Integrating the Healthcare Enterprise

IHE Patient Care Coordination (PCC) Technical Framework Supplement 2008-2009

Care Management (CM)

Draft for Trial Implementation

August 22, 2008

Forward

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

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

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

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

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

This IHE Patient Care Coordination (PCC) Technical Framework Supplement is issued for Trial Implementation through May 2009.

Comments and change proposals arising from Trial Implementation may be submitted to http://forums.rsna.org under the forum:

"Integrating the Healthcare Enterprise"

Select the sub-forum:

"IHE Patient Care Coordination 2008 Supplements for Trial Implementation"

The IHE IT Infrastructure Technical Committee will address these comments resulting from implementation, Connectathon testing, and demonstrations. Final text is expected to be published in June 2009, dependent upon results of IHE validation process.

Table of Contents

Content of the Technical Framework

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

Volume 1 - Overview

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

Volume 2 – Transactions and Content Profiles

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

How to Contact Us

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

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1.1 Preface to Volume 1 of the PCC Technical Framework

1.1.1 Intended Audience

The intended audience of this document is:

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

1.1.2 Related Information for the Reader

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

- Volume 1 of the Cross-Enterprise Document Sharing (XDS) Integration Profile documented in the ITI Infrastructure Technical Framework
- Volume 1 of the Notification of Document Availability (NAV) Integration Profile documented in the ITI Infrastructure Technical Framework
- Volume 1 of the Audit Trail and Node Authentication (ATNA) Integration Profile documented in the ITI Infrastructure Technical Framework http://www.ihe.net/Technical_Framework/index.cfm)
- HL7 Clinical Document Architecture Release 2: Section 1, CDA Overview.
- Care Record Summary – Implementation Guide for CDA Release 2 (US Realm): Section 1
- Presentations from IHE Workshop: Effective Integration of the Enterprise and the Health System - June 28–29, 2005: http://www.ihe.net/Participation/workshop_2005.cfm, June 2005
- Leveraging IHE to Build RHIO Interoperability
- Cross-Enterprise Document Sharing (XDS)
- Notification of Document Availability (NAV)
- Patient Care Coordination
- Use Cases for Medical Summaries
- Patient Care Coordination - Overview of Profiles

1.1.3 How this Volume is Organized

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

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

1.1.4 Conventions Used in this Document

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

1.1.4.1 Technical Framework Cross-references

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

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

where:

<domain designator>

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

<volume number>

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

<section number>

is the applicable section number.

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

1.1.4.2 IHE Actor and Transaction Diagrams and Tables

Each integration profile is a representation of a real-world capability that is supported by a set of actors that interact through transactions. Actors are information systems or components of information systems that produce, manage, or act on categories of information required by operational activities in the enterprise. Transactions are interactions between actors that communicate the required information through standards-based messages. The diagrams and tables of actors and transactions in subsequent sections indicate which transactions each actor in a given profile must support.

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

In some cases, a profile is dependent on a prerequisite profile in order to function properly and be useful. For example, Cross-Enterprise Sharing of Medical Summaries depends on Audit Trail and Node Authentication (ATNA). These dependencies can be found by locating the desired profile in the dependencies section of this document to determine which profile(s) are listed as prerequisites. An actor must implement all required transactions in the prerequisite profiles in addition to those in the desired profile.

1.1.4.3 Process Flow Diagrams

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

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

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

1.1.5 Copyright Permissions

IHE has been very fortunate in having the American College of Obstetricians and Gynecologists (ACOG) help us in the definition of the data found in the Antepartum Summary Profile (APS).

The Antepartum Summary Profile (APS) describes the content structures and specifications the American College of Obstetricians and Gynecologists (ACOG) views are necessary in an antepartum record. ACOG encourages the use of the content structures contained in the Antepartum Summary Profile of the Patient Care Coordination Technical Framework. ACOG does not endorse any EMR products. Companies or individuals that use these content structures in EMR product or service are prohibited from using ACOG's name and/or its logo on any promotional material, packaging, advertisement, website or in any other context related to the EMR product or service.

permission to do so from the copyright holders. More information is available from http://www.bradenscale.com/

2 Introduction

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

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

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

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

2.1 Relationship to Standards

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

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

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

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

2.2 Relationship to Product Implementations

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

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

2.3 Framework Development and Maintenance

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

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

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

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

2.4 About the Patient Care Coordination Integration Profiles

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

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

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

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

transaction in which they are used, whereas content bindings explain how the payload influences the transaction metadata.

