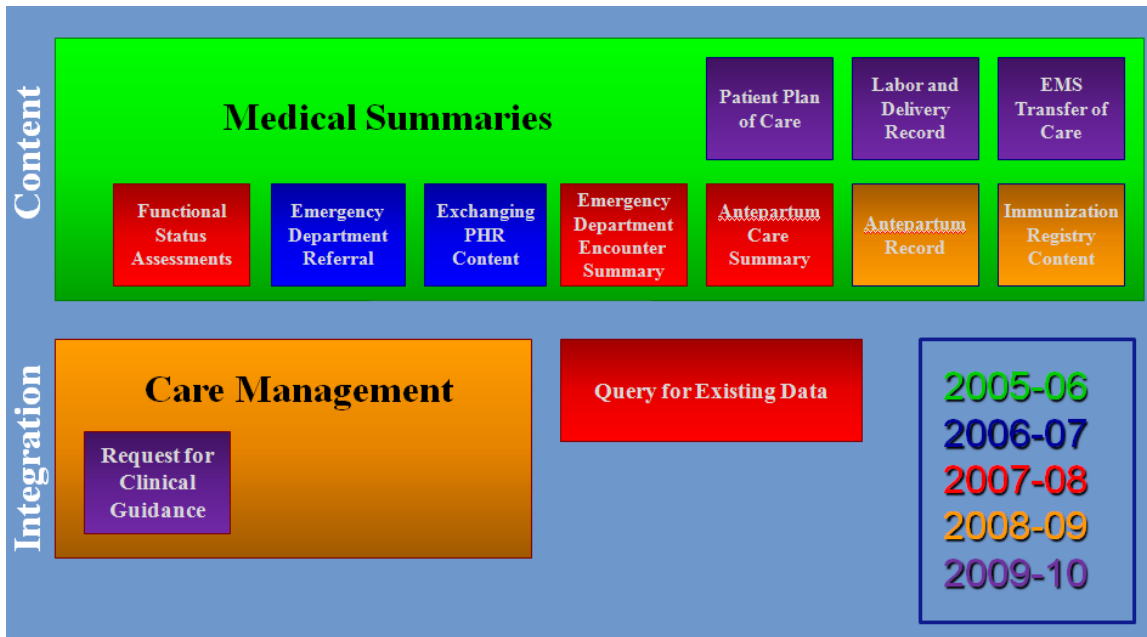
IHE Integration Profiles offer a common language that healthcare professionals and vendors can use to discuss integration needs of healthcare enterprises and the integration capabilities of information systems in precise terms. Integration Profiles specify implementations of standards that are designed 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 IHE 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 IHE 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.



415

Figure 2.1-1: IHE Patient Care Coordination Content Integration Profiles

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

- The IHE actors involved
- 420 • The specific set of IHE transactions exchanged by each IHE actor
- The content of the IHE transactions

425 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.

430 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:

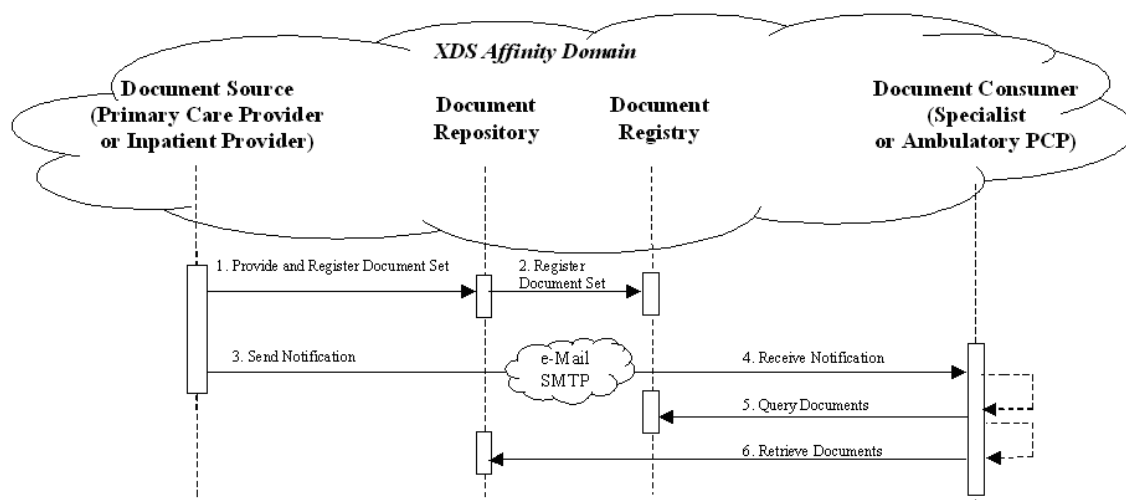
- A registry/repository-based infrastructure is defined by the IHE Cross-Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ), and notification of availability of documents (NAV).

435

- 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.
- 440
- 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/Resources/Technical_Frameworks.

445 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.



450 **Figure 2.1-2: 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).
- 455
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).
- 460

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.
- 465 5. 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.

Unplanned Access to past Content

470 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
475 XDS. Other process flows are possible using XDM and/or XDR.

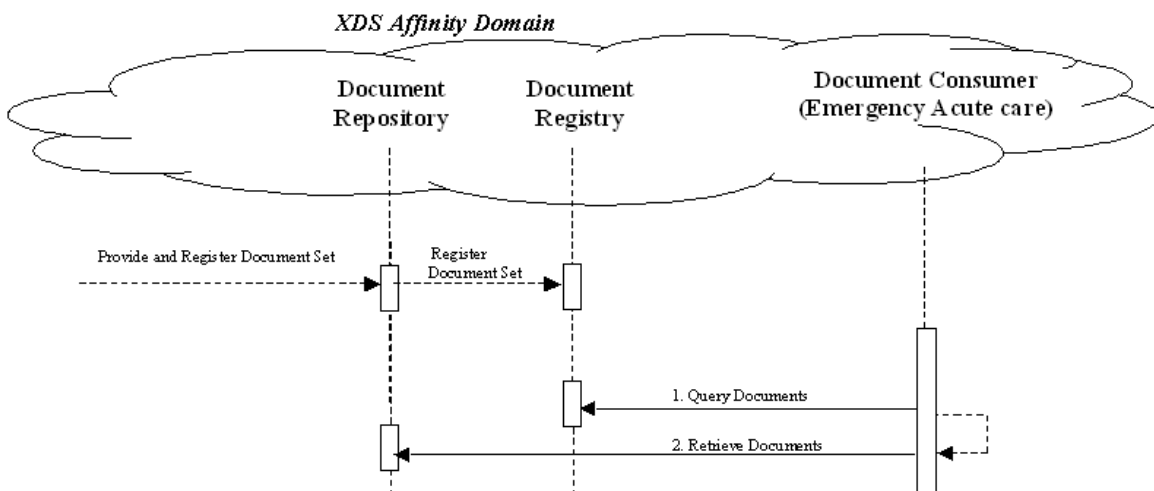


Figure 2.1-3: Unplanned Access Process Flow Diagram

480 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.

