ACC, AHA, HIMSS, and RSNA

Integrating the Healthcare Enterprise

IHE Quality Technical Framework
Year 1: 2007-2008

Volumes 1, 2, and 3

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Foreword

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

The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards, HL7, IEEE, 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.

The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology, Patient Care Device, Laboratory, Radiology, Patient Care, Quality, etc.) define specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. They are expanded annually, after a period of public review, and maintained regularly through the identification and correction of errors. The current version for these Technical Frameworks may be found at www.ihe.net .

The IHE Technical Frameworks identify a subset of the functional components of the healthcare enterprise, called IHE actors, and specify their interactions in terms of a set of coordinated, standards-based transactions. They describe 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. The subsequent volumes provide detailed technical descriptions of each IHE transaction.

This IHE Quality Technical Framework Year 1 is a working draft issued for Public Comment.

Comments shall be submitted before July 30, 2007 to:

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

Select the Quality Technical Framework

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Volume 1 Overview

1 Introduction

1.1 Overview of Technical Framework

This document, the IHE Quality Technical Framework (IHE Quality TF), defines specific implementations of established standards to achieve integration goals for the Quality domain. Such integration promotes appropriate sharing of medical information to support optimal patient care.

The IHE Quality TF will be expanded annually, after a period of public review, and maintained regularly through the identification and correction of errors.

The Quality TF 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 of the Quality Technical Framework (Quality TF-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. Quality TF-2 provides detailed technical descriptions of each Quality-specific IHE transaction. Quality TF-3 provides detailed specifications for content oriented profiles and includes content from specific device classes.

The Quality TF is part of a related set of IHE Technical Frameworks, including the following domain-specific documents:

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

The IHE Quality Integration Profiles rely on, and reference, the transactions defined in those other IHE Technical Framework documents. For the conventions on referencing other frameworks, see Section 1.6.4 within this volume.

1.2 Structure of the Technical Framework Document

The Technical Framework defines the relevant standards, and constraints on those standards, in order to implement specific use cases for the transfer of information between systems. This document is organized into 3 volumes as follows.

1.2.1 Volume 1 – Overview and Integration Profiles

This volume is provided as a high level overview of the Quality Domain Profiles, including descriptions of the use cases, 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 IHE Quality Domain Profiles.

1.2.2 Volume 2 – Transactions and Document Content

This volume is intended as a technical reference for the implementation of specific transactions in the use cases, including references to the relevant standards, constraints, and interaction diagrams. It also describes constraints on document content, such as vocabularies, and metadata passed in the transaction. It is intended for the technical implementers of the profile.

1.3 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. At its current level of development, it defines a coordinated set of transactions based on the HL7, IEEE, DICOM, W3C and other industry standards. As the scope of the IHE initiative expands, transactions based on other standards will be included as required.

In some cases, IHE recommends selection of specific options supported by these standards; however, IHE does not introduce technical choices that contradict conformance to these standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a standard. Referencing IHE as a standard is inappropriate. Conformance claims by product must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities shall use an IHE Integration Statement to describe the conformance of their product to the specifications in the IHE Technical Framework. The purpose of an IHE Integration Statement is to communicate in a uniform manner to the users of the corresponding product the IHE capabilities it has been designed to support. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration Statements from different implementations, a user familiar with the IHE concepts of actors and Integration Profiles should be able to determine whether and to what extent communications might be supported between products. See Quality TF-2:Appendix E for the format of such IHE Integration Statements. IHE encourages implementers to ensure that products implemented in accordance with the IHE Technical Framework also meet the full requirements of the standards underlying IHE, allowing the products to interact, although possibly at a lower level of integration, with products that have been implemented in conformance with those standards, but not in full accordance with the IHE Technical Framework.

1.4 Relationship to Real-world Architectures

The IHE actors and transactions described in the IHE Technical Framework are abstractions of real-world healthcare information system environments. While some of the transactions are traditionally performed by specific product categories (e.g. HIS, Electronic Patient Record, RIS, PACS, Clinical Information Systems, patient care devices or imaging modalities), the IHE Technical Framework

intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.

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

1.5 Conventions

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.

1.5.1 Actor and Transaction Diagrams and Tables

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

The tables of actors and transactions given in Section 3 indicate which transactions each actor must support.

In some cases in IHE, a profile is dependent on a pre-requisite profile in order to function properly and be useful. For Year 1 a single profile Patient-Level Export of Quality Data (PEQD) which uses other specific IHE profiles defined within PEQD. The long term goal is to encourage patient level data export for the delivery of quality care.

1.5.2 Interaction Diagrams

The descriptions of Integration Profiles that follow include Interaction Diagrams that illustrate how the profile functions as a sequence of transactions between relevant actors.

These diagrams are intended to provide a "big picture" so the transactions can be seen in the context of the overall 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 complementary transactions from other profiles may be interspersed.

In some cases the sequence of transactions may be flexible. Where this is the case there will generally be a note pointing out the possibility of variations.

The convention used in these diagrams is the arrow on the line for the transaction points from the initiator of the transaction to the destination.

1.5.3 Normative versus informative contents of the Technical Framework

Most parts of the Technical Framework describe required or optional characteristics of Integration Profiles, actors and transactions: these are normative. For a better understanding of the text, there also exist illustrating parts in the Technical Framework that are informative and non-normative.

According to IETF RFC 2119, certain words indicate whether a specific content of the Technical Framework is normative: either required (e.g. “must”, “required”, “shall”) or optional (e.g. “may”, “recommended”). Informative content does not contain these key words.

1.5.4 Technical Framework Referencing

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

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

<domain designator> is a short designator for the IHE domain (ITI = IT Infrastructure, RAD = Radiology, CARD = Cardiology, LAB = Laboratory, PCD = Patient Care Device)

<volume number> is the applicable volume within the given Technical Framework (e.g., 1, 2, 3), and <section number> is the applicable section number.

For example: ITI TF-1: 3.1 refers to Section 3.1 in volume 1 of the IHE IT Infrastructure Technical Framework, RAD TF-3: 4.33 refers to Section 4.33 in volume 3 of the IHE Radiology Technical Framework.

1.5.5 Transaction Referencing

When references are made to a transaction, the following format is used:

<domain designator>-<transaction number>, where:

<domain designator> is a short designator for the IHE domain (ITI = IT Infrastructure, RAD = Radiology, CARD = Cardiology, LAB = Laboratory, PCD = Patient Care Device, QUALITY = Quality)

<transaction number> is the applicable transaction number as specified in the Technical Framework for that domain.

Transactions may also be referenced by name, but only after that transaction name has been identified with its domain and transaction number within that Section of the document.

1.6 IHE Quality Current Year Scope

This document is published for Year 1 of the IHE Quality initiative. It will be the basis for the testing and exhibition process associated with the HIMSS 2008 annual meeting and other trial implementations during 2008 . The IHE Quality Technical Framework addresses the following primary features:

- The Patient-Level Export of Quality Data (PEQD) Integration Profile describes mechanisms to communicate patient-level data to local or third-party analyzer systems for management, aggregation and reporting of quantitative quality indicators or measurements to destination systems.
- The ACEI-ARB Content Profile describes a data set for the measurement of a quality indicator defined by the American Heart Association (AHA) and American College of Cardiology (ACC). This quality indicator is based on the prescription of an Angiotensin Converting Enzyme Inhibitor <ACEI> or Angiotensin Receptor Blocker <ARB> on discharge for a patient with an episode of Acute Myocardial Infarction <AMI>, who exhibits Left Ventricular Systolic Dysfunction <LVSD>.
- The scope of Year 1 does not include development of quality measures, exchange/import format of quality measures or components of the measures, real time alerts and reminders, orders or documentation templates, or other clinical decision support components. These are areas for consideration in Year 2 and subsequent Years.

1.7 Comments

The Quality Domain sponsoring organizations (ACC, AHA, HIMSS, RSNA) welcome comments on this document and the IHE initiative. They should be directed to ihe@himss.org.

1.8 Copyright Permission

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1.9 IHE Technical Framework Development and Maintenance Process

Since this is the first year for the IHE PEQD there is no previous version. For subsequent years the process which will be followed is illustrated in Figure 1 IHE Development Process.

The Technical Framework is continuously extended and maintained by the IHE Quality Technical Committee, in cooperation with the other domain-specific Technical Committees. The Development and Maintenance Process of the Framework follows a number of principles to ensure stability of the

specification both vendors and users may rely upon in specifying, developing and acquiring IHE compatible products.

The process is intended to address the need for extensions, clarifications and corrections while maintaining backward compatibility of framework definitions to support implementations claiming conformance to any previously defined Integration Profile and its actors.

To maintain stability of the IHE Technical Framework, modifications occur in a regular annual cycle (Figure 1) according to one of two controlled paths: new development, and maintenance.

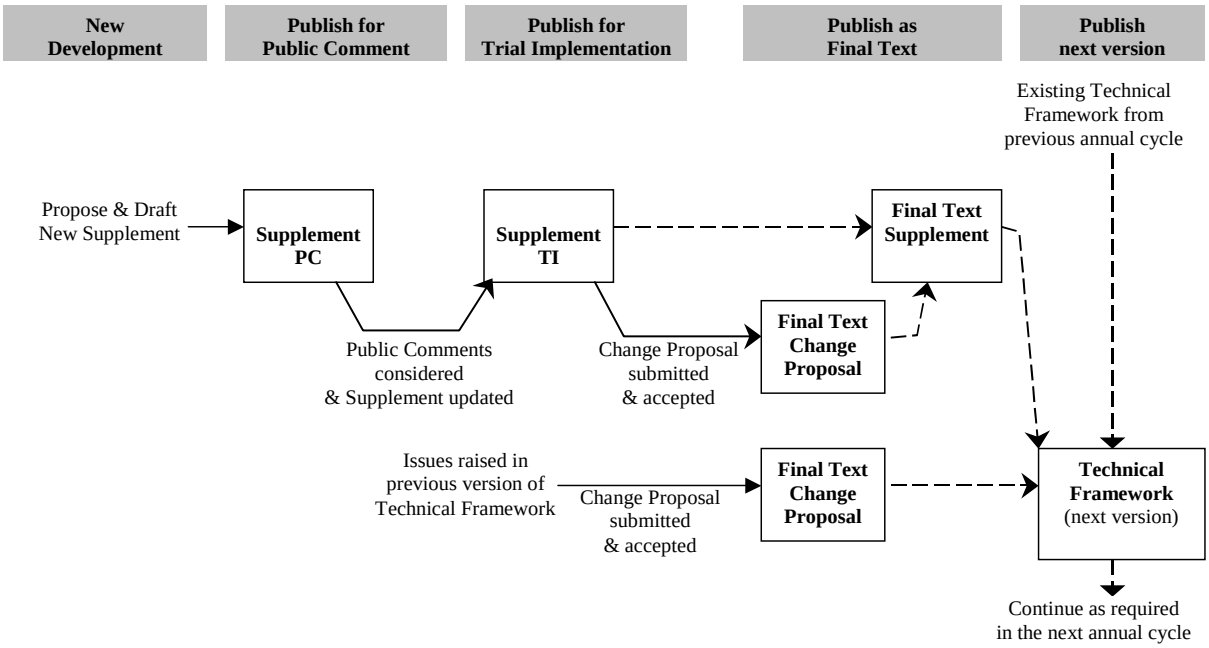

Figure 1 IHE Development Process

Figure 1 IHE Development Process shows the process of developing and maintaining the Technical Framework during an annual cycle. Dashed arrows indicate the assembly (merging) of text.

1.9.1 New Development – Extending the Existing Technical Framework

Each year, new functionality to be developed is identified by the IHE Quality Planning Committee. Individuals or organizations wishing to submit recommendations for new development are encouraged to join and participate in the Quality Planning Committee. The Technical Committee performs the necessary analysis and design work and generates new text for the Technical Framework. Generally, new functionality is published in the form of a Supplement. The scope of a Supplement is to make one of the following additions to the Technical Framework:

- A new Integration Profile, usually including the introduction of new actors and transactions.
- New actors in an existing Integration Profile: These may be either actors previously defined elsewhere in the Technical Framework, or new ones not yet defined. Transactions identifying the new actors responsibilities in this profile are identified or defined and may be designated as

required or optional. To avoid causing compatibility problems for systems that have already implemented that profile, no new required transactions are added for existing actors in the profile.

- New Options in an existing Integration Profile: These usually add optional transactions for existing actors in the profiles, or add optional features within existing transactions.
- Major conceptual changes: They do not change the behavior of existing Integration Profiles but may imply changes or additions to actors, transactions, or content in the future.

The publication process consists of certain phases and is clearly indicated on each document.

First, the text is published for **Public Comment** (with a "PC" designation). During the Public Comment period (typically 30 days), the text and a comment submission facility are available on the IHE Website. Following this period, the Technical Committee will review the comments.

Updated text of Supplements is then published for **Trial Implementation** (with a "TI" designation), based on the modifications resulting from the comments received.

IHE provides a process for vendors to test their implementation of the Trial Implementation specifications of IHE actors and Integration Profiles. The IHE testing process, culminating in a multi-party interactive testing event called the Connectathon, provides vendors with valuable feedback and provides a baseline indication of the conformance of their implementations. It also serves as a validation of the technical approach of the Trial Implementation specifications.

After trial implementations have been judged to have sufficiently exercised the new functionality (e.g., due to experience from the Connectathon), and the text is considered sufficiently stable, the new text will be published as **Final Text** (with a "FT" designation).

Final Text Supplements will be merged at the end of the annual development cycle with the current version of the Technical Framework resulting in a new version of the Technical Framework with an increased version number.

1.9.2 Maintenance of existing Technical Framework content

Despite the best efforts of the Technical Committee, a published current version of the Technical Framework or Trial Implementation documents may contain text that is incorrect, incomplete or unclear. Such issues are handled as Change Proposals and cover:

- Corrections: technical issues causing non-interoperability of implementations are fixed without introducing changes in functionality of a stable Integration Profile.
- Clarifications: text that can be misunderstood or is ambiguous is made easier to understand or disambiguated, without introducing any technical changes.

The publication process is the same for both Corrections and Clarifications, and addresses both changes to Trial Implementations and changes to a current version of the Technical Framework.

A **Submitted Change Proposal** results from issues raised by users, vendors or Technical Committee members, e.g. from experiences with Trial Implementation or Final Text Integration Profiles or at a Connectathon. The resulting Change Proposal document should explicitly state:

- the parts of the Technical Framework requested to be changed,
- a problem description,
- a rationale why the change is considered necessary,
- and a solution or approach to the problem.

The Technical Committee regularly considers Change Proposals which are then either accepted or rejected.

A **Rejected Change Proposal** is published with a rationale from the Technical Committee explaining why the change is not appropriate.

An **Accepted Change Proposal** is assigned to a member of the Technical Committee as a work item for further investigation with the goal to produce adequate clarifications or corrections. The resulting text will again be reviewed by the Technical Committee before being approved.

Once approved, a **Final Text Change Proposal** is published by the Technical Committee, and then is to be considered as effective. It will be merged into the next version of the Technical Framework at the end of the annual development cycle. Submitting a Change Proposal to a Final Text Change Proposal or a Final Text Supplement is not possible.

1.9.3 Use of Technical Framework

The current version of the Technical Framework is considered the primary reference document. Final Text Supplements and Final Text Change Proposals from the current annual cycle complement this document. Past Final Text documents are retained to provide convenient summaries of differences to prior versions of the Technical Framework or Trial Implementation versions of Supplements.

During the annual development and maintenance cycle, it is recommended to use Technical Framework documents for implementations as follows:

- Product Implementations
  Products implemented based on Trial Implementation text is expected to review the subsequent Final Text and update their products as necessary. Further, it is expected that vendors will monitor Final Text Change Proposals and make any corrections relevant to their product in a timely fashion.
- Connectathon Implementations
  Testing at the Connectathon will be based on the current version of the Technical Framework for the appropriate IHE Domain, plus any relevant Supplements for Trial Implementation and Final Text Change Proposals.