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

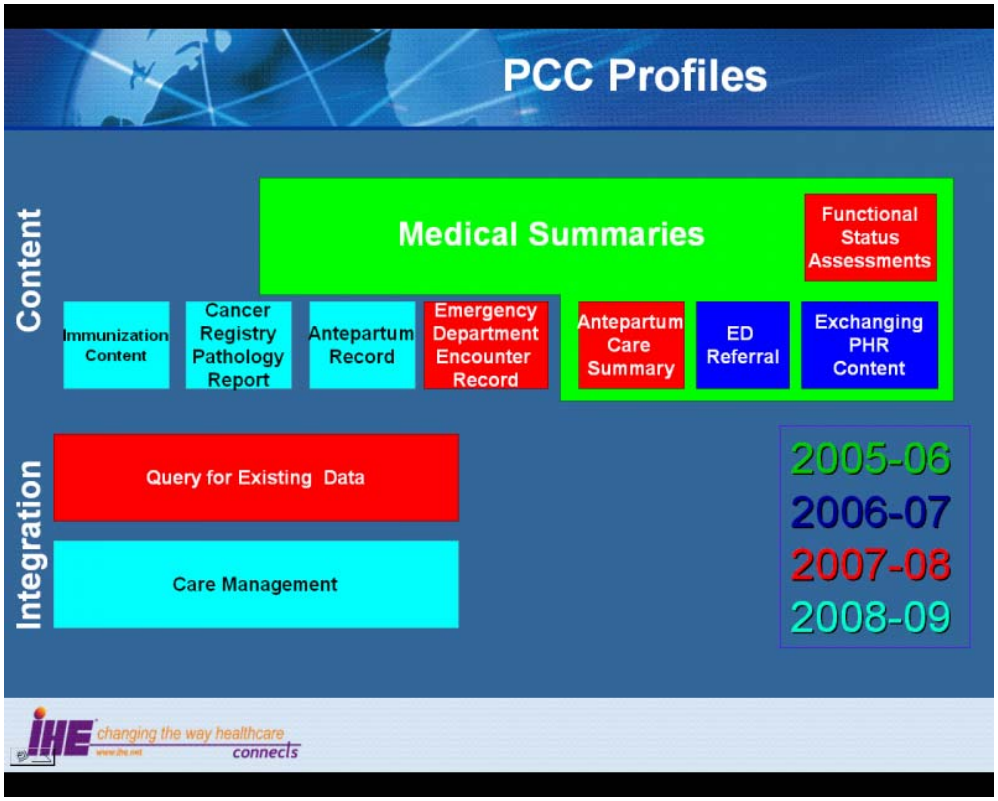

Figure 2.4-1 IHE Patient Care Coordination Content Integration Profiles

2.5 Dependencies of the PCC Integration Profiles

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

Integration Profile	Depends on	Dependency Type	Purpose
All PCC Content Profiles	*Audit Trail and Node Authentication (ATNA)*	Each Content Creator and Content Consumer actor shall be grouped with the ATNA Secured Node Actor	Required to manage audit trail of exported PHI, node authentication, and transport encryption.
	Consistent Time (CT)	Each Content Creator and Content Consumer actor shall be grouped with the Time Client Actor	Required to manage and resolve conflicts in multiple updates.
Functional Status Assessments (FSA)	*Cross Enterprise Document Exchange of Medical Summaries (XDS-MS)* OR *Exchange of Personal Health Record Content (XPHR)* OR *Emergency Department Referral (EDR)*	Content Consumers implementing the Functional Status Assessments profile shall be grouped with either the XDS-MS, XPHR or EDR Content Consumer. Content Creators implementing the Functional Status Assessments profile shall be grouped with either the XDS-MS, XPHR or EDR Content Creator.	Ensures that the Functional Status Assessment is communicated as part of an exchange of medical summary information.
Functional Status Assessments (QED)	*Audit Trail and Node Authentication (ATNA)*	Each actor in this profile shall be grouped with the ATNA Secure Node or Secure Application actor.	Required to manage audit trail of exported PHI, node authentication, and transport encryption.
	Consistent Time (CT)	Each actor in this profile shall be grouped with the Time Client Actor	Required to manage and resolve conflicts in multiple updates.

Table 2.5-1 PCC Profile Dependencies

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

2.6 PCC Integration Profiles Overview

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

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

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

The content of the transactions are presented as Content Integration Profiles. These are specification of the content to be exchange, along with explanations (called bindings) of how the content affects the transactions in which it is exchanged. It is expected that Content Integration Profiles will be used environments where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