485 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.

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

490 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
495 setting to another.

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
500 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.

2.1.2 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 vice versa. The purpose of this profile
is to support interoperability between PHR systems used by patients and the information systems
510 used by healthcare providers. This profile does not address all the data exchange requirements of
PHR systems. A PHR system may leverage other IHE Integration and Content Profiles for
interoperability in addition to the XPHR Content Profile. For example, a PHR Systems may
implement XDS-MS to import medical summaries produced by EHR systems, XDS-I to import
imaging information, XDS-Lab to import laboratory reports, et cetera.

2.1.3 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
520 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.

525 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.

530 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).

2.1.4 The Immunization Content Profile (IC)

535 The Immunization Content Profile (IC) provides a standard document to exchange immunization data. It is intended to facilitate the exchange of immunization data among multiple systems belonging to a single or to multiple organizations. Data exchange with and among the installed base of U.S. Immunization Information System (IIS) base was a critical consideration in formulating this profile. However, its intention is to go beyond data exchange among IISs, and facilitate immunization data exchange on a healthcare information network that includes
540 electronic medical record (EMR) systems, Health Information Exchanges, other public health systems, Personal Health Record (PHR) systems, and other stakeholder systems. Thus, the profile specifies common data formats for exchanging immunization data only, or for exchanging immunization data along with medical summary data needed for the overall care of a patient related to immunizations.

545 To accomplish this, IC includes a history of administered vaccines with such details as lot number, who administered the shot, and so forth, and handles immunization as well as other information related to the patient's care. For example, it includes medical history, medications, allergies, vital signs, and so forth.

2.2 Actor Descriptions

550 This section intentionally left blank.

2.3 Transaction Descriptions

This section intentionally left blank.

2.4 Dependencies

555 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.

Table 2.4-1: PCC Profile Dependencies

Integration Profile	Depends on	Dependency Type	Purpose
All PCC Content Profiles	<i>Consistent Time (CT)</i>	Each Content Creator and Content Consumer Actor shall be grouped with the Time Client Actor	Required to manage and resolve conflicts in multiple updates.

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

2.5 History of Annual Changes

565 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:

- 570 • **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.
- 575 • In the 2006-2007 cycle of the IHE Patient Care Coordination initiative, the following integration profiles were added to the technical framework.
- 580 • **Exchange of Personal Health Record Content (XPHR)** – provides a standards-based specification for managing the interchange of documents between a Personal Health Record used by a patient and systems used by other healthcare providers to enable better interoperability between these systems.
- 585 • **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.
Please Note: This profile was transferred to the ITI Domain in the Fall of 2007, and can be found at http://ihe.net/Technical_Frameworks/#IT
- 585 • **Pre-procedure History and Physical Content Profile (PPHP)** – supports the exchange of information allowing for the assessment and amelioration of risks related to a procedure. *Please Note: This profile has been withdrawn.*
- 585 • **Emergency Department Referral Profile (EDR)** – provides a means to communicate medical summary data from an EHR System to an EDIS System.

590 In the 2007-2008 cycle of the IHE Patient Care Coordination initiative, the following 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.
- 595 • **Emergency Department Encounter Summary (EDES)** - describes the content and format of records created during an emergency department visit. (Includes CTNN, EDPN, NN, TN)
- **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.
- 600 • **Query for Existing Data (QED)** - allows information systems to query data repositories for clinical information on vital signs, problems, medications, immunizations, and diagnostic results.
- **Public Health Laboratory Report (PHLAB)** - extends the XD*-LAB Profile to support reporting from public health laboratories for disease surveillance activities.

605 [Please Note: This profile has been subsequently moved to the XD-LAB specification, and can be found here http://www.ihe.net/Resources/Technical_Frameworks/#laboratory]

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.

610 In the 2008-2009 cycle of the IHE Patient Care Coordination initiative, the following 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)**
- **Immunization Content (IC)**

615 In the 2009-2010 cycle of the IHE Patient Care Coordination initiative, the following integration profiles were added as supplements to the technical framework.

- Antepartum Profiles (APE, APL, APHP, APS)
- Labor and Delivery Profiles (LDS, LDHP, MDS)
- Postpartum Visit Summary
- 620 • Newborn Discharge Summary
- Patient Plan of Care
- Perinatal Workflow (PW)

In the 2010-2011 cycle of the IHE Patient Care Coordination initiative, the following integration profiles were added as supplements to the technical framework.

- 625
- Reconciliation of Diagnoses, Allergies and Medications (RECON)
 - Transport Record Summary Profiles (includes ETS and ITS profiles)
 - EMS Transfer of Care (ETC) Profile was **deprecated**

2.6 Product Implementations

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

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

635 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 IHE PCC TF-1: Appendix C.

640 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
645 local patient id to that used in the document sharing domain. The exact mechanisms of such internal communication are outside the scope of the IHE Technical Framework.

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

650 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.

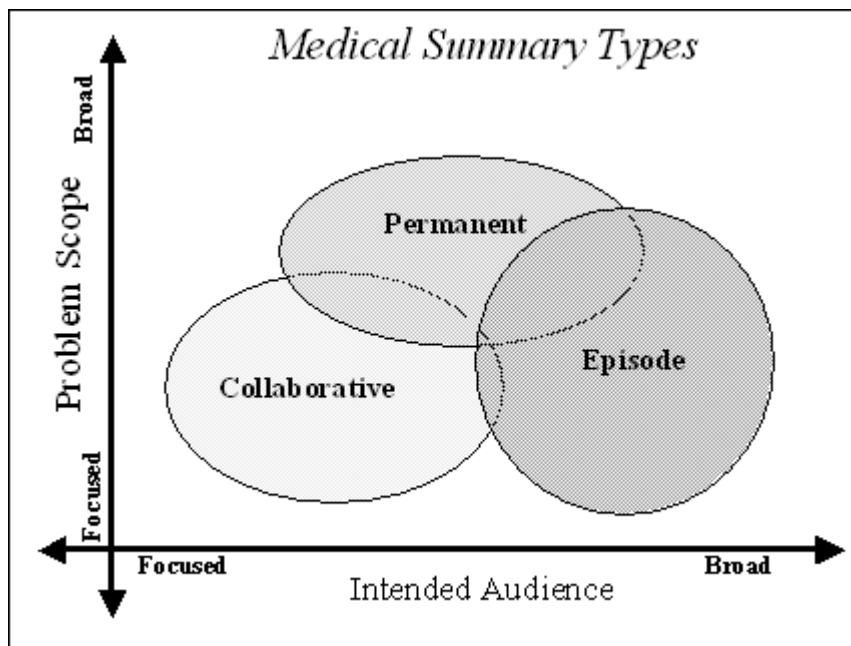
An acute care EMR serving a hospital might include a Document Source Actor, Document Consumer Actor, a Document Repository Actor, a Patient Identification Consumer Actor, as well as a Secure Node Actor. An Ambulatory EMR serving a physician practice might include a
655 Document Source Actor, Document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