2 Integration Profiles

IHE Quality Integration Profiles, depicted in Figure 2-1, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. Integration Profiles describe real-world scenarios or specific sets of capabilities of integrated systems. An Integration Profile applies to a specified set of actors, and for each actor specifies the transactions necessary to support those capabilities.

Integration Profiles provide a convenient way for both users and vendors to reference a subset of the functionality detailed in the IHE Technical Framework. They enable users and vendors to be more specific than simply requesting or promising overall IHE support, without laborious restatement of the details regarding IHE actors and transactions defined by the IHE Technical Framework.

2.1 Dependencies between Integration Profiles

In general, IHE Integration Profiles do not operate independently. Data that serve as useful input to one profile may have been produced as a result of implementing another profile.

Figure 2-1 provides a graphical view of the dependencies of IHE Quality Integration Profiles, as well as Profiles from other IHE Domains. The arrows in the diagram point from the dependent profile to the profile(s) on which it relies. The profiles shown with a thick border are Quality Profiles, the profiles shown with a thin border are defined by other IHE Domains. Table 2-1 describes the dependencies between the Integration Profiles in a tabular form.

There are of course other useful synergies that occur when different combinations of profiles are implemented, but those are not described in the table below. For instance, actors of the various Quality profiles may implement profiles of the IT Infrastructure domain for user authentication, time synchronization, etc.

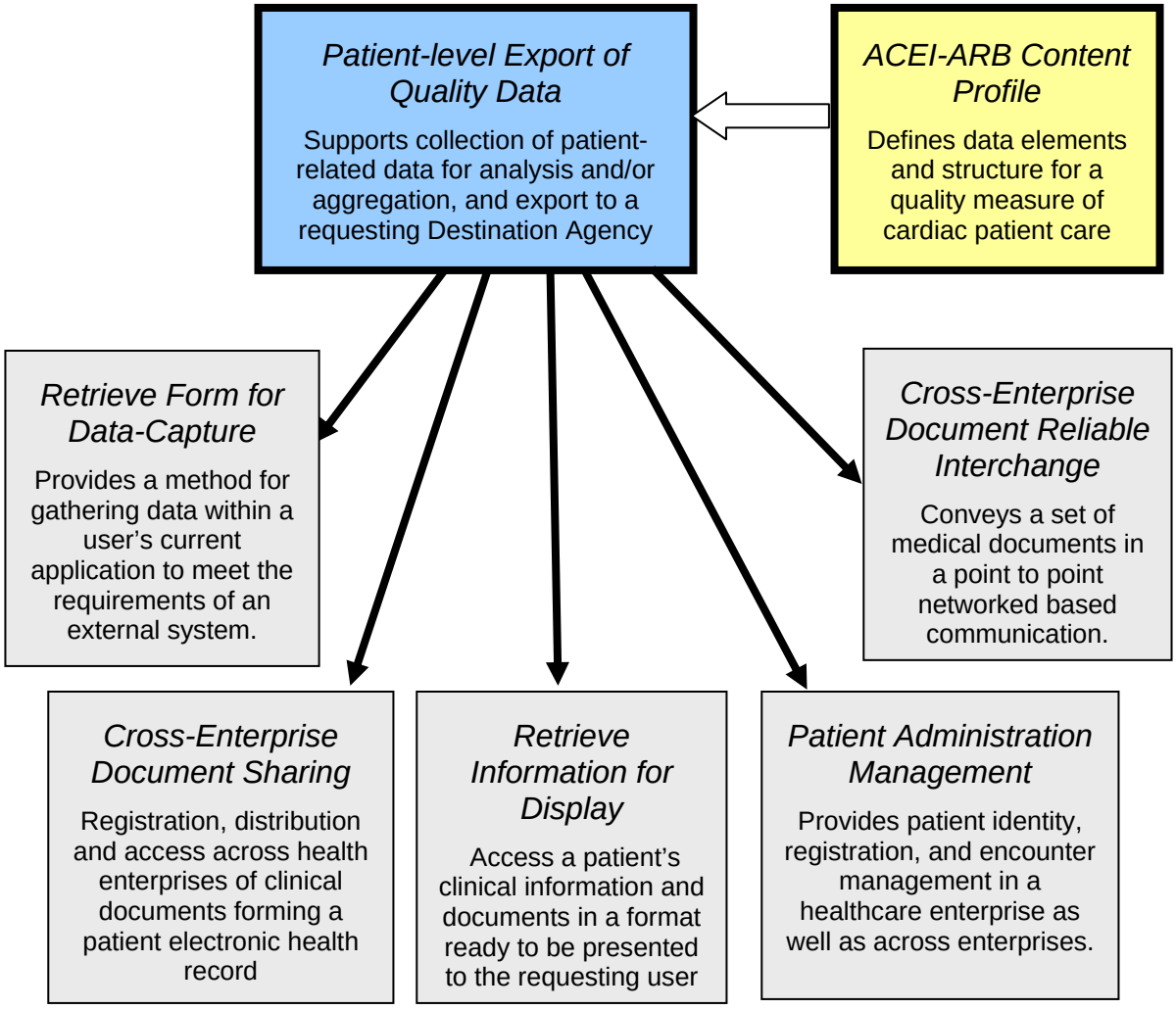

Figure 2-1 IHE Quality Integration Profiles

390 **Table 2-1 Quality Integration Profile Dependencies**

Integration Profile	Depends on	Dependency Type	Purpose

Patient-level Export of Quality Data (PEQD)	ITI-TF Retrieve Form for Data-Capture	Specialization and extension	
	ITI-TF Cross-Enterprise Document Reliable Interchange	Mandatory use	Used as mechanism for transfer of patient-level quality data
	ITI-TF Retrieve Information for Display	Optional use	Used for data access option
	ITI-TF Cross-Enterprise Document Sharing	Optional use	Used for data access option; used for data archive option
	ITI-TF Patient Administration Management	Optional use	Used for data access option
ACEI-ARB Content Profile	QUAL-TF Patient-level Export of Quality Data	Mandatory use	Used as mechanism for collection and transmission of quality measure content

Vendor products support an Integration Profile by implementing the appropriate actor-transactions as outlined in the Integration Profiles in Section 3. A product may implement more than one actor and more than one Integration Profile.

An actor must implement all required transactions in the prerequisite profiles in addition to those in the desired profile.

Actors (see Section 2.3) are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise.

Transactions (see Section 2.4) are interactions between actors that transfer the required information through standards-based messages.

2.2 Integration Profiles Overview

In the IHE Quality Technical Framework Volume 1, each Integration Profile is defined by:

- The IHE actors involved
- The specific set of IHE transactions required for each IHE actor.

These requirements are presented in the form of a table of transactions required for each actor supporting the Integration Profile. Actors supporting multiple Integration Profiles are required to support all the required transactions of each Integration Profile supported. When an Integration Profile depends upon another Integration Profile, all transactions required for the dependent Integration Profile have been included in the table.

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

Also note that there are critical needs 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.

2.2.1 Patient-level Export of Quality Data (PEQD)

With the ever increasing demands on hospitals and physicians to report their quality data to different entities, the process of collecting and reporting these data has become a resource drain. The Patient-level Quality Export of Quality Data (PEQD) profile addresses the need for consistent communication of Quality data to the local, regional or third party Analyzer / Aggregator for consistent, standardized evaluation of quality structural, process and outcome measures. Recipients of Quality performance data include, but are not limited to, external governmental or private agencies, organizational Quality Management professionals, healthcare providers, and healthcare consumers (individuals and employers).

2.2.2 ACEI-ARB Content Profile

The ACEI-ARB Content Profile describes a data set for the measurement of a quality indicator defined by the American Heart Association (AHA) and American College of Cardiology (ACC). This quality indicator is based on the prescription of an Angiotensin Converting Enzyme Inhibitor <ACEI> or Angiotensin Receptor Blocker <ARB> on discharge for a patient with an episode of Acute Myocardial Infarction <AMI>, who exhibits Left Ventricular Systolic Dysfunction <LVSD>.

2.3 Actor Descriptions

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise. The following are the actors defined by IHE and referenced throughout the rest of this document, as well as in other domain Technical Framework documents.

Monitoring Agent / Destination Agency – A system that provides definitions of quality measures to healthcare delivery organizations, and accepts reports of such quality measures from participating organizations.

Analyzer / Aggregator – A system that assembles quality measurement data from patient clinical records in accordance with measurement definitions, and provides reports of quality measures to the Monitoring Agent / Destination Agency.

Form Manager – The Form Manager actor provides the store of forms ready for use by a Form Filler.

Form Filler – The Form Filler actor requests froms from a Form Manager as and when required. When requesting a form the Form Filler actor can optionally provide context information in the form of pre-population data in the request for inclusion in the returned form. The Form Filler can also specify a Form Archiver actor. The Form Archiver actor specified by the Form Filler is in addition to any Form Archiver actors specified by the Form Manager.

Form Receiver – The Form Receiver actor receives completed or partially completed forms from a Form Filler and processes them. Such processing is out of the scope of the profile.

Form Archiver – The Form Archiver actor receives completed or partially completed forms instance data and stores these.

Document Source - The Document Source Actor is the producer and publisher of documents. It is responsible for sending documents to a Document Repository or Document Recipient. It also supplies metadata to the Document Repository Actor for subsequent registration of the documents with the Document Registry Actor.

Document Recipient - This actor receives a set of documents sent by another actor.

Document Consumer - The Document Consumer Actor queries a Document Registry Actor for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors.

Document Registry - The Document Registry Actor maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration.

Document Repository - The Document Repository is responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry. It assigns a URI to documents for subsequent retrieval by a Document Consumer.

Patient Encounter Source – A system responsible for adding, updating and maintaining encounter information about a patient. It supplies new and updated information to the Patient Encounter Consumer.

Patient Encounter Consumer – A system that uses patient encounter information provided by the Patient Encounter Source about a patient.

Display – A system that can request specific information or documents from an Information Source and display them.

Information Source – A system that responds to requests for specific information or documents and returns ready for presentation information to be displays on the requesting actor.

Report Creator – A system that generates and transmits clinical reports.

Enterprise Report Repository – A system that receives reports and/or references (pointers) to reports, and stores them for access throughout the healthcare enterprise.

The following table shows which actors are used in which Integration Profiles.

Table 2-2 Integration Profile Actors

Actor \ Integration Profile	PEQD
Analyzer / Aggregator	X

Actor \ Integration Profile	PEQD
Monitoring Agent / Destination Agency	X
Form Manager	X
Form Receiver	X
Form Filler	X
Form Archiver	X
Document Source	X
Document Recipient	X
Document Consumer	(See note 1)
Document Registry	(See note 2)
Document Repository	(See note 2)
Patient Encounter Consumer	(See note 1)
Patient Encounter Source	(See note 2)
Display	(See note 1)
Information Source	(See note 2)
Report Creator	(See note 1)
Enterprise Report Repository	(See note 2)

Notes: 1. This Actor is not part of the identified Profile, but must be grouped in an implementation with an Actor within the Profile. This grouping may be required as part of an option.

2. This Actor is not part of the identified Profile, but has a transaction with an Actor grouped in an implementation with an Actor within the Profile.

2.4 Transaction Descriptions

Transactions are interactions between actors that transfer the required information through standards-based messages. The following are the transactions defined by IHE and referenced throughout the rest of this document. Those transactions specified in other domain Technical Framework documents are identified with the domain identifier and transaction number.

Define Measure – Defines the content of patient level data and metadata required for calculation and the methodology for calculation for a quality measure. *[reserved for future editions]*

Provide and Register Document Set - A Document Source Actor submits a set of documents to a Document Repository or Document Receiver. For each document in the submitted set, the Document Source Actor provides both the document as an opaque octet stream and the corresponding metadata. [ITI-14]

Submit Report – Transmit patient-level quality data as a clinical document to an Enterprise Report Repository. *[reserved for future editions]*

Retrieve Form – This transaction retrieves the requested form from a Form Manager [ITI-34]

Submit Form – This transaction submits form instance data to a Form Receiver. [ITI-35]

Archive Form – This transaction submits form instance data to a Form Archiver. [ITI-36]

Retrieve Specific Information for Display – A request issued by a display system for specific information related to a patient returned in a ready for presentation information format. [ITI-11]

Retrieve Document for Display – A display system requests an instance of a uniquely identified persistent document under custodianship by an information source and receives its content ready for presentation. [ITI-12]

Query Registry - The Query Registry transaction is issued by the Document Consumer Actor to a Document Registry. The Document Registry Actor searches the registry to locate documents that meet the requester's specified query criteria. It will return a list of document entries that contain metadata found to meet the specified criteria including the locations and identifier of each corresponding document in one or more Document Repositories. [ITI-16]

Retrieve Document - A Document Consumer Actor initiates the Retrieve Document transaction. The Document Repository will return the document that was specified by the Document Consumer. [ITI-17]

Patient Encounter Management – The Patient Encounter Source registers or updates an encounter (inpatient, outpatient, pre-admit, etc.) and forwards the information to other systems implementing the Patient Encounter Consumer Actor. This information will include the patient's location and care providers for a particular (usually current) encounter. [ITI-31]

The following table shows which transactions are used in which Integration Profiles.

Table 2-3 Integration Profile Transactions

Transaction \ Integration Profile	PEQD
Provide and Register Document Set	X
Define Measure	
Submit Report	
Retrieve Form	X
Submit Form	X
Archive Form	X
Retrieve Specific Information for Display	(See note 1)
Retrieve Document for Display	(See note 1)
Query Registry	(See note 1)
Retrieve Document	(See note 1)
Patient Encounter Management	(See note 1)

Notes: 1. This Transaction is not formally part of the PEQD Profile, but an Actor within the Profile may be grouped in an implementation with an Actor that uses this Transaction. This Transaction and the grouped Actor are critical to the functionality of the PEQD Profile.

2.5 Product Implementations

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

- For a system, select which actors it will incorporate. (Multiple actors per system are acceptable).
- For each actor, select which Integration Profiles it will participate in.
- For each actor-profile, select which optional transactions will be implemented. All required transactions must be implemented for the profile to be supported. (Refer to the Integration Profile Tables in Sections 3-5)
- Finally, for each transaction, select which optional features will be supported. (Refer to the transaction descriptions in the appropriate domain TF)

Implementers should provide a statement describing which IHE actors, IHE Integration Profiles, optional transactions and optional features are incorporated in a given product. The recommended form for such a statement is defined in IHE PCD-TF2 Appendix E.

2.5.1 Grouping of Actors

In general, a product implementation may incorporate any single actor or combination of actors. However, in the cases specified below, the implementation of one actor requires the implementation of one or more additional actors:

- In the PEQD Profile, the Monitoring Agent / Destination Agency shall be grouped with a Document Receiver.
- In the PEQD Profile, the Analyzer / Aggregator shall be grouped with the Form Filler and with a Document Source.
- In the PEQD Profile, the Form Manager shall be grouped with the Form Receiver.

When multiple actors are grouped in a single product implementation, all transactions originating or terminating with each of the supported actors shall be supported (i.e., the IHE transactions shall be offered on an external product interface). The exceptions to this rule are any transactions defined between actors in the required groupings defined above.

When two or more actors are grouped together, it is presumed that there is data integration between those actors for the performance of logically associated functions, unless the product Integration Statement explicitly states the limits of inter-actor integration. Internal communication between actors is assumed to be sufficient to allow the necessary information flow to support their functionality; for example, the Analyzer / Aggregator provides necessary information to the Form Filler to support its PEQD functionality. The exact mechanisms of such internal communication are outside the scope of the IHE Quality Technical Framework.