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

3.1 Scope and Purpose

660 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.

665 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.



670 **Figure 3.1-1: Medical Summary Types**

675 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.

680 Patient transfers and, therefore, the summary documents that accompany these transfers can be categorized into 3 primary types: Episodic, Collaborative, or Permanent. These categories are important because they represent a breadth of use case scenarios for Medical Summaries. For example, summaries for collaborative transfers of care such as referral notes have a focused objective for providing the most relevant information about the patient intended *for a specific provider*. Collaborative summaries have a general audience that is generated as an artifact since they also provide the most relevant spot to obtain information about specific classes of patient
685 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.

690 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
695 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"
700 of the sending entity is appropriately maintained following the information transfer.

3.2 Process Flow

The basic process flow supported by XDS-MS mirrors current manual practices: someone gathers the appropriate documents from the patient medical record, copies them, packages them up with a cover letter explaining the reason the information is being sent, and then ships the
705 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.
710 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
715 between the two parties prior to the actual transfer of clinical information being initiated.

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

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

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

730 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

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

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

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

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

3.2.3 Content Interoperability Levels

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

750 Beyond this simple metadata, nearly all medical summary documents have organizational elements that group the relevant parts of the medical summary. For humans this allows for more rapid review because it is easier to skip to portions of interest for care. Computers too can take

advantage of this structuring. For example, it is relevant to see the list of discharge medications from a discharge summary in relation to current medications for comparison and reconciliation.

755 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
760 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
765 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
770 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.
775 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
780 content, reducing the risk for inconsistencies

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

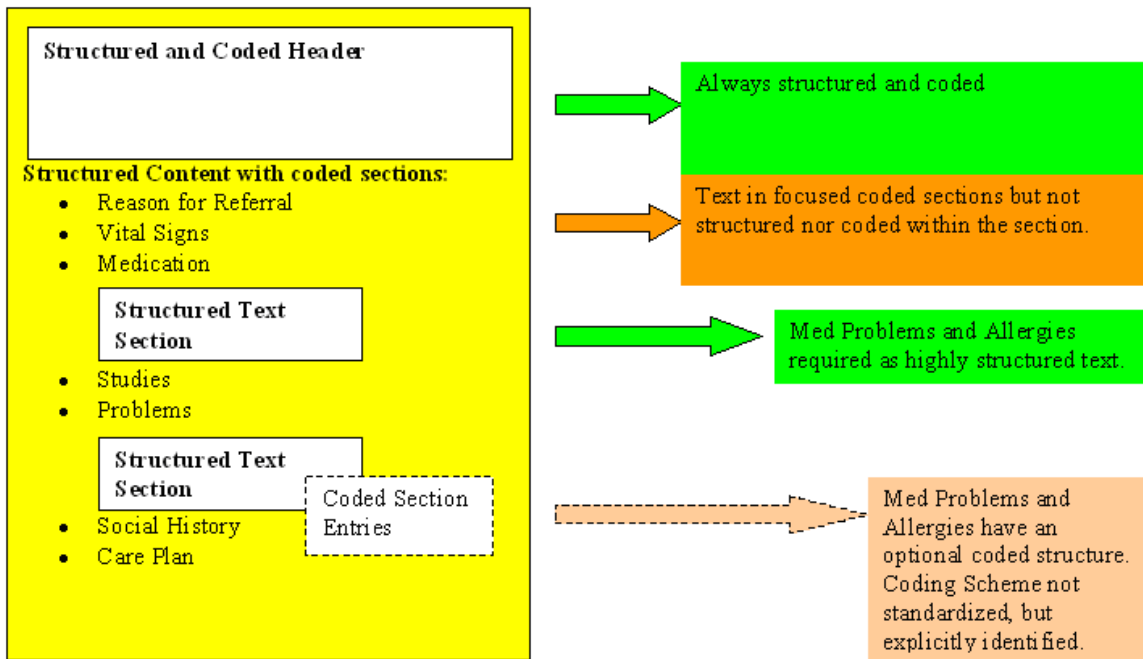


Figure 3.2.3-1: Tiered Interoperability Levels

785

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

3.2.4 Use Case Conclusion

790

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.

795

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.

800

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

805 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.
810 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 IHE PCC TF-2:4.1



Figure 3.3-1: XDS-MS Actor Diagram

815 **3.4 Options**

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

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

3.4.1 Content Consumer Options

3.4.1.1 View Option

820 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 IHE PCC
TF-2:3.1.1 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 intended by the Content Creator.

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

3.4.1.2 Document Import Option

830 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 IHE PCC TF-2:3.1.2 for more details on this option.

3.4.1.3 Section Import Option

835 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 IHE PCC TF-2:3.1.3 for more details on this option.

3.4.1.4 Discrete Data Import Option

840 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 IHE PCC TF-2:3.1.4 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 IHE PCC TF-2:6.3.1.3.

3.4.2.2 Discharge Summary Option

845 Content Creators implementing this option shall create Discharge Summaries that comply with the Discharge Summary Content Module in IHE PCC TF-2:6.3.1.4.

3.5 Coded Terminologies

850 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.

855 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.

860 An Example HL7 Conformance Profile is available to show how to construct such a statement.
865 See the [HL7 Refinement Constraint and Localization](#) for more details on HL7 conformance profiles.

3.6 Content Modules

865 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

870 All referral summaries shall be structured and coded as required by the [Referral Summary Content Module](#) described in IHE 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

875 All discharge summaries shall be structured and coded as required by the [Discharge Summary Content Module](#) described in IHE 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
880 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

885

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
890 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
Referral Summary PCC TF-2:6.1.1.3	Medical Document Binding to XDS, XDM and XDR PCC TF-2:4.1	Content Creator	O (Note 1)
		Content Consumer	R
Discharge Summary PCC TF-2:6.1.1.4	Medical Document Binding to XDS, XDM and XDR PCC TF-2:4.1	Content Creator	O (Note 1)
		Content Consumer	R

895

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)

900 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)

910 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

915 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.

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

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

925 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.

930 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.

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

3.9 Requirements of XDS-MS Actors

940 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

- 945 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.
- 950 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.
- 955 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

1. A Content Consumer shall be able to consume a Referral Summary and a Discharge Summary.
- 960 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.
4. A Content Consumer that implements the View option shall be able to:
 - Demonstrate rendering of the document for display.
 - 965 • Print the document.
 - Display the document with its original style sheet.
 - Support traversal of any links contained within the <linkHTML> elements in the narrative as described in PCC TF2-6.3.4.9.9.
5. A Content Consumer that implements the Document Import Option shall:
 - 970 • 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
975 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
980 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.
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.

985 **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 vice 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.

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.

1020 **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.



1030

Figure 4.2-1: XPHR Actor Diagram

4.3 Options

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

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

1035

4.3.1 Content Consumer Options

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 IHE PCC TF-2:3.1.1 for more details on this option.

1040

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

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

1045 **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 IHE PCC TF-2:3.1.2 for more details on this option.

4.3.1.3 Section Import Option

1050 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 IHE PCC TF-2:3.1.3 for more details on this option.

4.3.1.4 Discrete Data Import Option

1055 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 IHE PCC TF-2:3.1.4 for more details on this option.

4.3.2 Content Creator Options

1060 **4.3.2.1 Update Option**

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

4.4 Coded Terminologies

1065 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.

1070 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

1075 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 [HL7 Refinement Constraint and Localization](#) for more details on HL7 conformance profiles.

4.5 XPHR Content Modules

1080 4.5.1 PHR Extract Module

The content exchanged shall be structured and coded as required by the PHR Extract Module Content defined in IHE 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

1085 The content exchanged shall be structured and coded as required by the PHR Update Module Content defined in IHE 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
1090 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

1095 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.

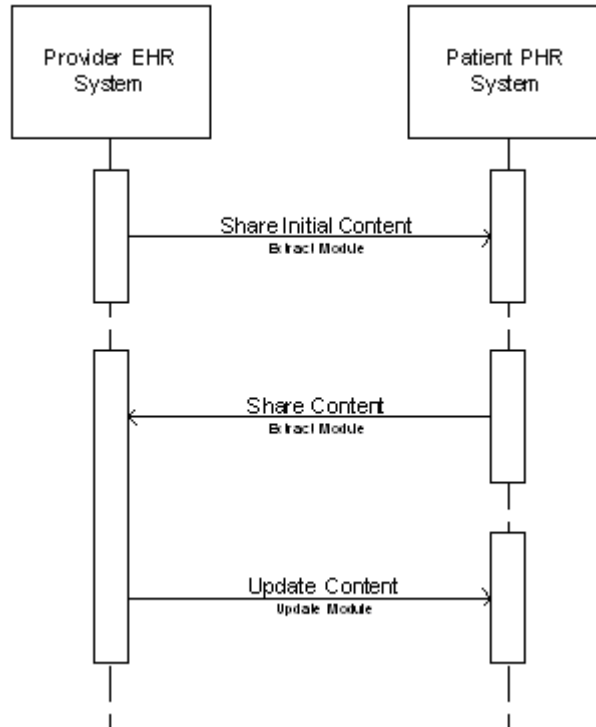
4.6.1 Personal Health Record (PHR) to ED/Primary Care EHR

1100 **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.).

1105 **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 on an office PC to display and/or import, as desired, the information provided on the

1110 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.



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Figure 4.6.1-1: Basic Process Flow in XPHR Profile

4.7 Grouping with Other Actors

1120 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.

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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.

1130

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

4.7.2 Document Digital Signature (DSG)

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

1135 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 framework.

1140 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.
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.
- 1145 3. A Content Creator shall be grouped with the Time Client Actor, and shall synchronize its clock with a Time Server.
4. A Content Creator shall be grouped with the Secure Node or Secure Application Actor of the ATNA Profile.
- 1150 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.
6. A Content Creator shall use secure communications for any document exchanges, according to the specifications of the ATNA Profile.

1155 **4.8.2 Content Consumer**

1. A Content Consumer shall be able to consume a PHR Extract and a PHR Update.
2. A Content Consumer shall implement the View Option or Discrete Data import option, or both.
- 1160 3. A Content Consumer that implements the Document Import or Section Import Option shall implement the View Option as well.
4. 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.
 - 1165 • Support traversal of any links contained within the <linkHTML> elements in the narrative as described in PCC TF2-6.3.4.9.9.
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.
- 1170 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.
- 1175 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.
- 1180 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

1190 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,
1195 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.

1200 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

1205 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
1210 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 IHE PCC TF-2:4.1.



1215 **Figure 5.1-1: EDR Actor Diagram**

5.2 Options

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

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

1220 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 IHE PCC TF-2:3.1.1 for more details on this option.

1225 A Content Creator Actor should provide access to a style sheet that ensures consistent rendering of the medical document content as was intended by the Content Creator.

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

1230 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 IHE PCC TF-2:3.1.2 for more details on this option.

5.2.1.3 Section Import Option

1235 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 IHE PCC TF-2:3.1.3 for more details on this option.

5.2.1.4 Discrete Data Import Option

1240 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 IHE PCC TF-2:3.1.4 for more details on this option.

5.3 Coded Terminologies

1245 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.

1250 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.

1255 An Example HL7 Conformance Profile is available to show how to construct such a statement. See the [HL7 Refinement Constraint and Localization](#) for more details on HL7 conformance profiles.

5.4 ED Referral Document Content Module

1260 The ED Referral content document module is defined in IHE 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 IHE 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

1265 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.

1270 **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
1275 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.

1280 **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.

1285 5.6 Grouping with other Profiles

5.6.1 Cross Enterprise Document Sharing, Media Interchange and Reliable Messages

1290 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.

1295 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 PCC TF-2:6.1.1.6	Medical Document Binding to XDS, XDM and XDR PCC TF-2:4.1	Content Creator	R
		Content Consumer	R

5.7 Requirements of EDR Actors

1300 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.