3 Patient-level Export of Quality Data (PEQD)

Healthcare quality is a broad term defined differently by many. Efforts are in progress for the standardization of quality measurement. An example of an international coordinating effort is the Organization for Economic Cooperation and Development (OECD) Health Care Quality Indicators (HCQI) Project, bringing together 23 OECD countries, international organizations, such as the World Health Organization (WHO) and the European Commission (EC), expert organizations such as the International Society of Quality in Healthcare (ISQua) and the European Society for Quality in Healthcare (ESQH), and several universities. (Information available at: International Journal for Quality in Health Care 2006 18(Supplement 1):1-4; doi:10.1093/intqhc/mzl019). The Institute of Medicine in the United States provided a direct, discreet and usable definition by itemizing six attributes of healthcare by which to measure and identify healthcare quality – safe, effective, efficient, patient-centered, timely and equitable; further defining five key areas in which information technology could contribute to an improved health care delivery system:

1. Access to the medical knowledge-base
2. Computer-aided decision support systems
3. Collection and sharing of clinical information
4. Reduction in errors
5. Enhanced patient and clinician communication

To most effectively achieve the goals of quality, measurement is a key component. Measurement of quality is intended to determine the effectiveness and efficiency of care and to faciliate improvement in care processes and ultimately patient outcomes. Therefore, for the purpose of this profile the Quality Domain includes:

- Aggregate measures of performance,
- Individual case reporting of adverse events
- Concurrent delivery of care based on evidence-generated guidelines and protocols of care

In this regard, there are three dimensions of quality measurement as described by Donabedian (Donabedian A. Evaluating the quality of medical care. 1966. Milbank Q. 2005;83(4):691-729):

- Structural (presence of specific factors in the environment)
- Process (compliance with specific procedures)
- Outcome (achievement of specific status by the patient) components of quality and quality measurement.

These three dimensions can also be described by the previously stated six IOM aims (safe, effective, efficient, patient-centered, timely and equitable) and with reference to overuse, underuse and misuse of services.

Healthcare quality measures are quantitative indicators that are utilized to evaluate the quality of specific healthcare activities. Quality measures are developed by certain healthcare stakeholders for

a variety of uses such as support for operations, resource utilization, and performance improvement. The measures, which are often called “indicators”, serve to inform the stakeholders or guide certain actions that will help improve performance or quality of healthcare delivery process or service. In some cases, the measures serve to enforce accountability for certain healthcare activities that are known to impact quality. Given the magnitude of the reliance on quality measures for health policy and provider accountability, these measures must be meaningful, scientifically sound, and interpretable to all the stakeholders.

An example of a quality measure evaluates recommended angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARBs) treatments for patients with coronary artery disease (CAD) and acute myocardial infarction (AMI). These recommendations are based on clinical practice guidelines (CPGs) developed by American Heart Association (AHA) and American College of Cardiology (ACC). (CPGs are systematically developed statements to provide guidance to healthcare professionals and patients focused on “what should be” regarding the management of patients). Cinical performance measures (quality measures) (CPMs) are metrics derived from CPGs, or are otherwise evidence based, to assess “what is”.

There is abundant evidence that there are gaps in the care for patients with CAD and AMI. Assessing the performance of physicians, physician groups, hospitals and integrated delivery systems should be undertaken for multiple purposes, to include supporting internal quality improvement, for public reporting to ensure accountability and to facilitate patient choice of provider and in support of pay for performance (P4P) programs.

For all these purposes the data elements described in the measure numerator and denominator will need to be recorded in the medical record and collected at the patient level, then used to construct the measure according to the detailed specification described by the measure developer. Once the measure is so constructed, aggregation to create a performance rate will need to be undertaken. Rates of performance are then fed back to the healthcare professionals (physicians and others) for use in quality improvement projects, and reported externally to the public and other stakeholders as described above.

The use of performance measures needs to be integrated with similarly constructed point of care clinical decision support. (See figure below).

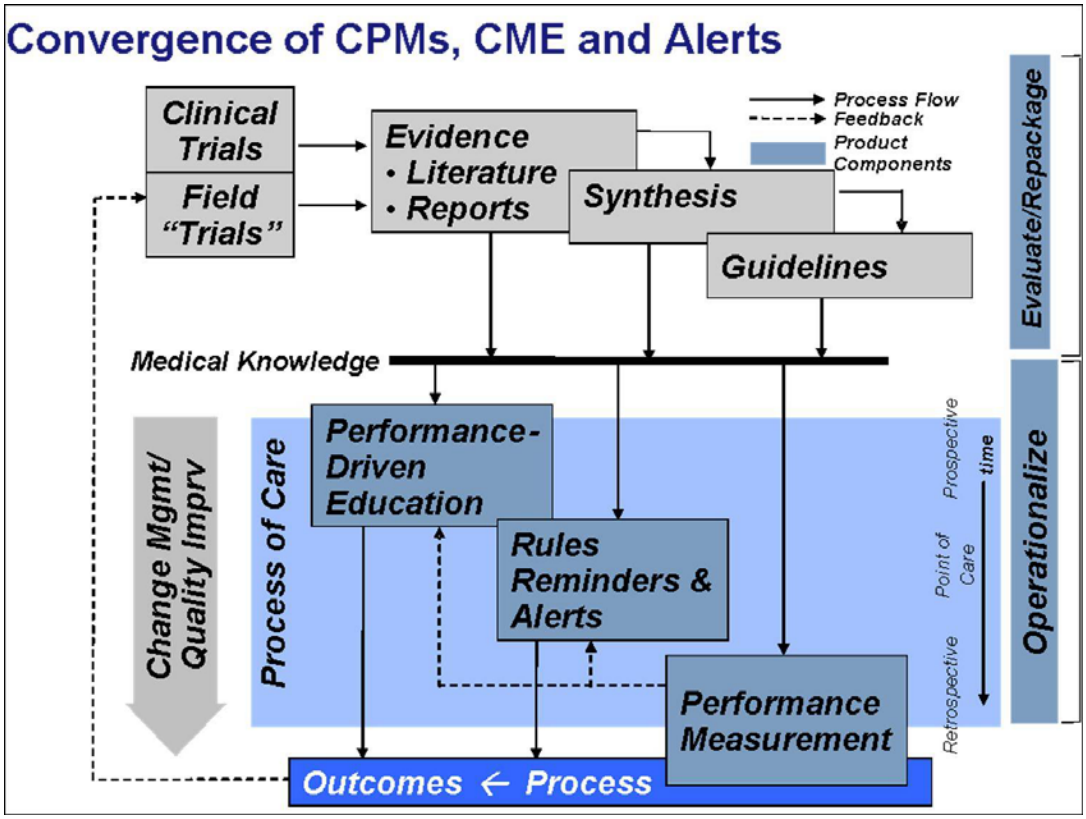

Figure 3 Performance Measures and Clinical Decision Support

The Patient-level Quality Export of Quality Data (PEQD) profile addresses the need for consistent communication of Quality data to a local, regional or third party Analyzer / Aggregator for consistent, standardized evaluation of quality structural, process and outcome measures. Recipients of Quality performance data include, but are not limited to, external governmental or private agencies, organizational Quality Management professionals, healthcare providers, and healthcare consumers (individuals and employers).

PEQD provides a standard methodology for automating this process, including access to the following categories of data:

- Measure definition and method of expression
- Demographics (sources: ADT, Financial systems)
- Results (Laboratory, Imaging)
- Substance Administration
- Procedures
- Location
- Events
- Clinical Observations / Findings
- Problems (Conditions, including but not limited to Allergies)

- Diagnoses
- History (patient or provider generated)

PEQD is a specialization and extension of the Retrieve Form for Data-Capture Profile defined in the IHE IT Infrastructure Technical Framework (see Appendix B.1).

The PEQD Profile does not address issues of privacy, security, and confidentiality associated with communication of Quality data. Such issues are covered by various Profiles defined in the IHE IT Infrastructure Technical Framework that may be implemented in conjunction with this Profile.

Note: For the purpose of trial implementation and demonstrations in 2008, the assumption is made that the PEQD profile is implemented for export from a single enterprise on a secure network. Additional security considerations are on the IHE Quality roadmap for subsequent years.

3.1 Actors/Transactions

Figure 3-1 diagrams the actors involved with this profile and the transactions between actors. The Figure identifies those actors from other Profiles that are grouped with the Form Filler and Analyzer / Aggregator actor under various options. It also identifies those actors that are functionally used primarily in direct patient care contexts.

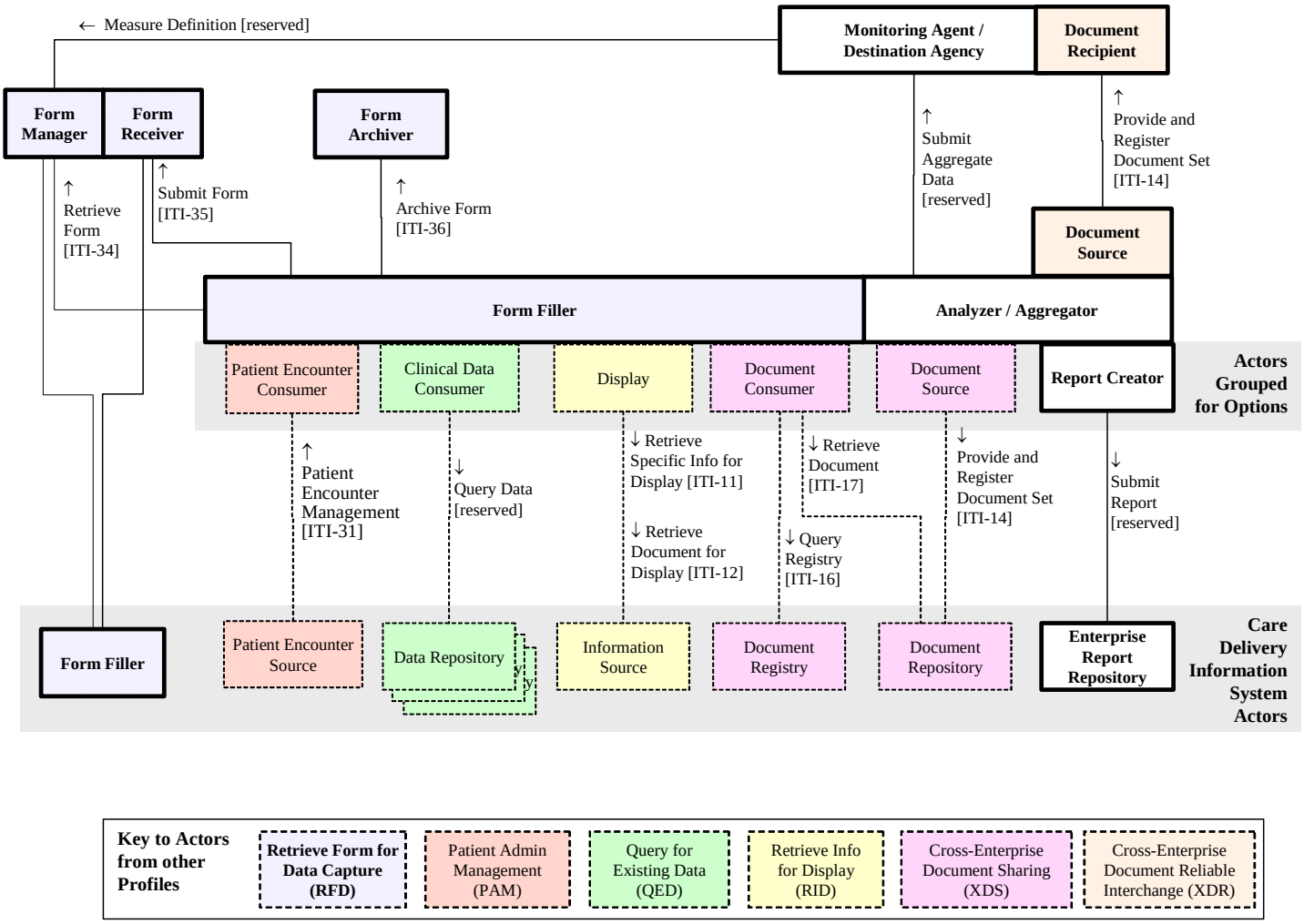

Figure 3-1: Patient-level Export of Quality Data (PEQD) Actors and Transactions

675 Table 3-1 lists the transactions for each actor directly involved in the PEQD Integration Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options defined by this Integration Profile that implementations may choose to support is listed in Section 3.2.

Table 3-1 PEQD - Actors and Transactions

Actor	Transactions	Optionality	Section

Actor	Transactions	Optionality	Section
Monitoring Agent / Destination Agency			
Document Receiver	Provide & Register Document Set [ITI-15]	R	
Form Manager	Retrieve Form [ITI-34]	R	
Form Receiver	Submit Form [ITI-35]	R	
Form Filler	Retrieve Form [ITI-34]	R	
	Submit Form [ITI-35]	R	
	Archive Form [ITI-36]	O	
Form Archiver	Archive Form [ITI-36]	R	
Analyzer / Aggregator			
Document Source	Provide & Register Document Set [ITI-15]	R	
Report Creator			
Enterprise Report Repository			
Document Consumer	Query Registry [ITI-16]	O	
	Retrieve Document [ITI-17]	O	
Patient Encounter Consumer	Patient Encounter Management [ITI-31]	O	
Display	Retrieve Specific Info for Display [ITI-11]	O	
	Retrieve Document for Display [ITI-12]	O	
Clinical Data Consumer			

680 Refer to Section 2.1 for other profiles that may be pre-requisites for this profile.

The following subsections describe required actor groupings.

3.1.1 Form Manager and Form Receiver

For the PEQD Profile, the Form Manager and Form Receiver actors must be grouped in an implementation. This allows the Form Manager to receive a partially completed form submitted by
685 a Form Filler actor, and provide it at a later time to the same or a different Form Filler actor.

Note that in contrast to the use in the Retrieve Form for Data-Capture Profile, the Form Receiver actor in the PEQD profile is not the ultimate recipient of the collected data; it is only an interim receiver to manage the collected data until it is ready to be submitted to the Monitoring Agent / Destination Agency.

690 ### 3.1.2 Analyzer / Aggregator and Form Filler

For the PEQD Profile, the Analyzer / Aggregator and Form Filler actors must be grouped in an implementation. This allows the Form Filler to obtain a quality measure form, and fill it out using a

variety of data sources (including manual data entry). The form may be returned to the Form Manager / Form Receiver for temporary storage.

3.1.3 Analyzer / Aggregator and Document Source

For the PEQD Profile, the Analyzer / Aggregator and Document Source must be grouped in an implementation. This allows the Analyzer / Aggregator to submit patient-level quality measure documents via the Document Source to the Monitoring Agent / Destination Agency grouped with a Document Receiver.

3.1.4 Monitoring Agent / Destination Agency and Document Receiver

For the PEQD Profile, the Monitoring Agent / Destination Agency must be grouped with a Document Receiver. This allows the Monitoring Agent / Destination Agency to receive patient-level quality measure documents via the Document Receiver.

3.2 PEQD Integration Profile Options

Many actors have Options defined in order to accommodate variations in use across domains or implementations. Options that may be selected for this Integration Profile are listed in Table 3-2 along with the actors to which they apply.

Table 3-2 PEQD - Actors and Options

Actor	Option Name	Vol & Section
Analyzer / Aggregator	*ADT Trigger*	
	RID Data Access	
	XDS Data Access	
	QED Data Access (not this year)	
	ERR Submission	
	XDS Submission	
Document Source	*On-line Mode*	ITI-TF 2: 3.15.4.1.2.3
Monitoring Agent / Destination Agency	*No options defined*	
Document Receiver	*On-line Mode*	ITI-TF 2: 3.15.4.1.2.3
Form Manager	No options defined	
Form Receiver	*No options defined*	
Form Filler	*Archive Form*	ITI-TF 2: 7.3
Form Archiver	*No options defined*	
Report Creator	*No options defined*	
Enterprise Report Repository	*No options defined*	

3.2.1 ADT Trigger Option

When the Analyzer / Aggregator actor implements the ADT Trigger Option, it is grouped with the Patient Encounter Consumer actor of the Patient Administration Management Profile. It receives ADT messages (especially admission and discharge) as triggers for the collection of quality measurement data.

3.2.2 RID Data Access Option

When the Analyzer / Aggregator actor implements the RID Data Access Option, it is grouped with the Display actor of the Retrieve Information for Display Profile. It queries and retrieves clinical documents or data from an Information Source for the collection of quality measurement data.

Note: This Option may be used to obtain information held in the Medical Records department or in a clinical specialty department. When a retrieved document is in the CDA format, it may contain structured data entries in computer-processable XML form. In this case, the Analyzer / Aggregator may be able to automatically extract data items for quality measurement purposes. However, in the general case information retrieved through the RID Profile must be presented to a human user for interpretation.

3.2.3 XDS Data Access Option

When the Analyzer / Aggregator actor implements the XDS Data Access Option, it is grouped with the Document Consumer actor of the Cross Enterprise Document Sharing Profile. It queries and retrieves clinical documents from a Document Registry and Repository for the collection of quality measurement data.

Notes: 1. The Cross Enterprise Document Sharing Profile requires the Document Consumer to use the patient ID used in the affinity (document sharing) domain; it may obtain this ID using the Patient Identity Cross-Reference Profile.

2. The Cross Enterprise Document Sharing Profile requires the Document Consumer to be a secure node under the Audit Trail and Node Authentication Profile.

3.2.4 QED Data Access Option (reserved)

3.2.5 ERR Submission Option

When the Analyzer / Aggregator actor implements the ERR Submission Option, it is grouped with a Report Creator actor. It sends collected quality measurement data as a clinical document for storage in an Enterprise Report Repository (part of an Electronic Medical Records (EMR) system).

3.2.6 XDS Submission Option

When the Analyzer / Aggregator actor implements the XDS Submission Option, it is grouped with the Document Source actor of the Cross Enterprise Document Sharing Profile. It sends collected quality measurement data as a clinical document for storage in a Document Repository.

Notes: 1. The Cross Enterprise Document Sharing Profile requires the Document Source to use the patient ID used in the affinity (document sharing) domain; it may obtain this ID using the Patient Identity Cross-Reference Profile.

2. The Cross Enterprise Document Sharing Profile requires the Document Source to be a secure node under the Audit Trail and Node Authentication Profile.

3.2.7 Archive Form Option

The Archive Form Option allows a Form Filler to submit, for archival purposes, the form instance data to a Form Archiver.

Note: The ERR Submission Option uses an HL7 v2 MDM message to transport the quality measurement data, the XDS Submission Option uses an ebXML message, and the Archive Form Option uses an HTTP message.

3.2.8 On-line Mode Option

In the On-line Mode Option the Document Source and the Document Recipient use the HTTP web-service based on-line transmission mode of the Cross Enterprise Document Reliable Interchange Profile to exchange the set of documents.

Notes: 1. The default transmission in the Cross Enterprise Document Reliable Interchange Profile is an off-line mode using e-mail (SMTP).

2. The Cross Enterprise Document Reliable Interchange Profile requires the Document Source and Document Recipient to be secure nodes under the Audit Trail and Node Authentication Profile.

3.3 PEQD Use Cases and Interactions

This Section describes the specific use cases and interactions defined for the PEQD Profile.

In the following use cases, unless otherwise specified, the “User” role is a human interacting with the system that implements the Form Filler and Analyzer / Aggregator actor. This user is an individual responsible for collecting and forwarding quality data, and may typically be a Quality Management department staffer, a nurse, or an administrator.

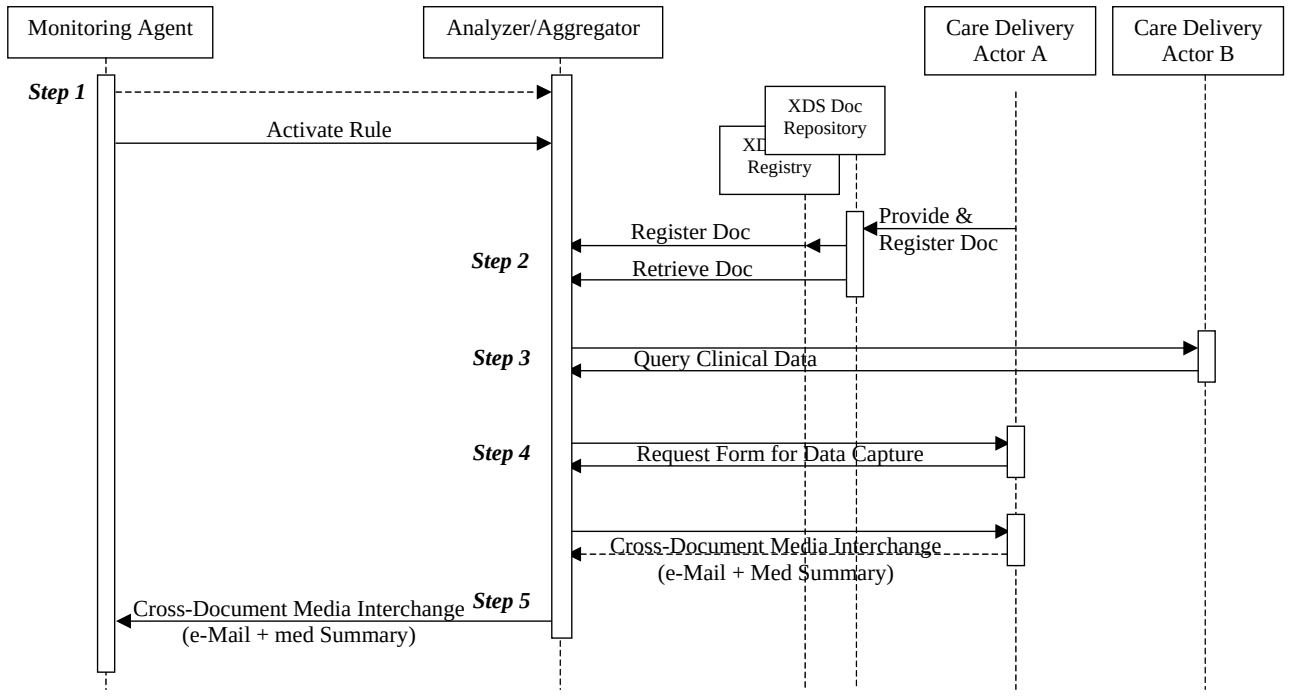

Figure X ITI Aggregate Data Profile v.4.5 (21 May 2007).

3.3.1 Case Q1: Manual Quality Data Collection

The Monitoring Agent / Destination Agency provides a definition of the quality data measure to the Form Manager at the participating healthcare provider organization by a method outside the scope of this profile. The quality measure definition may actually originate from a separate organization, but is selected by the Monitoring Agent / Destination Agency.

The Form Manager (with human participation) revises the quality data measure form as necessary for local data collection. This may involve mapping from data elements as defined by the quality data measure to the data elements used within the healthcare provider organization.

During the course of patient care, healthcare providers may use their point of care information system (acting as a Form Filler actor) to retrieve a form for collection of quality data. This may involve manual or automated filling of the form. This form, either completely or partially completed, is submitted to the Form Manager / Form Receiver actor.

After the encounter, a user responsible for quality data collection is notified of patient subject candidate for quality data collection by a method outside the scope of this profile (e.g., a paper list of discharged patients for the day). The User at the Analyzer / Aggregator retrieves the appropriate form for quality data collection measures. This may be a partially/wholly filled out form for the patient from the point of care data entry, or a blank form.

The User reviews the patient medical record for a match of the patient to the target population for a particular quality data measure (e.g., clinical condition, exclusion categories, etc.). A manual method may be used to access/review the patient medical record.

The User fills in a form for patient, abstracting from the medical record as required, and validating all information. The form may include a mechanism to indicate that it is complete and ready to be sent to the Monitoring Agent / Destination Agency. If the form is complete, but other conditions for submission are not met (e.g., forms must be submitted in batch at the end of a calendar quarter), the form is submitted to the Form Manager / Form Receiver actor for temporary storage until submission conditions are met.

The User may require further clarification from the healthcare provider on items in the medical record, e.g., to determine if a specific treatment is within a general category specified by the quality data measure. In this situation, the form with the request for clarification is returned to the Form Manager / Form Receiver, which makes it available to the healthcare provider (interacting via a Form Filler actor) for clarification. After providing the clarification, the provider's Form Filler actor resubmits the form to the Form Manager / Form Receiver.

The user is notified of the availability of forms to be sent to the Monitoring Agent / Destination Agency by a method outside the scope of this profile (e.g., a calendar reminder of the date for quarterly report submission). The user interacts with the Analyzer / Aggregator to retrieve the forms from the Form Manager and to submit the forms. If required by the Monitoring Agent / Destination Agency, the Analyzer / Aggregator anonymizes or pseudonymizes the data before submission. The

Analyzer / Aggregator may submit individual patient-level data, or it may submit aggregated data as required by the Destination Agency.

If required by configured workflow rules of the Analyzer / Aggregator, copies of the submitted forms are sent to the Form Archiver. If required by configured workflow rules, copies of the submitted forms are stored in the clinical documentation system (e.g., local EMR, or XDS-RHIO) as part of the patient record.

3.3.2 Case Q2: Triggered quality data collection and submission

Analyzer / Aggregator is notified of patient subject candidate through ADT discharge message.

Analyzer / Aggregator retrieves form for quality data collection measures.

Analyzer / Aggregator uses discharge information to further match candidate for particular quality data measure, and creates queue of work items for user (conceptual model only – mechanism is implementation specific).

User at Analyzer / Aggregator retrieves work item, and continues processing as described in Case Q1. Completed form is returned to Form Manager / Form Receiver actor.

A calendar-based trigger within the Analyzer / Aggregator causes all completed forms to be retrieved from the Form Manager; the forms are submitted to the Monitoring Agent / Destination Agency and archived as described in Case Q1.

3.3.3 Case Q3: Automated filling of quality data elements

Monitoring Agent/Destination Agency endorses quality measure and details data requirement (i.e., health issue, ICD9-CM, LOINC, CPT, NDC codes, etc) for submission as well as standard mechanism for reporting quality measure.

Electronic health record system (EHRS) at reporting institution, acting as an automated Form Filler actor, incorporates algorithm for collecting data requirements needed to report and submit quality measures endorsed by Monitoring Agent/Destination Agency into software design. EHRS allows for manual data entry of information requiring human cognition or for missing data elements.

The Form Manager at reporting institution assesses EHRS capability to accurately capture, store, and retrieve data elements required by the quality measure. The Form Manager also performs (as indicated) initial mapping of data (i.e., medication terminology) for each quality measure.

The document has identified workflow from the standpoint of retrospective analysis thus far. I.e., at the trigger of a pre-defined activity during or at the end of a hospital admission or an ambulatory encounter, summary documents are available for analysis for the rule or protocol identified by the destination agency. In some cases, the destination agencies will require information to be captured and transmitted concurrently during the active care process for an individual patient. In that case

during the course of patient care, the patient and the applicable health issue is identified by the EHR. In a later version of this framework, the workflow for management of data capture and transmission within an encounter will be addressed.

1. Retrospective Use Case

- The course of patient care progresses as usual and an activity occurs that has been pre-defined within a measure to initiate measurement data collection (e.g., discharge for a hospitalized patient).
- The Form Manager/Form Receiver is notified of the end of the activity for the patient based on the discharge trigger.
- The Form Manager/Form Receiver queries the patient record for applicable health issues for the measure (e.g., discharge diagnoses).
- For each patient with appropriate discharge diagnosis, the Analyzer/Aggregator pulls additional documents to obtain required data elements for denominator inclusion and exclusion criteria, and for numerator inclusion and exclusion criteria.
- The Form Manager/Form Receiver reviews the patient and health issue eligibility for the quality measure.
- The Form Manager/Form Receiver returns to the EHRS user the data element form populated with existing data.
- The EHRS provides the User information as to the missing data elements, or those data elements that require further clarification. If data are readily available, the User may manually enter or edit the information presented on form as deemed necessary (User acting as a Form Filler actor).
- If the User requires more time (e.g., for completion of pending test results) or further clarification, the EHRS allows the form to be temporarily archived for future retrieval. The form can be further manually modified by the institution's other Form Filler actor/s.
- The User returns the complete forms to the Form Manager/Form Receiver for review.
- The Form Manager/Form Receiver notifies User on the completed forms to be sent to Monitoring Agent/Destination Agency. Upon User action, the Form Manager/Form Receiver transmits the quality measure form/s to the Monitoring Agent/Destination Agency. The EHRS or the Form Manager/Form Receiver maintains records of submitted forms for future retrieval and analyses.

4 ACEI-ARB Content Profile

The ACEI-ARB Content Profile describes a data set for the measurement of a quality indicator defined by the American Heart Association (AHA) and American College of Cardiology (ACC). This quality indicator is based on the prescription of an Angiotensin Converting Enzyme Inhibitor <ACEI> or Angiotensin Receptor Blocker <ARB> on discharge for a patient with an episode of Acute Myocardial Infarction <AMI>, who exhibits Left Ventricular Systolic Dysfunction <LVSD>.

This measurement is one of the ACC / AHA STEMI/NSTEMI Performance Measures[1] . This measure requires a broad range of data from the categories of data presented to a quality measurement analyzer, including: principal diagnosis, result data (Left Ventricular Ejection Fraction <LVEF>), age, discharge status and destination, problem and allergy data (contraindications for medication avoidance), medications prescribed, and contextual data such as the patient ID and originating source of information (e.g., hospital location, address and identifier).

Table 1: AMI ICD-9 Diagnosis Codes

ICD-9 Code	Description
410.01	Anterolateral wall, acute myocardial infarction-initial episode
410.11	Other anterior wall, acute myocardial infarction-initial episode
410.21	Inferolateral wall, acute myocardial infarction-initial episode
410.31	Inferoposterior wall, acute myocardial infarction-initial episode
410.41	Other inferior wall, acute myocardial infarction-initial episode
410.51	Other lateral wall, acute myocardial infarction-initial episode
410.61	True posterior wall, acute myocardial infarction-initial episode
410.71	Subendocardial, acute myocardial infarction initial episode
410.81	Other specified sites, acute myocardial infarction-initial episode
410.91	Unspecified site, acute myocardial infarction-initial episode

The following specifications are listed in the JCAHO Specification Manual, accessible at: Specifications Manual for National Hospital Quality Measures, version 2.2b (Version 2.2b is applicable beginning with 4/1/2007 discharges through 9/30/07 discharges)

JCAHO Medications for ACEI/ARB Measure – This list is provided for information purposes. For up-to-date lists, reference the JCAHO Specification Manual directly since changes to medications are very likely and potentially frequent.	
ACEIs	**ARBs**
Accupril	Atacand
Accuretic	Atacand HCT

[1] Krumholz HM, Anderson JL, Brooks NH, *et. al.* ACC/ AHA Clinical Performance Measures for Adults with ST-Elevation and non-ST Elevation Myocardial Infarction: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures, *Circulation. 2006, Available at:* http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.106.172860v1. Accessed 23 May 2007.

JCAHO Medications for ACEI/ARB Measure – This list is provided for information purposes. For up-to-date lists, reference the JCAHO Specification Manual directly since changes to medications are very likely and potentially frequent.