5.7.1 Content Creator

1. A Content Creator shall be able to create an ED Referral according to the specification for that content profile found in IHE PCC TF-2:6.1.1.7.
- 1305 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.
- 1310 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.

1315 **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.
- 1320 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 <linkHTML> elements in the narrative as described in PCC TF2-6.3.4.9.9.
- 1325 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.
- 1330 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.
- 1335 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.
9. A Content Consumer shall log events for any views of stored clinical content.
- 1340 10. A Content Consumer shall use secure communications for any document exchanges, according to the specifications of the ATNA Profile.

6 The Immunization Content Profile (IC)

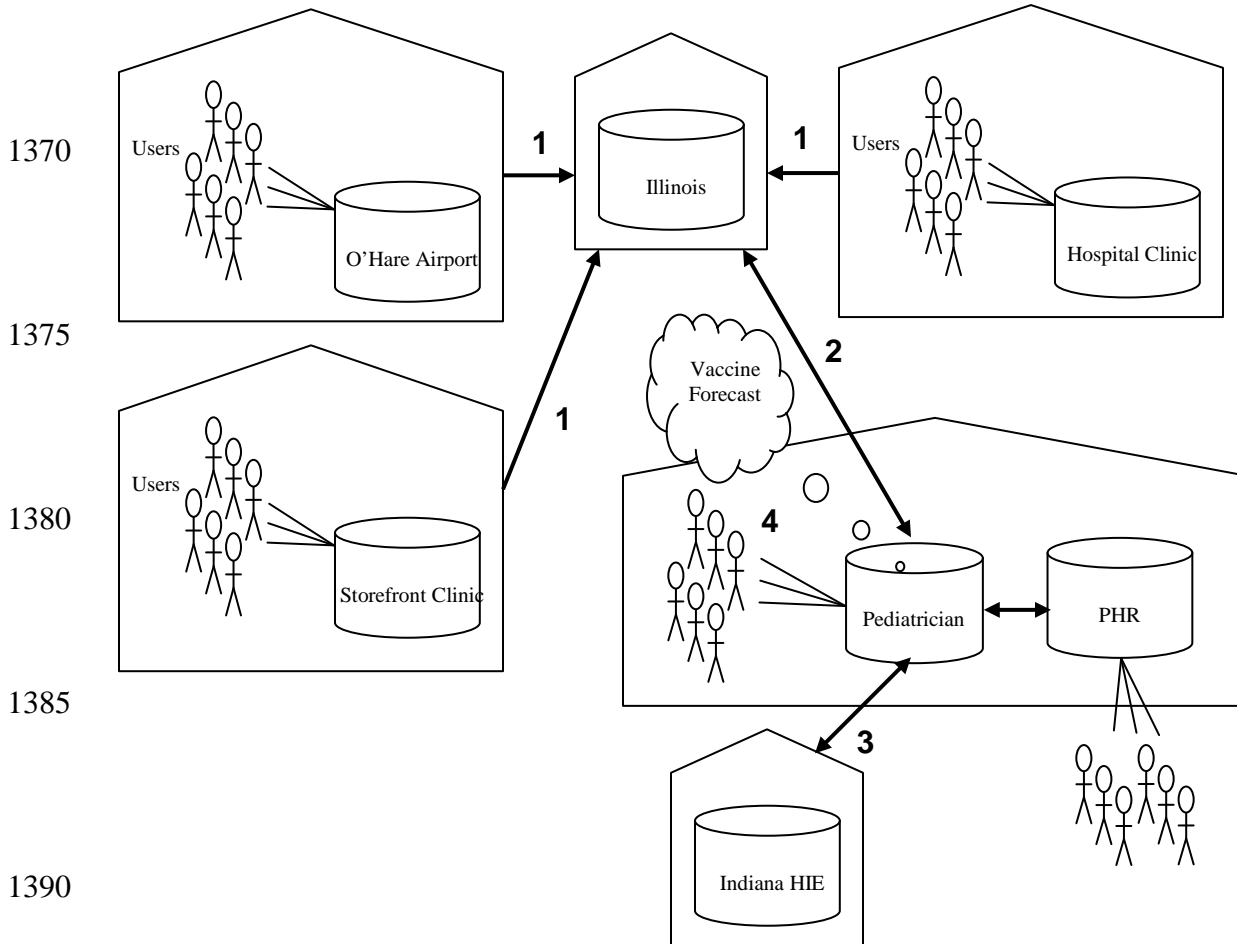
- 1345 The Immunization Content Profile (IC) provides a standard document to exchange immunization data. It is intended to facilitate the exchange of immunization data among multiple systems belonging to a single or to multiple organizations. Data exchange with and among the installed base of U.S. Immunization Information System (IIS) base was a critical consideration in formulating this profile. However, its intention is to go beyond data exchange among IISs, and facilitate immunization data exchange on a healthcare information network that includes
- 1350 electronic medical record (EMR) systems, Health Information Exchanges, other public health systems, Personal Health Record (PHR) systems, and other stakeholder systems. Thus, the profile specifies common data formats for exchanging immunization data only, or for exchanging immunization data along with medical summary data needed for the overall care of a patient related to immunizations.
- 1355 To accomplish this, IC includes a history of administered vaccines with such details as lot number, who administered the shot, and so forth, and handles immunization as well as other information related to the patient's care. For example, it includes medical history, medications, allergies, vital signs, and so forth.

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6.1 Use Cases

The following progression of use cases is illustrated in the drawing below.

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6.1.1 Use Case 1: Immunization Information System Participation

1395 Various provider organizations - airport flu shot clinics, storefront vaccine clinics, and hospital vaccine clinics - wish to submit immunization histories for patients to a regional Immunization Information System (IIS) with appropriate patient consent. The provider IT departments configure HL7 Version 2.3.1 connections with the IIS. Each time immunizations are recorded, records of the administered vaccines are automatically sent to the IIS using an HL7 version 2.3.1 standard format. This is representative of the present-state use case in the U.S.

1400 **6.1.2 Use Case 2: Immunization Yellow Card**

A pediatrician's office produces official immunization records (sometimes called "Yellow Card") for patients. The provider electronic medical record (EMR) system retrieves demographic information and records of immunization its immunization repository. To supplement its records with immunizations that the patient may have received from other providers, it queries the regional Immunization Information System (IIS). It passes the immunization content to a software module or service that prints the information in the official Yellow Card format.