ACEIs	ARBs
Aceon	Avalide
Altace	Avapro
Benazepril	Benicar
Benazepril Hydrochloride	Benicar HCT
Benazepril/amlodipine	Candesartan
Benazepril/hydrochlorothiazide	Candesartan/hydrochlorothiazide
Capoten	Cozaar
Capozide	Diovan
Capozide 25/15	Diovan HCT
Capozide 25/25	Eprosartan
Capozide 50/15	Eprosartan/hydrochlorothiazide
Capozide 50/25	Hyzaar
Captopril	Irbesartan
Captopril HCT	Irbesartan/hydrochlorothiazide
Captopril/hydrochlorothiazide	Losartan
Enalapril	Losartan/hydrochlorothiazide
Enalapril Maleate/diltiazem	Micardis
Enalapril Maleate/hydrochlorothiazide	Micardis HCT
Enalapril/diltiazem	Olmesartan
Enalapril/felodipine	Olmesartan/hydrochlorothiazide
Enalapril/hydrochlorothiazide	Tasosartan
Enalaprilat	Telmisartan
Fosinopril	Telmisartan/hydrochlorothiazide
Fosinopril Sodium/ hydrochlorothiazide	Teveten
Lexxel	Teveten HCT
Lisinopril	Valsartan
Lisinopril/hydrochlorothiazide	Valsartan/hydrochlorothiazide
Lotensin	Verdia
Lotensin HCT	
Lotrel	
Mavik	
Moexipril	
Moexipril Hydrochloride	
Moexipril Hydrochloride/hydrochlorothiazide	
Moexipril/hydrochlorothiazide	
Monopril	
Monopril HCT	

JCAHO Medications for ACEI/ARB Measure – This list is provided for information purposes. For up-to-date lists, reference the JCAHO Specification Manual directly since changes to medications are very likely and potentially frequent.	
ACEIs	**ARBs**
Monopril HCT 10/12.5	
Perindopril	
Perindopril Erbumine	
Prinivil	
Prinzide	
Quinapril	
Quinapril HC1	
Quinapril HC1/HCT	
Quinapril Hydrochloride/hydrochlorothiazide	
Quinapril/hydrochlorothiazide	
Quinaretic	
Ramipril	
Tarka	
Teczem	
Trandolapril	
Trandolapril/verapamil	
Trandolapril/verapamil hydrochloride	
Uniretic	
Univasc	
Vaseretic	
Vasotec	
Zestoretic	
Zestril	

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JCAHO LVSF Assessment Inclusion Table			
Echocardiogram (echo)	**Cardiac Catheterization (cath) with Left Ventriculogram (LV gram)**	**Other Tests**	**Left Ventricular Systolic Function (LVSF)**
2-D 3-D cardiac ultrasound Doppler color flow mapping M-mode echo transesophageal echocardiogram (TEE)	cardiac cath with mention of LVSF cardiac/coronary angiogram with LV gram cardiac/coronary angiogram with mention of LVSF cardiac/coronary arteriogram with LV gram cardiac/coronary arteriogram with mention of LVSF left heart cath with mention of LVSF left ventriculogram	adenosine myocardial perfusion stress test with mention of LVSF cardiac blood pool imaging cardiac MRI with mention of LVSF Cardiolite scan with mention of LVSF CT scan of chest with mention of LVSF gated blood pool imaging study gated heart study gated ventriculogram left ventricular gated wall motion analysis multiple gated acquisition scan (MUGA) myocardial perfusion imaging with mention of LVSF myocardial SPECT imaging with mention of LVSF myocardial SPECT study with mention of LVSF positron emission tomography (PET) with mention of LVSF radionuclide myocardial perfusion imaging with mention of LVSF radionuclide ventriculography Sestamibi scan with mention of LVSF SPECT imaging with mention of LVSF SPECT perfusion imaging with mention of LVSF stress perfusion imaging with mention of LVSF stress SPECT imaging with mention of LVSF stress SPECT perfusion imaging with mention of LVSF	akinesis biventricular dysfunction biventricular heart failure diastolic dysfunction diastolic function diastolic impairment dyskinesis ejection fraction (EF) endstage cardiomyopathy hypokinesis left ventricular diastolic dysfunction left ventricular diastolic function left ventricular dysfunction (LVD) left ventricular ejection fraction (LVEF) left ventricular failure left ventricular function (LVF) left ventricular systolic dysfunction (LVSD) left ventricular systolic failure systolic dysfunction systolic function ventricular function

JCAHO LVSF Assessment Inclusion Table			
Echocardiogram (echo)	**Cardiac Catheterization (cath) with Left Ventriculogram (LV gram)**	**Other Tests**	**Left Ventricular Systolic Function (LVSF)**
		technetium scan with mention of LVSF thallium stress test with mention of LVSF wall motion study Table 1.3 Moderate/Severe Systolic Dysfunction Inclusion Table	

Moderate/Severe Systolic Dysfunction Inclusion Table (JCAHO)

Note: Moderate/severe biventricular heart failure and endstage cardiomyopathy are also inclusions.

Biventricular dysfunction described as:	Ejection fraction (EF) described as:	Hypokinesis described as:	Left ventricular (LV) akinesis described as:
marked	abnormal	diffuse	marked
moderate	compromised	generalized	moderate
moderate-severe	decreased	global	moderate-severe
severe	depressed		severe
significant	diminished		significant
substantial	impaired		substantial very severe
the severity is not specified	low		
very severe	poor		
	reduced		
	very low		

Moderate/Severe Systolic Dysfunction Inclusion Table (JCAHO)

Note: Moderate/severe biventricular heart failure and endstage cardiomyopathy are also inclusions.

Left ventricular dysfunction (LVD) described as:	Left ventricular ejection fraction (LVEF) described as:	Left ventricular function (LVF) described as:	Left ventricular (LV) hypokinesis described as:
marked	abnormal	abnormal	involving the entire left ventricle
moderate	compromised	compromised	marked
moderate-severe	decreased	decreased	moderate
severe	depressed	depressed	moderate-severe
significant	diminished	diminished	severe
substantial	impaired	impaired	significant
the severity is not specified	low	low	substantial
very severe	poor	poor	very severe
	reduced	reduced	
	very low	very low	

Moderate/Severe Systolic Dysfunction Inclusion Table (JCAHO)

Note: Moderate/severe biventricular heart failure and endstage cardiomyopathy are also inclusions.

Left ventricular systolic dysfunction (LVSD) described as:	Left ventricular systolic failure described as:	Left ventricular systolic function (LVSF) described as:	Systolic dysfunction described as:	Systolic function described as:
marked	marked	abnormal	marked	abnormal
moderate	moderate	compromised	moderate	compromised
moderate-severe	moderate-severe	decreased	moderate-severe	decreased
severe	severe	depressed	severe	depressed
significant	significant	diminished	significant	diminished
substantial	substantial	impaired	substantial	impaired
the severity is not specified	the severity is not specified	low	the severity is not specified	low
very severe	very severe	poor	very severe	poor
		reduced		reduced
		very low		very low

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Moderate/Severe Systolic Dysfunction Inclusion Table (JCAHO)

Note: Moderate/severe biventricular heart failure and endstage cardiomyopathy are also inclusions.

JCAHO LVSD Notes Table	NUMERIC EFs
When the severity of systolic dysfunction is not specified in the test report or other documentation (e.g., "LVD"), the inference is being made that the degree of systolic dysfunction is clinically significant – that is, the systolic dysfunction is moderate or severe in degree. The Moderate/Severe Systolic Dysfunction Inclusion Table is limited to moderate/severe systolic dysfunction terms most commonly found in medical record documentation. Abstractors may need to exercise judgment in determining how to abstract terms that are not covered in the inclusion and exclusion lists (e.g., "mildly reduced EF" = 'No'). It is recommended that organizations establish a systemic way of tracking such decisions so that future cases with similar terms can be abstracted in a consistent manner. The LVSF inclusion terms from the LVF Assessment variable should not automatically be considered synonyms of the LVSD inclusion terms in the Moderate/Severe Systolic Dysfunction Inclusion Table (e.g., Diastolic dysfunction is an inclusion for LVSF in the LVF Assessment variable. "Impaired LVF" is an inclusion for LVSD. "Impaired diastolic dysfunction" should not be considered LVSD.). Hypokinesis should be inferred to be "left ventricular" when described as a finding from a diagnostic test of left ventricle, e.g. "LV heart cath showed marked hypokinesis."	The numeric EF may be documented as a percentage (%), whole number, or decimal. Convert all decimals to percentages (e.g., 0.40 = 40). The value should be between 5 and 80 If the EF is documented as less than (<) or greater than (>) a given number, use the value one whole number below or above the given number. E.g., "EF< 40%" – Use 39%; "EF>40%" – Use 41%. If the EF is not documented as a whole number, round fractions to the nearest whole number (e.g., 39.5% = 40%, 39.4% = 39%). If both calculated and estimated values are documented on an LVSF assessment test report, use the calculated value. If the EF is documented as a range, use the midpoint and consider this an estimated value. E.g., LVEF of "35-45%." Use 40%

Moderate/Severe Systolic Dysfunction Inclusion Table (JCAHO)

Note: Moderate/severe biventricular heart failure and endstage cardiomyopathy are also inclusions.

JCAHO LVSD Notes Table	NUMERIC EFs
Results from an in-hospital LVSF assessment test that may not have been available to the physician/advanced practice nurse/physician assistant (physician/APN/PA) by the time of discharge (i.e., filed into the chart after the patient was discharged) should still be used in abstraction if present in the medical record at that time. When there are two or more documented LVSFs, use the LVSF closest to discharge (or closest to hospital arrival, if ONLY pre-arrival LVSFs are documented). If unable to determine which LVSF is closest to discharge (or closest to arrival, in the case where only pre-arrival LVSFs are documented), select "Yes" if any of the documented LVSFs is an EF less than 40% or a narrative description consistent with moderate or severe systolic dysfunction. In the following examples, "Yes" would be selected: EF 50% per MUGA report from previous hospital stay included in chart, "Recent echo showed moderate LVD" per consultation report. "Echo last March showed preserved systolic function" per consultation report, "LVSD" noted in history section of H&P. "Patient admitted with known LVSD" per H&P, "Hx mild biventricular heart failure" per consultation report. EXCEPTION: When an LVSF assessment is done during the hospitalization and LVSF results from this assessment are documented, disregard other LVSF notations where testing/timeframe is unknown, and use only those findings known to be from the most recent in-hospital LVSF assessment in abstraction of LVSD in these cases. E.g., Echo done on hospital day 1 showed EF 45%, "Left ventricular dysfunction" per discharge summary (Not in reference to in-hospital echo). Select "No" for LVSD. Refer to Appendix H, LVSF Assessment Inclusion Table 1.2, Echo, Cardiac Cath with LV gram, and "other Tests" lists, for a listing of LVSF assessment tests.	as an estimated EF value. If the EF is documented as "about 40%" or "approximately 40%", use 40% and consider this an estimated value.

- The intent of this variable is to capture the most recent known LVSF. In cases where there are no LVSF results documented from a recent LVSF assessment test, but there is an LVSF documented from an earlier time period, use that earlier LVSF, as it is the most recent known LVSF. E.g., MUGA was done in the hospital and there are no LVSF results documented (no numeric EF, no qualitative description), but an echo from 3 months prior to arrival showed an EF of 35% - Select "Yes" for LVSD).
- In cases of conflicting documentation, where there are two or more different descriptions of LVSF in reference to the same, most recent test:
  - If there is one or more numeric EFs in combination with one or more narrative descriptions of LVSF, use the numeric EF(s) over the narrative LVSF description(s). Examples:
    - "EF 35%" per echo report, "Echo indicates normal systolic function" per progress note. Select "Yes" for LVSD
    - "Moderate LV dysfunction with EF 45%" noted on MUGA report. Select "No" for LVSD.

Moderate/Severe Systolic Dysfunction Inclusion Table (JCAHO)

Note: Moderate/severe biventricular heart failure and endstage cardiomyopathy are also inclusions.

JCAHO LVSD Notes Table	NUMERIC EFs

- "Reduced EF of 45%" per consultation report. Select "No" for LVSD.

- If there are two or more numeric EFs which conflict with each other, select "Yes" if either EF is less than 40%. EXCEPTION: If calculated vs. estimated EFs, take the calculated EF over the estimated EF, as directed in the "NUMERIC EFs" Notes
- If only narrative descriptions of LVSF are documented (no numeric EFs), and two or more descriptions conflict with each other, select "Yes" if either narrative description is consistent with moderate or severe systolic dysfunction. EXCEPTION: The following terms should be DISREGARDED when at least one narrative description of LVSF with severity specified (e.g., mild, moderate, severe, normal, preserved) is also documented:
  - Biventricular dysfunction, severity not specified
  - Ejection fraction (EF) described as abnormal, compromised, decreased, depressed, diminished, impaired, or reduced
  - Left ventricular dysfunction (LVD), severity not specified
  - Left ventricular ejection fraction (LVEF) described as abnormal, compromised, decreased, depressed, diminished, impaired, or reduced
  - Left ventricular function (LVF) described as abnormal, compromised, decreased, depressed, diminished, impaired, or reduced
  - Left ventricular systolic dysfunction (LVSD), severity not specified
  - Left ventricular systolic failure, severity not specified
  - Left ventricular systolic function (LVSF) described as abnormal, compromised, decreased, depressed, diminished, impaired, or reduced
  - Systolic dysfunction, severity not specified
  - Systolic function described as abnormal, compromised, decreased, depressed, diminished, impaired, or reduced
  - Examples:
    - Findings of "decreased LVF" and "mild left ventricular dysfunction" are noted on MUGA report. Select "No" for LVSD.
- "Echo showed mild-moderate LVD" in progress note, "LVSD" per echo report, Select "No" for LVSD.

4.1 ACEI-ARB Use Cases

TBSL – use by HQA, CMS, etc.
Storage in an EMR or XDS-RHIO for subsequent local use *Need to explain need for this segment*

Glossary

ACC: American College of Cardiology http://www.acc.org/

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

ADT: Admit, Discharge & Transfer.

Connectathon: IHE testing process a weeklong interoperability testing event where participating companies to test their implementation of IHE capabilities with corresponding systems from industry peers.

CT: Consistent Time Integration Profile.

DOB: Date of Birth.

EHR: Electronic Health Record.

eMPI: Enterprise Master Patient Index.

EMR: Electronic Medical Record.

HIMSS: Healthcare Information and Management Systems Society.

HIS: Hospital Information System.

HL7: Health Level 7. http://www.hl7.org/

IHE: Integrating the Healthcare Enterprise.

IETF: Internet Engineering Task Force. http://www.ietf.org/

MPI: Master Patient Index – see eMPI.

Interaction Diagram: A diagram that depicts data flow and sequencing of events.

IT: Information Technology.

MPI: Master Patient Index.

MRN: Medicare Record Number or Medical Record Number.

NEMA: National Electrical Manufacturers Association.

P4P: Pay for Performance – a model to reward healthcare providers with better outcomes

Role: The actions of an actor in a use case.

RFC: Request for comment. http://www.rfc-editor.org/

RSNA: Radiological Society of North America. http://www.rsna.org/

Scope: A brief description of the transaction.

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

UID: Unique Identifier

W3C: World Wide Web Consortium. http://www.w3.org/

Summary of Relevant Profiles from Other Domains

This appendix calls out specific Integration Profiles defined in the IHE IT Infrastructure and Patient Care Coordination Technical Frameworks. These Integration Profiles are sufficiently important to the Quality domain that they have been explicitly included in the IHE Quality Technical Framework. However, they are specified only by reference to their original definition in the other Technical Frameworks, with notes and use cases on their applicability to Quality. **There are no additional technical requirements defined in this Appendix.**

The full specification of the Profiles identified in this Appendix can be found in the IHE Technical Framework documents of other domains. These descriptions are provided for reference related to their use in the Quality domain.

A.1 Retrieve Form for Data Capture (RFD)

The full specification of the Retrieve Form for Data Capture Profile is found in **ITI-TF Supplement 2007-2008**.

The Retrieve Form for Data-Capture Profile (RFD) provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of a form from a form source, the display and completion of that forms, and the return of instance data from the display application to the source application of the data so captured. In addition, RFD provides a mechanism by which amendments to the data captured can be made.

In this use case a healthcare provider site uses an Electronic Health Record (EHR) to document patient care. The EHR acts as the local home application for the provider's personnel. The Analyzer / Aggregator, whether within the enterprise or external to it requires data from the provider, some of which reside in the EHR's database, the rest requiring data entry by the EHR's users. RFD enables the EHR user to retrieve a data capture form from the external agency, to fill out the form, and to return the data to the Analyzer / Aggregator without leaving the provider's local home application, the EHR. The profile also permits the Analyzer / Aggregator to indicate that there is a need to clarify points about the data so captured and provides the mechanisms to allow the data to be modified..

The RFD Form Filler permits automatic form population and provides a generic mechanism by which this can be accomplished. However, the profile does not speak to the issue of content, such that normative vocabularies and other enablers of semantic interoperability for each quality measure requires work by the Form Manager. Specific content specifications can be provided, as required, by Form Managers for individual quality measures to operate within RFD resulting in a much greater level of interoperability will result.

The same approach has been taken with the clarification mechanism, the profile providing a generic mechanism to allow the Analyzer / Aggregator to indicate issues with data that have been captured and permit the healthcare provider a means to correct the data. The profile does not dictate the mechanism employed or content required to achieve such corrections.

In this profile, the Analyzer / Aggregator provides data capture forms in a schema appropriate to its needs. The profile intends to minimize the work that the displaying application should do, and to bring over fully functional forms that carry with them the instruction necessary to complete the form. The profile supports negotiation between the form display and form provider systems, so that iterative exchanges can deal with issues like form selection, completion of a series of forms, partial completion of forms, returning to forms partially filled out in earlier sessions. RFD also supports archiving a copy of the completed form.

RFD also offers the capability to leverage industry standards that address both the structure and content of forms used for data capture. HL7's Individual Case Safety Record (ICSR) and CDISC's Operational Data Model (ODM) provide examples

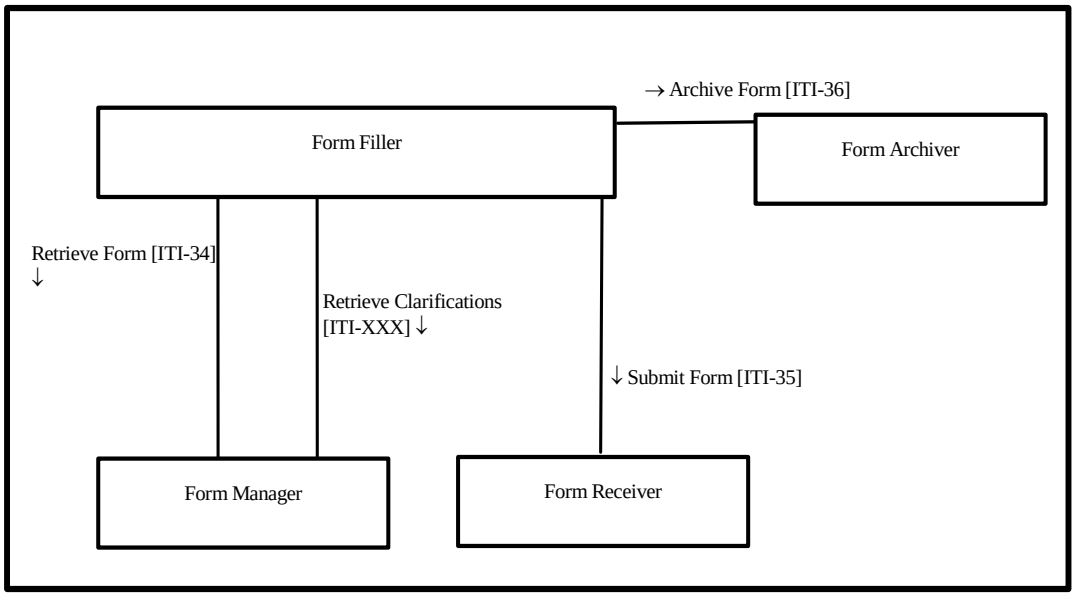

Figure A.1 RFD Actor/Transactions

A.2 Retrieve Information for Display (RID)

The full specification of the Retrieve Information for Display Profile is found in **ITI-TF 1:3**.

The Retrieve Information for Display (RID) Integration Profile provides simple and rapid read-only access to patient-centric clinical information that is located outside the user's current application but is important for better patient care (for example, access to lab reports from the Quality Management department). It supports access to existing persistent documents in well-known presentation formats such as CDA, PDF, JPEG, etc. It also supports access to specific key patient-centric information such as allergies, current medications, summary of reports, etc. for presentation to a clinician.

Figure B.2-1 shows the actors involved in this Profile and the transactions between actors.

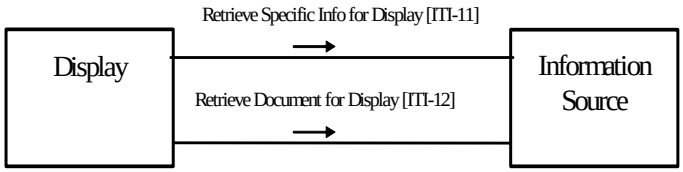

Figure B.2-1. Retrieve Information for Display Diagram

A.2.1 RID Process Flow

A user, through the Display actor, requests information related to a patient. The request may be constrained to a particular type of information (e.g., a list of laboratory reports, or a list of current medications), or may include other filtering keys (last N documents, date range, etc.). The Information Source actor responds with the requested information in a "ready for presentation" format; the Display actor simply displays the information to the person that triggered the request.

The clinician may also request retrieval of a specific document for display, either from a list returned from the Information Source, or using an access pointer obtained by some other mechanism (e.g., included as a reference in another document). The Display actor may request a specific document presentation format for the retrieved document. Again, the Information Source actor responds to the request, and may convert the requested document from its native storage format to the requested presentation format.

A.2.2 Quality Use Cases

In the Quality domain, this Profile may be used to obtain information held in the Medical Records department or in a clinical specialty department. In particular, this Profile may be used to obtain information critical to the collection of a quality measure, such as patient history and physical exam data, advance medical directives, blood chemistry reports, and current medications. As such, the Display actor of this profile has a significant adjunct role for the PEQD Profile, and its use is a named option for the Analyzer / Aggregator actor to access information and documents from the patient's electronic health record (EHR).

When a retrieved document is in the CDA format, it may contain structured data entries in computer-processable XML form. In this case, the Analyzer / Aggregator may be able to automatically extract data items for quality measurement purposes. However, in the general case information retrieved through the RID Profile must be presented to a human user for interpretation.

A.3 Cross-Enterprise Document Sharing (XDS)

The full specification of the Cross-Enterprise Document Sharing Integration Profile is found in **ITI-TF 1:10**.

The Cross-Enterprise Document Sharing Integration Profile facilitates the registration, distribution and access across health enterprises of patient electronic health records. Cross-Enterprise Document Sharing provides a standards-based specification for managing the sharing of documents between any healthcare enterprises, ranging from private physician offices, to clinics, to acute care in-patient facilities.

The XDS Integration Profile assumes that these enterprises belong to one or more *clinical affinity domains*. A clinical affinity domain is a group of healthcare enterprises that have agreed to work together using a common set of policies and share a common infrastructure. Examples of affinity domains include:

- Community of Care supported by a Regional Health Information Organization (RHIO)
- An Integrated Delivery Network (IDN)
- Specialized or Disease-oriented Care Communities
- Insurance Provider Supported Communities

Within a clinical affinity domain, certain common policies and business rules must be defined. They include how patients are identified, consent is obtained, and access is controlled, as well as the format, content, structure, organization and representation of clinical information. This Integration Profile does not define specific policies and business rules; however, it has been designed to accommodate a wide range of such policies to facilitate the deployment of standards-based infrastructures for sharing patient clinical documents.

Figure H.4-1 diagrams the actors involved with this profile and the transactions between actors.

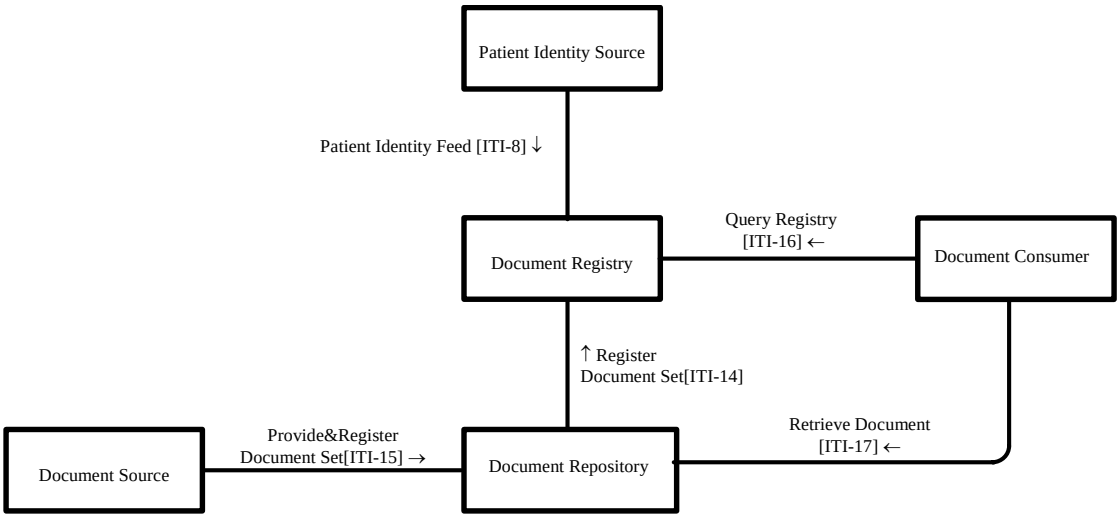

Figure H.4-1 Cross-Enterprise Document Sharing Diagram

Notes: 1. This Profile requires all actors be grouped with a Secure Node Actor as defined in the IHE Audit Trail and Node Authentication (ATNA) Integration Profile (see ITI-TF 1:9).

2. The effective use of this Profile assumes the use of the Patient Identity Cross-Reference (PIX) Profile (see ITI-TF 1:5) to enable the Document Source systems to obtain and apply the Patient ID used in the clinical affinity domain to documents registered for sharing.

3. The effective use of this Profile requires profiling the specific document formats to be used in the clinical affinity domain (see H.2.3).

A.3.1 XDS Process Flow

A clinician submits a set of documents to be shared (e.g., a History and Physical report, and an ECG) through a Document Source Actor (e.g., his local EHR system). This system sends the documents and the corresponding metadata to the Document Repository, using the Patient ID used in the shared domain (which may be different than the ID used in the local EHR). The Document Repository is responsible to persistently store these documents, and to register them in the Document Registry using the Register Documents transaction by forwarding the document metadata received from the Document Source Actor.

This document metadata will be used to create an XDS Document Entry in the registry. The Document Registry Actor ensures that document metadata is valid before allowing documents to be registered.

There may be several Document Repositories in the clinical affinity domain, but all register their documents with a single Document Registry for the domain. A Document Repository may be bundled with the Document Source, or with the Document Registry, or may be an independent system.

A care provider elsewhere in the network wishes to retrieve the patient's shared documents (e.g., in preparation for a diagnostic exam). That provider through a Document Consumer Actor issues a

Query Registry transaction to the Document Registry. The Document Registry Actor searches the registry to locate documents that meet the provider's specified query criteria. It will return a list of document entries that contain metadata found to meet the specified criteria including the locations and identifier of each corresponding document in one or more Document Repositories. The provider identifies the documents he is interested in seeing, and the Document Consumer Actor initiates the Retrieve Document transaction. The Document Repository will return the document that was specified by the Document Consumer.

A.3.2 Quality Use Cases

In the Quality domain, each quality measure will require a content profile with the data element specifications for patient-level reporting and the calculation methodology for aggregate analysis and reporting. The Framework for 2007 specifies the content requirements for one measure. Other measures can be evaluated via desktop testing to identify new use cases or modifications to the existing generic use case to inform the work effort for 2008 and beyond. The individual measure for 2007 is angiotensin converting enzyme inhibitor (ACEI) or antiotensin receptor blocker (ARB) prescription at discharge for patients with acute myocardial infarction with left ventricular systolic dysfunction (ACC/AHA STEMI/NSTEMI Performance Measures: http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.106.172860v1, page 16)

A.3.3 XDS Content Profiles

XDS provides a general mechanism for sharing of documents between different healthcare enterprises. However, certain use cases require the specification of the content or structure of shared documents to ensure interoperability. This is the purpose of XDS Content Profiles.

XDS-MS Medical Summary

The full specification of the Cross-Enterprise Document Sharing of Medical Summaries Profile is found in PCC TF-1:3.

By their nature, Medical Summaries form a class of clinical documents that contain the most relevant portions of the patient medical record. 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.

The XDS-MS Profile facilitates transfer of care by defining 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 defines 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.

Most of the XDS Quality use cases would utilize the XDS-MS content profile for exchanging a summary of an episode of care – the summary record of an office visit, of an in-patient cath procedure, or of an emergency department encounter.

A.3.4 XDS Related Profiles

Patient Identity Cross-Referencing (PIX)

Audit Trail and Node Authentication (ATNA)

Consistent Time (CT)

A.4 Cross-Enterprise Document Reliable Interchange (XDR)

A.5 Patient Administration Management (PAM)

ITI Technical Framework Supplement 2005-2006, Patient Administration Management (PAM) Integration Profile

A.6 Query for Existing Data (QED)

Volume 2 - Transactions and Document Content

4.2 Relation of this Volume to the Technical Framework

The IHE Technical Framework is based on actors that interact through transactions using some form of content.

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

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

The implementation of the transactions described in this PCC TF-2 support the specification of Integration Profiles defined in PCC TF-1. The role and implementation of these transactions require the understanding of the Integration profile they support.

There is often a very clear distinction between the transactions in a messaging framework used to package and transmit information, and the information content actually transmitted in those messages. This is especially true when the messaging framework begins to move towards mainstream computing infrastructures being adopted by the healthcare industry.

In these cases, the same transactions may be used to support a wide variety of use cases in healthcare, and so more and more the content and use of the message also needs to be profiled,

sometimes separately from the transaction itself. Towards this end IHE has developed the concept of a Content Integration Profile.

Content Integration Profiles specify how the payload of a transaction fits into a specific use of that transaction. A content integration profile has three main parts. The first part describes the use case. The second part is binding to a specific IHE transaction, which describes how the content affects the transaction. The third part is a Content Module, which describes the payload of the transaction. A content module is specified so as to be independent of the transaction in which it appears.

4.2.1 Content Modules

The Technical Framework organizes content modules categorically by the base standard. At present, the Technical Framework uses only one base standard, CDA Release 2.0, but this is expected to change over time. Underneath each standard, the content modules are organized using a very coarse hierarchy inherent to the standard. So for CDA Release 2.0 the modules are organized by document, section, entry, and header elements.

Each content module can be viewed as the definition of a "class" in software design terms, and has associated with it a name. Like "class" definitions in software design, a content module is a "contract", and the Technical Framework defines that contract in terms of constraints that must be obeyed by instances of that content module. Each content module has a name, also known as its template identifier. The template identifiers are used to identify the contract agreed to by the content module. The Technical Committee is responsible for assigning the template identifiers to each content module.

Like classes, content modules may inherit features of other content modules of the same type (Document, Section or Entry) by defining the parent content module that they inherit from. They may not inherit features from a different type. Although information in the CDA Header is in a different location that information in a CDA Entry, these two content modules are considered to be of the same type, and so may inherit from each other when necessary.

The Technical Framework uses the convention that a content module cannot have more than one parent (although it may have several ancestors). This is similar to the constraint in the Java™ programming language, where classes can derive from only one parent. This convention is not due to any specific technical limitation of the technical framework, but does make it easier for software developers to implement content modules.

Each content module has a list of data elements that are required (R), required if known (R2), and optional (O). The presentation of this information varies with the type of content module, and is described in more detail below. Additional data elements may be provided by the sender that are not defined by a specific content module, but the receiver is not required to interpret them.

Required data elements must always be sent. Data elements that are required may under exceptional circumstances have an unknown value (e.g., the name of an unconscious patient). In these cases the sending application is required to indicate the reason that the data is not available.