6.1.3 Use Case 3: Personal Health Record

The provider wishes to make the assembled immunization information available in the patient's Personal Health Record (PHR). The pediatrician's office EMR system includes the retrieved immunization information in its complete care provision information about the patient. The standard Care Provision information contains current conditions, allergies and past adverse events, medications, vital signs, past medical history such as disease history, and so forth, in addition to immunizations. Knowing that the patient also has visited providers in a neighboring state, the EMR system queries the neighboring state's Health Information Exchange (HIE) to retrieve additional care provision information in a standard format. Since the neighboring state IIS is also part of the HIE, the retrieved information also includes immunizations. The pediatrician's office EMR system combines the retrieved and local information and sends it to the provider's PHR system in a standard format.

6.1.4 Use Case 4: Vaccine Forecast

The pediatrician's office wishes to run an automated Clinical Decision Support Service to calculate which immunizations are due on the next visit, and to assist with reminder/recall. The service may be integrated within the EMR or may be accessed externally using a web service interface. The service accepts a standard XML-based payload in Immunization Content format. The pediatrician's EMR system submits the patients Care Provision data that it has previously assembled to the Clinical Decision Support Service and receives immunization recommendations in return. It records the care plan and uses it in reminder/recall.

6.2 Actors/Transaction

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



Figure 6.2-1: Immunization Content Actor Diagram

1440 **6.3 Options**

Table 6.3-1: Immunization Content Options

Actor	Option	Location in Vol. 2
Content Consumer	View Option (Note 1)	IHE PCC TF-2:3.1.1
	Document Import Option (Note 1)	IHE PCC TF-2:3.1.2
	Section Import Option (Note 1)	IHE PCC TF-2:3.1.3
	Discrete Data Import Option (Note 1)	IHE PCC TF-2:3.1.4

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

6.3.1 View Option

1445 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 IHE PCC TF-2:3.1.1 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 intended by the Content Creator.

1450 The Content Consumer Actor shall be able to present a view of the document using this style sheet if present.

6.3.2 Document Import Option

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

1455 See the Document Import Option in IHE PCC TF-2:3.1.2 for more details on this option.

6.3.3 Section Import Option

1460 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 IHE PCC TF-2:3.1.3 for more details on this option.

6.3.4 Discrete Data Import Option

1465 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 IHE PCC TF-2:3.1.4 for more details on this option.

6.4 Coded Terminologies

1470 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.

1475 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 that 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.

1480 An Example HL7 Conformance Profile is available to show how to construct such a statement. See the [HL7 Refinement Constraint and Localization](#) for more details on HL7 conformance profiles.

6.5 Process Flow

1485 There are several process flows for use of this content profile. The document oriented process flows are described in IHE PCC TF-1:2.6 PCC Profiles Overview, where the content being exchanged is are documents conforming to the Immunization Content module.

1485 Another process flow uses this same content in a message used for clinical decision support. In this process flow, the content creator and content consumer actors are grouped with the Care Manager and Decision Support Actors of the Request for Clinical Guidance Profile.

1. A Care Manager Actor acquires the medical and immunization history of a patient.
- 1490 2. The Care Manager Actor submits the relevant portions of this medical history along with the complete immunization history to the Decision Support Service using PCC-12 Request for Clinical Guidance Transaction.

3. The Decision Support Service processes the result and returns a response to the Care Manager Actor in that same transaction.
4. The Care manager then applies the return information. How this information is used by the care manager is out of scope of this profile.

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This process flow is shown below in Figure 6.5-1.

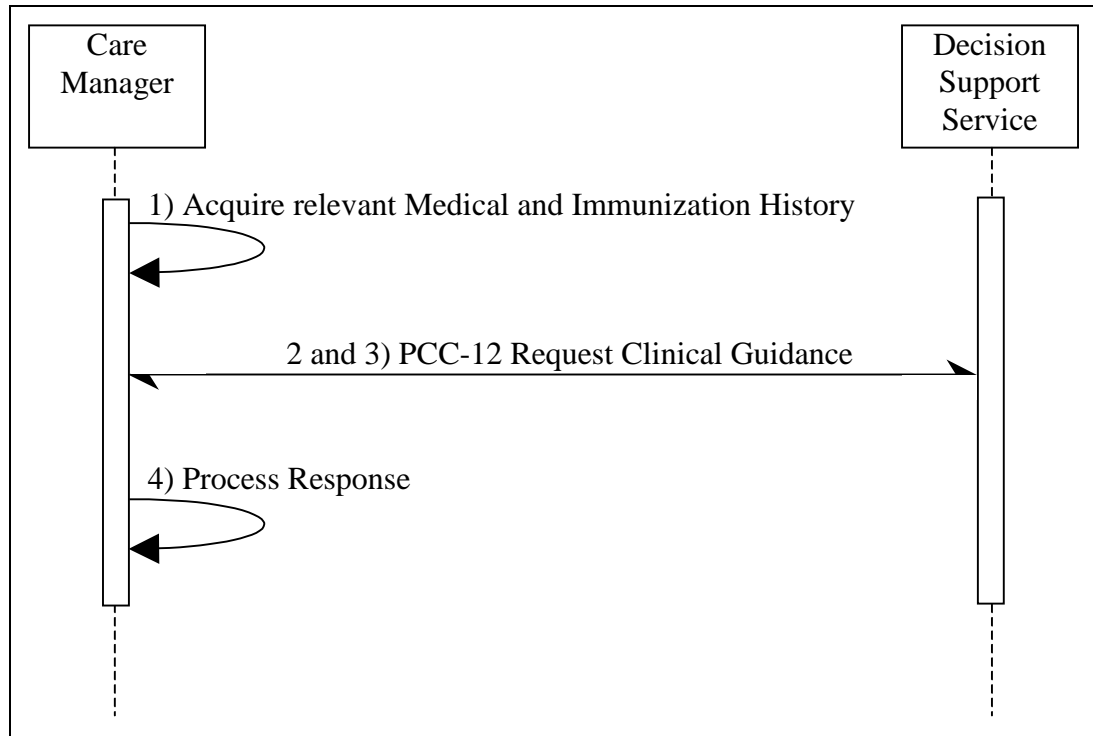


Figure 6.5-1: Process Flow for Clinical Decision Support

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6.6 Immunization Content Module

The Immunization Content Module is designed to provide a record of a patient's immunizations, document planned immunizations, provide details about the effectiveness of past immunizations, and to propose immunizations to be given as part of the overall care plan for the patient. This content module is fully defined in IHE PCC TF-2:6.3.1.10.