Data elements that are marked required if known (R2) must be sent when the sending application has that data available. The sending application must be able to demonstrate that it can send all required

if known elements, unless it does not in fact gather that data. When the information is not available, the sending application may indicate the reason that the data is not available.

Data elements that are marked optional (O) may be sent at the choice of the sending application. Since a content module may include data elements not specified by the profile, some might ask why these are specified in a content module. The reason for specifying the optional data elements is to ensure that both sender and receiver use the appropriate semantic interpretation of these elements. Thus, an optional element need not be sent, but when it is sent, the content module defines the meaning of that data element, and a receiver can always be assured of what that data element represents when it is present. Senders should not send an optional data element with an unknown value. If the value is not known, simply do not send the data element.

Other data elements may be included in an instance of a content module over what is defined by the Technical Framework. Receivers are not required to process these elements, and if they do not understand them, must ignore them. Thus, it is not an error to include more than is asked for, but it is an error to reject a content module because it contains more than is defined by the framework. This allows value to be added to the content modules delivered in this framework, through extensions to it that are not defined or profiled by IHE. It further allows content modules to be defined later by IHE that are refinements or improvements over previous content modules.

In order to retain this capability, there are a few rules about how the Technical Committee creates constraints. Constraints that apply to any content module will always apply to any content modules that inherit from it. Thus, the "contracts" are always valid down the inheritance hierarchy. Secondly, data elements of a content module will rarely be deprecated. This will usually occur only in the cases where they have been deprecated by the base standard. While any specific content module has a limited scope and set of use cases, deprecating the data element prevents any future content module from taking advantage of what has already been defined when a particular data element has been deprecated simply because it was not necessary in the original use case.

4.2.1.1 Document Content Module Constraints

Each document content module will define the appropriate codes used to classify the document, and will also describe the specific data elements that are included. The code used to classify it is specified using an external vocabulary, typically LOINC in the case of CDA Release 2.0 documents. The set of data elements that make up the document are defined, including the whether these data elements must, should or may be included in the document. Each data element is typically a section within the document, but may also describe information that is contained elsewhere within of the document (e.g., in the header). Each data element is mapped into a content module via a template identifier, and the document content module will further indicate whether these are data elements are required, required if known or optional.

Thus, a document content module shall contain as constraints:

- The template identifier of the parent content module when there is one.
- The LOINC code or codes that shall be used to classify the document.

- A possibly empty set of required, required if known, and optional section content modules, and their template identifiers.
- A possibly empty set of required, required if known, and optional header content modules, and their template identifiers.
- Other constraints as necessary.

The template identifier for the document will be provided in the narrative, as will the legal LOINC document type codes and if present, any parent template identifier.

The remaining constraints are presented in two tables. The first table identifies the relevant data elements as determined during the technical analysis, and maps these data elements to one or more standards. A simplified example below shows a table that might have been used to develop a content profile for birthplace, if we ever wanted to go to such detail.

Data Elements	HL7 V3 ADDR Data Type
Address Line	<streetAddressLine>
City	<city>
State	<state>
Zip Code	<postalCode>
County	<county>
Country	<country>

Table 1.1.1.1.a – Birthplace content profile example

The second table actually provides the constraints, wherein each data element identified in the first table is repeated, along with whether it is required, required if known, or optional. Following this column is a reference to the specification for the content module that encodes that data element, and the template identifier assigned to it. The simple example below completes the content specification described above.

Data Elements	Opt	Reference	Template ID
Address Line	R	PCC TF-2:4.2.1.1	3
City	R	PCC TF-2:4.2.1.1	4
State	R	PCC TF-2:4.2.1.1	5
Zip Code	R	PCC TF-2:4.2.1.1	6
County	R2	PCC TF-2:4.2.1.1	7
Country	O	PCC TF-2:4.2.1.1	8

Table 1.1.1.1.b – Contrained Birthplace content profile example

Section Content Module Constraints

Section content modules will define the content of a section of a clinical document. Sections will usually contain narrative text, and so this definition will often describe the information present in the narrative, although sections may be wholly comprised of subsections.

Sections may contain various subsections, and these may be required, required if known or optional. Sections may also contain various entries, and again, these may be required, required if known, or optional. A section may not contain just entries; it must have at least some narrative text or subsections to be considered to be valid content.

Again, sections can inherit features from other section content modules. Once again, sections are classified using an external vocabulary (again typically this would be LOINC), and so the list of possible section codes is also specified. Sections that inherit from other sections will not specify a LOINC code unless it is to restrict the type of section to smaller set of LOINC codes specified by one of its ancestors.

Thus, a section content module will contain as constraints:

- The template identifier of the parent content module when there is one.
- The LOINC code or codes that shall be used to classify the section.
- A possibly empty set of required, required if known, and optional section content modules, and their template identifiers for the subsections of this section.
- A possibly empty set of required, required if known, and optional entry content modules, and their template identifiers.
- Other constraints as necessary.

These constraints are presented in this document using a table for each section content module, as shown below in Figure 4.2-1.

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.12	
Parent Template	1.3.6.1.4.1.19376.1.5.3.1.3.11	
General Description	The list of surgeries section shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.	
Valid LOINC CODES	**Opt**	**Description**
10167-5	R	HISTORY OF SURGICAL PROCEDURES
Sub-sections		**Description**
None Specified		
Entries		**Description**
Procedure	R	IHE Procedure Structure
1.3.6.1.4.1.19376.1.5.3.1.4.4	R2	References

Figure 4.2-1 A Section RBR Diagram for the List of Surgeries Section

4.2.1.2 Entry and Header Content Modules

Entry and Header content modules are the lowest level of content for which content modules are defined. These content modules are associated with classes from the HL7 Reference Information Model (RIM). These "RIM" content modules will constrain a single RIM class. Entry content modules typically constrain an "Act" class or one of its subtypes, while header content modules will normally constrain "Participation", "Role" or "Entity" classes, but may also constrain an "Act" class.

Entry and Header content modules will describe the required, required if known, and optional XML elements and attributes that are present in the CDA Release 2.0 instance. Header and Entry content modules may also be built up using other Header and Entry content modules.

An entry or header content module may also specify constraints on the vocabularies used for codes found in the entry, or data types for the values found in the entry.

Thus, an entry or header content module will contain as constraints:

- The template identifier of the parent content module when there is one.
- A description of the XML elements and attributes used in the entry, along with explanations of their meaning.
- An indication of those XML elements or attributes that are required, required if known, or optional.
- Vocabulary domains to use when coding the entry.
- Data types used to specify the value of the entry.
- Other constraints as necessary.

5 IHE Transactions

This section defines each IHE transaction in detail, specifying the standards used, and the information transferred.

At present, all transactions used by the Quality Profiles appear in ITI TF-2. Specializations, constraints, and options defined for the Quality Profiles are described below.

5.1 Form Manager and Form Receiver Specialization

Grouping

Receive and regurgitate

5.2 Form Filler and Analyzer / Aggregator Specialization and Options

Grouping

5.2.1 ADT Trigger Option

When the Analyzer / Aggregator actor implements the ADT Trigger Option, it is grouped with the Patient Encounter Consumer actor of the Patient Administration Management Profile. It receives ADT messages (especially admission and discharge) as triggers for the collection of quality measurement data.

5.2.2 RID Data Access Option

When the Analyzer / Aggregator actor implements the RID Data Access Option, it is grouped with the Display actor of the Retrieve Information for Display Profile. It queries and retrieves clinical documents or data from an Information Source for the collection of quality measurement data.

Note: This Option may be used to obtain information held in the Medical Records department or in a clinical specialty department. When a retrieved document is in the CDA format, it may contain structured data entries in computer-processable XML form. In this case, the Analyzer / Aggregator may be able to automatically extract data items for quality measurement purposes. However, in the general case information retrieved through the RID Profile must be presented to a human user for interpretation.

5.2.3 XDS Data Access Option

When the Analyzer / Aggregator actor implements the XDS Data Access Option, it is grouped with the Document Consumer actor of the Cross Enterprise Document Sharing Profile. It queries and retrieves clinical documents from a Document Registry and Repository for the collection of quality measurement data.

Notes: 1. The Cross Enterprise Document Sharing Profile requires the Document Consumer to use the patient ID used in the affinity (document sharing) domain; it may obtain this ID using the Patient Identity Cross-Reference Profile.

2. The Cross Enterprise Document Sharing Profile requires the Document Consumer to be a secure node under the Audit Trail and Node Authentication Profile.

5.2.4 QED Data Access Option (reserved)

5.2.5 ERR Submission Option

When the Analyzer / Aggregator actor implements the ERR Submission Option, it is grouped with a Report Creator actor. It sends collected quality measurement data as a clinical document for storage in an Enterprise Report Repository (part of an Electronic Medical Records (EMR) system).

5.2.6 XDS Submission Option

When the Analyzer / Aggregator actor implements the XDS Submission Option, it is grouped with the Document Source actor of the Cross Enterprise Document Sharing Profile. It sends collected quality measurement data as a clinical document for storage in a Document Repository.

Notes: 1. The Cross Enterprise Document Sharing Profile requires the Document Source to use the patient ID used in the affinity (document sharing) domain; it may obtain this ID using the Patient Identity Cross-Reference Profile.

2. The Cross Enterprise Document Sharing Profile requires the Document Source to be a secure node under the Audit Trail and Node Authentication Profile.

5.2.7 Archive Form Option

The Archive Form Option allows a Form Filler to submit, for archival purposes, the form instance data to a Form Archiver.

Note: The ERR Submission Option uses an HL7 v2 MDM message to transport the quality measurement data, the XDS Submission Option uses an ebXML message, and the Archive Form Option uses an HTTP message.

5.2.8 On-line Mode Option

In the On-line Mode Option the Document Source and the Document Recipient use the HTTP web-service based on-line transmission mode of the Cross Enterprise Document Reliable Interchange Profile to exchange the set of documents.

Notes: 1. The default transmission in the Cross Enterprise Document Reliable Interchange Profile is an off-line mode using e-mail (SMTP).

2. The Cross Enterprise Document Reliable Interchange Profile requires the Document Source and Document Recipient to be secure nodes under the Audit Trail and Node Authentication Profile.

6 IHE Bindings

This section describes how the payload used in a transaction of an IHE profile is related to and/or constrains the data elements sent or received in those transactions. This section is where any specific dependencies between the content and transaction are defined.

A content integration profile can define multiple bindings. Each binding should identify the transactions and content to which it applies.

6.1 ACEI-ARB Document Binding to XDS, XDM and XDR

This binding defines a transformation that generates metadata for the XDSDocumentEntry element of appropriate transactions from the XDS, XDM and XDR profiles given a ACEI-ARB quality measure document and information from other sources. The other sources of information include the configuration of the Document Source actor, the Affinity Domain, the site or facility, local agreements, other documents in the registry/repository, and this Content Profile.

The source for all required and optional attributes have been defined in this section. Three tables describe the three main XDS object types: XDSDocumentEntry, XDSSubmissionSet, and XDSFolder. XDSSubmissionSet and XDSDocumentEntry are required. Use of XDSFolder is optional.

The columns of the following tables are:

- **<XXX> attribute** – name of an XDS attribute.
- **Optional?** - Indicates the required status of the XDS attribute, and is one of R, R2, or O (optional). This column is filled with the values specified in the XDS Profile as a convenience.
- **Constrained?** – Indicates where this Content Profile further constrains this attribute.
- **Extended Discussion?** – Indicates which section provides addition details of the handling of this attribute.
- **Source Type** – Will contain one of the following values:

Source Type	Description
SA	Source document Attribute – value is copied directly from source document. The Source/Value column identifies where in the source document this attribute comes from. Specify the location in XPath when possible.
SAT	Source document Attribute with Transformation – value is copied from source document and transformed. The Source/Value column identifies where in the source document this attribute comes from. Specify the location in XPath when possible. Extended Discussion column must not be empty and the transform must be defined in the extended discussion
FM	Fixed (constant) by Mapping - for all source documents. Source/Value column contains the value to be used in all documents.
FAD	Fixed by Affinity Domain – value configured into Affinity Domain, all documents will use this value.

CAD	Coded in Affinity Domain – a list of acceptable codes are to be configured into Affinity Domain. The value for this attribute shall be taken from this list.
CADT	Coded in Affinity Domain with Transform - a list of acceptable codes are to be configured into Affinity Domain. The value for this attribute shall be taken from this list.
n/a	Not Applicable – may be used with an optionality R2 or O attribute to indicate it is not to be used.
DS	Document Source – value comes from the Document Source actor. Use Source/Value column or Extended Discussion to give details.
O	Other – Extended Discussion must be 'yes' and details given in an Extended Discussion.

Source/Value – This column indicates the source or the value used.

The following tables are intended to be summaries of the mapping and transforms. The accompanying sections labeled 'Extended Discussion' are to contain the details as necessary.

6.1.1 XDSDocumentEntry Metadata

XDSDocumentEntry Attribute	Optional?	Constrained ?	Extended Discussion ?	Source Type	Source/Value
authorSpecialty	R2		6.1.2.1	CAD	
authorInstitution	R2			SA	/ClinicalDocument/author /assignedAuthor /representedOrganization/name
authorPerson	R2		6.1.2.2	SAT	$person <= /ClinicalDocument/author
classCode	R		6.1.2.3	CADT	Must be consistent with /ClinicalDocument/code/@code
classCodeDisplayName	R		6.1.2.4	CADT	Must be Consitent with /ClinicalDocument/code/@code
confidentialityCode	R		6.1.2.5	CADT	/ClinicalDocument/ confidentialityCode/@code
creationTime	R			SA	/ClinicalDocument/effectiveTime
eventCodeList	O		6.1.2.6	CADT	
eventCodeDisplayNameList	R (if event Code is valued)			CADT	
formatCode	R		6.1.2.7	FM	/ClinicalDocument/templateI

				d
healthcareFacility TypeCode	R	6.1.2.8	O	Must be concistent with /clinicalDocument/code
healthcareFacility TypeCodeDisplay Name	R	6.1.2.8	O	Must be concistent with /clinicalDocument/code
intendedRecipient	R2	6.1.2.2	SAT	$person <= /ClinicalDocument/intendedRecipient
languageCode	R		SA	/ClinicalDocument/languageCode
legalAuthenticator	O	6.1.2.2	SAT	$person <= /ClinicalDocument/ legalAuthenticator
mimeType	R		FM	text/xml
parentDocument Relationship	R (when applicable)		SA	/ClinicalDocument/relatedDocument/@typeCode
parentDocumentId	R (when parent Document Relationship is present)	6.1.2.9	SAT	$docID <= /ClinicalDocument/ relatedDocument/parentDocument/ id
patientId	R	6.1.2.10	SAT	$patID <= /ClinicalDocument/recordTarget/ patientRole/id
practiceSettingCode	R	6.1.2.11	CAD	
practiceSettingCode DisplayName	R	4.1.2.10	CAD	
serviceStartTime	R2		SA	/ClinicalDocument/documentationOf/ serviceEvent/effectiveTime/low/ @value
serviceStopTime	R2		SA	/ClinicalDocument/documentationOf/ serviceEvent/effectiveTime/high/ @value
sourcePatientId	R		DS	
sourcePatientInfo	R		DS	
Title	O		SA	/ClinicalDocument/title
typeCode	R		SA	/ClinicalDocument/code/@code
typeCodeDisplay Name	R		SA	/ClinicalDocument/code/@displayName
uniqueId	R	6.1.2.12	SAT	$docID <= /ClinicalDocument/id

6.1.2 Extended Discussion of XDSDocumentEntry Metadata

6.1.2.1 authorSpecialty

This metadata element should be based on a detailed defined classification system for healthcare providers such as those found in SNOMED-CT, or the HIPPA Healthcare Provider Taxonomy.