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The collection of information making up this content module is described in Table 6.6-1 below and discussed in more detail following it.

Table 6.6-1: Immunization Care Plan Data Elements

Data Element / Section	Description	Opt
History of Immunizations	This section lists of immunizations previously given to a patient. For each immunization given this list should include the date it was given, the name of the vaccine, a coded value for the vaccine, the lot number of the vaccine, the manufacturer of the vaccine, the provider giving the immunization, and any reactions or adverse events caused by the immunization, and the severity of those reactions, and if refused, the reason for the refusal.	R
Authors and Informants	The source of the information may be the patient, parent or guardian, another provider, immunization registry, et cetera. The IHE PCC technical framework supports recording of the author or informant that provided the information being recorded in all coded entries.	R
History of Past Illness	The history of past illnesses section includes clinical diagnoses relevant to immunizations. This may include prior illnesses that convey immunity or otherwise influence an immunization recommendation.	R2
Problem List	The problem list includes those relevant to immunization recommendations, including current illnesses, conditions or risks (e.g., immunosuppression) that might be contraindications for providing an immunization.	R2
Allergies and Intolerances	This section includes those allergies or intolerances to substances commonly used in vaccinations, e.g., egg albumin, et cetera, as well as allergies or intolerances to other medications or immunizations	R2
Medications	This is the list of relevant medications for the patient.	R2
Lab Results	The laboratory results section may include information about antibody tests or titers that show that immunization has or has not been already conferred to a patient. This section may also include information about the results of point of care tests, such as a TB test.	R2
Coded Vital Signs	This section supports the recording of Vital signs such as height and weight. These enable dosing calculations to be performed. Other vital signs (e.g., temperature) may be included to enable the identification potential contraindications for immunization (e.g., fever).	R2
Gestational Age at Birth	In the case of premature birth, immunizations are determined based upon the adjusted age of the infant. The gestational age at birth can be used to determine the adjusted age.	R2
Pregnancy History	This section may be present to include information about current pregnancy status for the patient, as this can also influence the type of vaccinations that may be proposed.	R2
Advance Directives	This section includes advance directives that would influence the immunizations proposed for a patient.	R2
Immunization Recommendation	Immunization recommendations indicate the immunizations that are proposed or intended for the patient and their schedule. It may reference specific guidelines to activate certain protocols (e.g., travel to a foreign country).	C (See note 1)

1510 Note 1: This data element is required when this content is used with the Request for Clinical Guidance (RCG) Profile, and is required if known (R2) otherwise.

The material necessary to generate an immunization record is required of all instances of this content module. This record may be used to electronically exchange the immunization record of a patient as a clinical document.

1515 This content module includes information relevant to a clinical decision support service that reviews the immunization history and care plan present within it to make immunization recommendations. The immunization recommendations include those immunizations and encounters that are proposed and should identify the guidelines from which the recommendations are derived. Material needed for generating these recommendations is required if known in the

1520 data elements described in Table 6.6-1 above. Note also that some of this information may not be available (or provided) to the generating application.

A Content Creator Actor that implements this content profile shall be able to demonstrate that it can create a document that is sufficient for both uses. We note that not all uses of this content profile will require that level of output. There are cases where the data produced must be limited
1525 to a smaller set due to policy considerations. For example, when the document is used as immunization record necessary to for enrollment in a school, the Content Creator Actor needs to be able to conform to local law, regulation, and policy regarding the information permitted in the exchange.

Thus, content creators must be also configurable to generate the appropriate result.

1530 The immunization recommendations found in this content module support the specification of a proposed immunization. This is a proposal for treatment of a patient that can be reviewed by a decision support service, or could be output from a decision support service. This can also be described as being part of the intended plan of care for the patient. In this case, the intended treatments can be reviewed and potentially updated by a decision support service, or can serve as
1535 persistent documentation of the current plan for other uses (e.g., reminder/recall notices). The section template is described in more detail in IHE PCC TF-2: 6.3.3.6.13 Immunization Recommendations. The immunization recommendation entry details with the machine readable content is described further in IHE PCC TF-2: 6.3.4.49.

1540 The clinical statements about immunizations can be augmented with additional clinical statements to provide more detail on the immunization dosing. Immunization dosing can become complex due to the use of combination vaccines. Combination vaccines provide multiple antigens protecting against multiple disease conditions. A single immunization dose given to a patient can result in multiple antigens being used. It is the antigen doses that matter when trying to determine what immunizations are necessary for the patient. Guidelines vary by antigen with
1545 respect to the appropriate immunization interval and dose. One antigen within a combination vaccine may not be considered effective, while others could be. The Antigen Dose entry described in IHE PCC TF-2:6.1.4.51 to provide these details

The information exchanged can include alerts used to inform clinicians about exceptional conditions. Alerts can be applied to existing immunization events to provide an evaluation of the effectiveness of those events. Alerts can identify other relevant clinical data that could impact the immunization care plan (e.g., pregnancy) or subsequent medical treatment (e.g., potential medication interactions). Alerts are described in more detail in IHE PCC TF-2:6.1.4.50.

6.7 Grouping

1555 6.7.1 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 actors of this profile when it is used to share immunization histories and plans as

1560 clinical documents. 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.

1565 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.

Table 6.7.1-1: Bindings to XDS, XDR and XDM Profiles

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

6.7.2 Request for Clinical Guidance

1570 To support the generation of immunization recommendations through a clinical decision support service, the Care Manager and Decision Support Service actors of the RCG Profile shall each be grouped with the Content Creator and Content Consumer actors of this profile. This supports the exchange of Immunization Content containing the patient’s immunization history and care plan (from the Care Manager to the Decision Support Service Actor) and the updated immunization history and plan with immunization recommendations (from the Decision Support Service Actor to the Care Manager).

1575 Appendix F Transforming CDA Documents to Care Record Messages found in the Request for Clinical Guidance Profile Supplement describes the model by which the Immunization Content document found in this profile can be transformed to the Care Record message used in the Request for Clinical Guidance transaction.

1580 This profile places specific requirements upon the Care Manager and Decision Support Service actors that are over and above those specified within the Immunization Content Module itself. These are detailed below.

6.7.2.1 Care Manager Requirements

1585 The Care Manager as the Content Creator shall create at least one proposed Immunization Recommendation Entry specifying the type of immunization being requested and may include a reference to the guidelines to apply.

1590 This module shall contain a required immunization recommendation. The proposed immunization shall contain a required proposal for immunization entry. The effective time of the proposal shall be present to indicate the time range of the request for immunizations to be given. The proposal may include a reference to one or more specific guidelines to indicate that this proposal is intended to comply with those guidelines.