6.1.2.2 authorPerson, legalAuthenticator and intendedRecipient

The author, legal authenticator or intendedRecipient can be formatted using the following XPath expression, where $person in the expression below represents /ClinicalDocument/author, /ClinicalDocument/legalAuthenticator or /ClinicalDocument/intendedRecipient respectively.

```
concat(
$person/id/@extension,"^",
$person/assignedPerson/name/family,"^",
$person/assignedPerson/name/given,"^",
$person/assignedPerson/name/middle,"^",
$person/assignedPerson/name/suffix,"^",
$person/assignedPerson/name/prefix,"^",
$person/assignedPerson/name/degree,"^^&",
$person/id/@root,"&ISO"
)
```

6.1.2.3 classCode

Derived from a mapping of /ClinicalDocument/code/@code to an Affinity Domain specified coded value to use and coding system.

Affinity Domains are encouraged to use the appropriate value for Type of Service, based on the LOINC Type of Service [see Page 53 of the LOINC User's Manual].

6.1.2.4 classCodeDisplayName

DisplayName of the classCode derived.Derived from a mapping of /ClinicalDocument/code/@code to the appropriate Display Name based on the Type of Service.

6.1.2.5 ConfidentialityCode

Derived from a mapping of `/ClinicalDocument/confidentialityCode/@code` to an Affinity Domain specified coded value and coding system.

6.1.2.6 EventCodeList and eventCodeDisplayNameList

These values express a collection of keywords that may be relevant to the consumer of the documents in the registry. Public comment is sought on what value sets would be of use.

6.1.2.7 formatCode

The format code shall be the OID associated with the template identifier used to identify the content module that the document conforms to. See PCC TF-2:7.1.2 for a list of values that can be used as format codes.

6.1.2.8 healthcareFacilityTypeCode and healthcareFacilityTypeCodeDisplayName

A fixed value assigned to the Document Source and configured form a set of Affinity Domain defined values.

6.1.2.9 parentDocumentId and uniqueId

The parentDocumentId and/or uniqueId can be formatted using the following XPath expression, where $docID in the expression below represents the appropriate identifier.

concat($docID/@root,"^", $docID/@extension)

6.1.2.10 patientId

The patientId can be formatted using the following XPath expression, where $patID in the expression below represents the appropriate identifier.

concat($patID/@extension,"^^^&", $patID/@root, "&ISO")

6.1.2.11 practiceSettingCode and practiceSettingCodeDisplayName

These elements should be based on a coarse classification system for the class of specialty practice. Recommend the use of the classification system for Practice Setting, such as that described by the Subject Matter Domain in LOINC.

6.1.2.12 uniqueId

concat($docID/@root,"^", $docID/@extension)

6.1.3 XDSSubmissionSet Metadata

XDSSubmissionSet attribute	Optional?	Constrained?	Extended Discussion ?	Source Type	Source/ Value
authorDepartment	R2		Yes	CAD	See 1.4.1.2.1
authorInstitution	R2			SA	/ClinicalDocument/author/assign /representedOrganization/name

authorPerson	O	R2	Yes	SAT	$person <= /ClinicalDocument/au See 1.4.1.2.2
comments	R2		Yes		string(//section[@code='42349-1 This is the reason for referral present.
contentTypeCode	R			CAD	
contentTypeCode DisplayName	R			CAD	
patientId	R		Yes	SAT	$patID <= /ClinicalDocument/recordTarget /patientRole/id See 1.4.1.2.6
sourceId	R			DS	
submissionTime	R			DS	
uniqueId	R				

6.1.4 Use of XDS Submission Set

This content format uses the XDS Submission Set to create a package of information to send from the source to the receiver. The submission set shall contain a single .

6.1.5 Use of XDS Folders

No specific requirements identified.

6.1.6 Configuration

This Medical Summary Content Profile requires that Content Creators and Content Consumers using these documents be configured with institution and other specific attributes or parameters. Implementers should be aware of these requirements to make such attributes easily configurable.

7 IHE Content Modules

This section provides a number of modules used to describe the content of a payload found in an IHE transaction. It specifies the standards used, and the constraints on those standards. Content modules are transaction neutral. They do not have dependencies upon the transaction that they appear in. Those dependencies are specified in the Bindings listed above.

The implementation of the document content modules specified in this section requires an understanding of the transactions and the integration profiles they support. These Content Modules provide the clinical information content for documents that are shared using ITI transactions specified by the XDS, XDM and XDR Integration Profiles. See ITI TF-1 and ITI TF-2 for more details on these profiles.

7.1 Namespaces and Vocabularies

This section lists the namespaces and identifiers defined or referenced by the IHE PCC Technical Framework, and the vocabularies defined or referenced herein.

7.1.1 Namespaces for Vocabularies used in this Document

The following vocabularies are referenced in this document. An extensive list of registered vocabularies can be found at http://hl7.amg-hq.net/oid/frames.cfm.

codeSystem	codeSystemName	Description
1.3.6.1.4.1.19376.1.5.3.1	IHE PCC Template Identifiers	See section 7.1.2 below.
1.3.6.1.4.1.19376.1.5.3.2	IHEActCode	See section 7.1.3 below.
2.16.840.1.113883.5.112	RouteOfAdministration	See the HL7 RouteOfAdministration Vocabulary
2.16.840.1.113883.5.1063	SeverityObservation	See the HL7 SeverityObservation Vocabulary
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.103	ICD-9CM (diagnosis codes)2	International Classification of Diseases, Clinical Modifiers, Version 9
2.16.840.1.113883.6.104	ICD-9CM (procedure codes)	International Classification of Diseases, Clinical Modifiers, Version 9
2.16.840.1.113883.6.26	MEDCIN	A classification system from MEDICOMP Systems.
2.16.840.1.113883.6.88	RxNorm	RxNorm
2.16.840.1.113883.6.63	FDDC	First DataBank Drug Codes
2.16.840.1.113883.6.12	C43	Current Procedure Terminology 4 (CPT-4) codes.

Table 7.1-1 Vocabularies Used

[2] The ICD-9CM codes were split into the diagnosis and procedure subsets by the HL7 Vocabulary TC in January of 2004

[3] This value is the requested symbolic name for CPT-4 as it was registered with HL7.

7.1.2 IHE PCC Template Identifiers

This document defines the template identifiers shown in the table below. The root namespace (OID) for these identifiers is 1.3.6.1.4.1.19376.1.5.3.1.

Template Identifier	Description	Reference
1.3.6.1.4.1.19376.1.5.3.1.1	CDA Document Template Identifiers	7.4
1.3.6.1.4.1.19376.1.5.3.1.1.1	Medical Document Template	7.4.1.1
1.3.6.1.4.1.19376.1.5.3.1.1.2	Medical Summary Template Identifier and XDS-MS formatCode	7.4.1.2
1.3.6.1.4.1.19376.1.5.3.1.1.3	Referral Summary Template	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.1.4	Discharge Summary Template	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.2	CDA Header Template Identifiers	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3	CDA Section Template Identifiers	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.1	Reason for Referral	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.2	Reason for Referral (Structured)	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.3	Hospital Admission Diagnosis	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.4	History of Present Illness	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.5	Hospital Course	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.6	Active Problems	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.7	Discharge Problems	**Error!**

		Reference source not found.
1.3.6.1.4.1.19376.1.5.3.1.3.8	Resolved Problems	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.9	History of Outpatient Visits	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.10	History of Inpatient Admissions	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.11	List of Surgeries	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.12	List of Surgeries (structured)	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.13	Allergies and Other Adverse Reactions	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.14	Family Medical History	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.15	Family Medical History (structured)	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.16	Social History	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.17	Functional Status	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.18	Review of Systems	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.19	Medications	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.20	Admission Medication History	**Error!**

		Reference source not found.
1.3.6.1.4.1.19376.1.5.3.1.3.21	Hospital Medications	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.22	Hospital Discharge Medications	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.23	Immunizations	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.24	Physical Exam	**Error! Reference source not found.**

1.3.6.1.4.1.19376.1.5.3.1.3.25	Vital Signs	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.26	Hospital Discharge Physical Exam	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.27	Results	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.28	Results (structured)	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.29	Hospital Studies Summary	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.30	Hospital Studies Summary (structured)	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.31	Care Plan	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.32	Discharge Disposition	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.33	Discharge Diet	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.34	Advance Directives	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.3.35	Advance Directives (structured Reference)	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4	CDA Entry Template Identifiers	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.1	The template identifier used to identify a severity observation.	**Error! Reference source not found.**

1.3.6.1.4.1.19376.1.5.3.1.4.1.1	The template identifier used to identify a clinical status observation.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.1.2	The template identifier used to identify a health status observation.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.2	The template identifier used to identify a comment on an observation.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.3	The template identifier used to identify instructions in medication order.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.4	The template identifier used to identify references to external documents.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.5.1	The template identifier used to identify observation elements that indicate a concern.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.5.2	The template identifier used to identify observation elements that indicate a problem of concern.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.5.3	The template identifier used to identify observation elements that indicate an allergy or adverse reaction of concern.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.5	The template identifier used to identify observation elements that describe patient problem.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.6	The template identifier used to identify observation elements that describe patient allergy or adverse reaction.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.6.1	The template identifier used to identify observation elements that describe manifestations of an allergy; the symptom, sign, or diagnosis observation, e.g. rash, weal (hive), or urticaria.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.7	The template identifier for a <substanceAdministration> event that records medication administration events or requests. This is the root template for all medications.	**Error! Reference source not**

		found.
1.3.6.1.4.1.19376.1.5.3.1.4.7.1	This template identifier identifies medications that do not require complex processing for dose (e.g., split, tapered, conditional dosing or combination medications).	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.8	The template identifier for a <substanceAdministration> event that records tapered dose information in subordinate <substanceAdministration> events.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.9	The template identifier for a <substanceAdministration> event that records split dose information in subordinate <substanceAdministration> events.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.10	The template identifier for a <substanceAdministration> event that records conditional dose information in subordinate <substanceAdministration> events.	**Error! Reference source not found.**
1.3.6.1.4.1.19376.1.5.3.1.4.11	The template identifier for a <substanceAdministration> event that records combination medication component information in subordinate <substanceAdministration> events.	**Error! Reference source not found.**

Table 5.1-2 IHE PCC Template Identifiers

7.1.3 IHEActCode Vocabulary 1.3.6.1.4.1.19376.1.5.3.2

CCD ASTM/HL7 Continuity of Care Document

CCR ASTM CCR Implementation Guide

The IHEActCode vocabulary is a small vocabulary of clinical acts that are not presently supported by the HL7 ActCode vocabulary. The root namespace (OID) for this vocabulary is 1.3.5.1.4.1.19376.1.5.3.2. These vocabulary terms are based on the vocabulary and concepts used in the CCR and CCD standards listed above.

Code	Description
COMMENT	This is the act of commenting on another act.
INSTRUCT	This is the act of providing instructions regarding the use of medication.
PROBLEM	This is the undifferentiated process of establishing a symptom, finding, or diagnosis.
SX	This is the act of recording observations about the patient made by the patient or other persons.
COMPLAINT	This is the act of recording the concern of the patient.
FX	This is the act of examining the patient to find something out, "a finding".
CLINSTATUS	This is a specific finding about the clinical status of a problem, allergy or medication.
HLTHSTATUS	This is a specific finding of patient health status.
DX	This is the act of diagnosing an abnormality or illness, and is exactly equivalent to the HL7 ActCode vocabulary term of the same name.

FUNCLIMIT	This is the diagnosis of a functional limitation.

Table 5.1-3 IHEActCode Vocabulary

7.2 Conventions

Various tables used in this section will further constrain the content. Within this volume, the follow conventions are used.

R = Required Data Element

A "Required" data element is one that shall always be provided. If there is information available, the data element must be present. If there is no information available, or it cannot be transmitted, the data element must contain a value indicating the reason for omission of the data. (See PCC TF-2: 5.3.4.2 for a list of appropriate statements).

R2 = Required Section if data present.

A "Required if data present" data element is one that shall be provided when a value exists. If the information cannot be transmitted, the data element shall contain a value indicating the reason for omission of the data

If no such information is available to the creator or if such information is not available in a well identified manner (e.g. buried in a free form narrative that contains additional information relevant to other sections) or if the creator requires that information be absent, the R2 section shall be entirely absent. (See section PCC TF-2: 5.3.4.2 for a list of appropriate statements).

O = Optional section.

An optional data element is one that may be provided, irrespective of whether the information is available or not. If the implementation elects to support this optional section, then its support shall meet the requirement set forth for the "Required if data present" or R2.

Note: The definitions of R, R2, and O differ slightly from other IHE profiles. This is due in part to the fact that local regulations and policies may in fact prohibit the transmission of certain information, and that a human decision to transmit the information may be required in many cases.

7.3 Folder Modules

This section contains modules that describe the content requirements of XDS Folders. At present, the IHE PCC Technical Framework has not defined any Folder Modules.

7.4 CDA Release 2.0 Content Modules

This section contains content modules based upon the HL7 CDA Release 2.0 Standard, and related standards and/or implementation guides.

7.4.1 CDA Document Content Modules

7.4.1.1 Medical Documents 1.3.6.1.4.1.19376.1.5.3.1.1.1

This section defines the base set of constraints used by almost all medical document profiles described the PCC Technical Framework.

7.4.1.1.1 Standards

CDAR2 Clinical Document Architecture, Release 2.0, 2005, HL7

CRS Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm), 2006, HL7.

7.4.1.1.2 Document Specification

The constraints for encoding of the CDA Header (Level 1), and codes for sections within the section body follow all Level 1 constraints found in the HL7 Care Record Summary Implementation Guide, with the exception that the constraints on the type of document and its narrative content are not adopted by this content profile[4].

7.4.1.1.2.1 Style sheets

Document sources should provide an XML style sheet to render the content of the Medical Summary document. The output of this style sheet shall be an XHTML Basic (see http://www.w3.org/TR/xhtml-basic/) document that renders the clinical content of a Medical Summary Document as closely as possible as the sending provider viewed the completed document. When a style sheet is provided a processing instruction including a link to the URL for the XML style sheet must be included in the document, and the style sheet must be available to all receivers. Within an XDS Affinity domain this shall be via an HTTP or HTTPS GET. When using XDM or XDR to exchange documents, the stylesheet must also be exchanged. The style sheet should not rely on graphic or other media resources. If graphics other media resources are used, these shall be accessible in the same way. The content creator need not be the provider of the resources.

When a Content Creator provides a style sheet, Content Consumers must provide a mechanism to render the document with that style sheet. Content Consumers may view the document with their own style sheet.

7.4.1.1.2.2 Distinctions of None

Information that is sent must clearly identify distinctions between

- None
  It is known with complete confidence that there are none. Used in the context of problem

[4] Level 1 constraint on the CRS document type and content are specific to summary documents, and would not be applicable to other kinds of documents (such as an H&P or Operative Note).

and medication lists, this indicates that the sender knows that there is no relevant information that can be sent.[5]

- None Known
  None are known at this time, but it is not known with complete confidence than none exist. Used in the context of allergy lists, where essentially, it is impossible to prove the negative that no allergies exist, it is only possible to assert that none have been found to date.
- None Known Did Ask (NKDA)
  None are known at this time, and it is not known with complete confidence than none exist, but the information was requested. Also used in the context of allergy lists, where essentially, it is impossible to prove the negative that no allergies exist, it is only possible to assert that none have been found to date.
- Unknown
  The information is not known, or is otherwise unavailable.

In the context of CDA, sections that are required to be present but have no information should use one of the above phrases where appropriate.

7.4.1.2 Medical Summary Content 1.3.6.1.4.1.19376.1.5.3.1.1.2

7.4.1.2.1 Standards

CDAR2 Clinical Document Architecture, Release 2.0, 2005, HL7

CRS Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm), 2006, HL7.

CCD ASTM/HL7 Continuity of Care Document (Draft)

7.4.1.2.2 Document Specification

A medical summary is a type of medical document, and incorporates the constraints defined for medical documents found in section 7.4.1.1 Medical Documents above.

The medical summary further constrains CDA Release 2.0 by adopting all Level 1 and Level 2 constraints of the HL7 Care Record Summary.

[5] There may in fact be relevant information, but local regulation may prohibit disclosure.