6.7.2.2 Decision Support Service Requirements

1595 The Decision Support Service Actor shall duplicate the content provided to it in the original request, annotating or augmenting that content as needed. It shall create immunization recommendations proposing the vaccinations that should be given for the proposed immunization, or record why no recommendation can be made.

1600 When immunizations are needed the immunization recommendation in the response should include at least one suggested list of encounters in which immunizations will be provided. Each encounter will contain one or more proposed immunization activities describing the vaccine to be given.

6.7.3 Notification of Document Availability (NAV)

1605 A Document Source may provide the capability to issue a Send Notification Transaction per the ITI Notification of Document Availability (NAV) Integration Profile in order to notify one or more Document Consumer(s) of the availability of one or more documents for retrieval. One of the Acknowledgement Request options may be used to request from a Document Consumer that an acknowledgement should be returned when it has received and processed the notification. A Document Consumer should provide the capability to receive a Receive Notification Transaction per the NAV Integration Profile in order to be notified by Document Sources of the availability of one or more documents for retrieval. The Send Acknowledgement option may be used to issue
1610 a Send Acknowledgement to a Document Source that the notification was received and processed.

6.7.4 Document Digital Signature (DSG)

1615 When a Content Creator Actor needs to digitally sign a document in a submission set, it may support the Digital Signature (DSG) Content Profile as a Document Source. When a Content Consumer Actor needs to verify a Digital Signature, it may retrieve the digital signature document and may perform the verification against the signed document content.

1620 **Appendix A 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.

Actor	Definition
Content Creator	The Content Creator Actor is responsible for the creation of content and transmission to a Content Consumer.
Content Consumer	A Content Consumer Actor is responsible for viewing, import, or other processing of content created by a Content Creator Actor.

1625 **Appendix B Transaction Definitions**

Appendix C How to Prepare an IHE Integration Statement

1630 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.

1635 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.).

1640 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.

1645 **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

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business interruption and loss of revenue, arising from any use of, or reliance upon, any IHE Integration Statement.

C.1 Structure and Content of an IHE Integration Statement

An IHE Integration Statement for a product shall include:

- 1655 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.
- 1660 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:"
- 1665 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 1. (Note: The vendor may also elect to indicate the version number of the Technical Framework referenced for each Integration Profile.)
- 1670 Note that implementation of the integration profile implies implementation of all required transactions for an actor as well as selected options.

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

1. Specific internet address (or universal resource locator [URL]) where the vendor's Integration Statements are posted
- 1675 2. URL where the vendor's standards conformance statements (e.g., HL7, DICOM, etc.) relevant to the IHE transactions implemented by the product are posted.
3. URL of the IHE Initiative's web page for general IHE information www.himss.org/ihe.

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

1680 **C.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.net	In Europe: www.ihe-europe.org	In Japan: www.jira-net.or.jp/ihe-j

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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.

Appendix D Glossary

1690 **Adverse Event** – An Adverse Event (AE) is any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen¹.

¹ Adapted from the NINDS Glossary of Clinical Research Terms, Last updated November 24, 2008, retrieved from http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm

- 1695 **Antigen** – A component of a disease-causing agent that stimulates an immune response. More commonly, the disease which a vaccine is supposed to protect against. In the context of immunization, the latter is the meaning of interest.²
- 1700 **Combination Vaccine** – A vaccine product containing antigens to more than one disease. Combination vaccines are commonly used to reduce the number of “needle sticks” required to give multiple vaccines at the same time. A combination vaccine is effectively the same thing as a Multiple Antigen Vaccine or a Poly-valent Vaccine.
- Contraindication** – Any medical, environmental, genetic, or other condition that makes a treatment inadvisable. Contraindications include increased likelihoods of a serious Adverse Events, reduced effectiveness of treatment, or duplicative therapies.
- 1705 **Dose of Antigen / Vaccine Component** – Immunization CDS will analyze an existing immunization history by vaccine component, or doses of antigen, in order to build a proposed immunization care plan (ICP).
- 1710 **Dose of Vaccine / Administered Dose** – This is a quantity of medication or vaccine substance that is administered as a single shot. It will contain one *or more* doses of antigens. Immunization histories are typically recorded in terms of administered doses of vaccine, rather than doses of antigens.
- Guidelines** – Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances³.
- 1715 **Immunization Recommendation** – A set of proposed immunizations to be given to a patient, including the dates to give them. The recommendation may be general, or it may be focused on a particular disease (such as an influenza pandemic) or a particular risk situation (such as travel to places with high risk factors for certain diseases).
- Immunization Information System (IIS)** – A software system designed to collect all information about immunizations given to a certain population. An IIS is typically funded or sponsored by a Public Health Department or Ministry.
- 1720 **Immunization Interval** – A measure of the interval between doses of antigens. For maximum effectiveness against the targeted disease, many vaccines must have booster shots given after the initial dose. The recommended interval varies by vaccine. In most cases, administration of a vaccine with less than the minimum immunization interval reduces the effectiveness of the

² From the HL7 Glossary, retrieved from <http://www.hl7.org/v3ballot2009may/html/help/glossary/glossary.htm>

³ Field MJ, Lohr KN. Guidelines for Clinical Practice: from development to use. Washington DC: National Academic Press, 1992. Retrieved from http://www.nap.edu/openbook.php?record_id=1863&page=27#p200063cf8960027001

1725 vaccine, and one that is substantially longer than the recommended interval exposes a person to a higher risk of contracting the disease during the period of delay.

Immunization Recommendation – A collection of proposed immunizations and encounters which a provider may use to develop an immunization care plan. Also known as an Immunization or Vaccine Forecast.

Immunization Registry – See Immunization Information System.

1730 **Ineffective Dose** – This is a dose of administered vaccine or vaccine component which may be predictably less effective than desired, due to inadequate immunization interval, expired vaccine, concurrent administration of antibiotics, vaccine recall, improper vaccine storage, or other issues.

Invalid Dose – See Ineffective Dose.

Multiple Antigen Vaccine – See Combination Vaccine.

1735 **Precaution** – A statement indicating any medical, environmental, genetic, or other condition that may increase the likelihood of an Adverse Event, or reduce the effectiveness of the medication or immunization. A clinician should review the risks and weigh them against the benefits of the vaccine before deciding whether or not to proceed with the immunization.

1740 **Vaccine** – This is a substance designed to be administered to a person in order provide protection against future disease. See also Combination Vaccine.