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

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

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

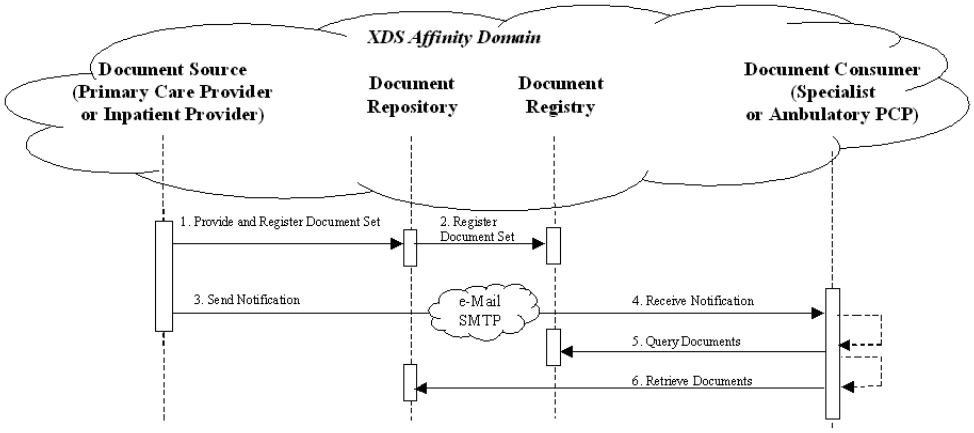

Figure 2.6-1 Use Case Process Flow Diagram

These steps are:

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

2.6.1 Unplanned Access to past Content

In many cases, a provider may need to assess information from the patient care history, and patients may have content in the XDS repository from prior visits to other providers. For example, Medical Summaries, as well as other documents such as laboratory and radiology reports are critical for emergency physicians and nurses to provide the best care

to patient in acute conditions. The figure below shows the transactions required for this use case, again, using XDS. Other process flows are possible using XDM and/or XDR.

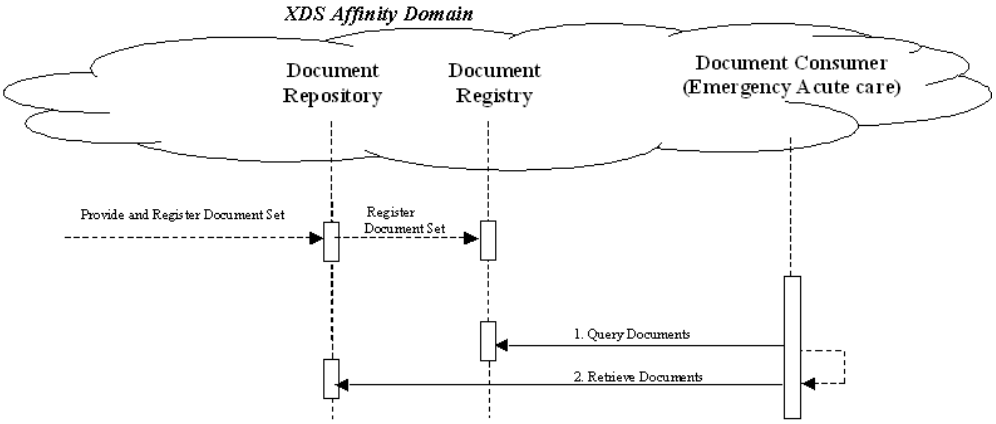

Figure 2.6-2 Unplanned Access Process Flow Diagram

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

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

2.7 History of Annual Changes

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

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

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

- **Exchange of Personal Health Record Content (XPHR) –** provides a standards-based specification for managing the interchange of documents between a Personal Health Record used by a patient and systems used by

other healthcare providers to enable better interoperability between these systems.

- **Basic Patient Privacy Consents (BPPC) –** enables XDS Affinity Domains to be more flexible in the privacy policies that they support, by providing mechanisms to record patient privacy consents, enforce these consents, and create Affinity Domain defined consent vocabularies that identify information sharing policies.
  Please Note: This profile was transferred to the ITI Domain in the Fall of 2007, and can be found here *http://www.ihe.net/Technical_Framework/index.cfm#IT*
- **Pre-procedure History and Physical Content Profile (PPHP) –** supports the exchange of information allowing for the assessment and amelioration of risks related to a procedure. *Please Note: This profile has been withdrawn.*
- **Emergency Department Referral Profile (EDR) –** provides a means to communicate medical summary data from an EHR System to an EDIS System.

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

- **Antepartum Care Summary (APS) -** describes the content and format of summary documents used during Antepartum care.
- **Emergency Department Encounter Summary (EDES) -** describes the content and format of records created during an emergency department visit.
- **Functional Status Assessment Profile (FSA) -** supports the handoff of assessment information between practitioners during transfers of care by defining the Functional Status Assessment option on the XDS-MS and XPHR profiles.
- **Query for Existing Data (QED) -** allows information systems to query data repositories for clinical information on vital signs, problems, medications, immunizations, and diagnostic results.
- **Public Health Laboratory Report (PHLAB) -** extends the XD*-LAB profile to support reporting from public health laboratories for disease surveillance activities. [Please Note: This profile has been subsequently moved to the XD-LAB specification, and van be found here http://www.ihe.net/Technical_Framework/index.cfm#LAB]

In addition, all content within the technical framework was revised in the 2007-2008 cycle to encourage compatibility with the ASTM/HL7 Continuity of Care Document Implementation Guide.

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

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

- **Immunization Content (IC) -** describes the content and format of summary documents used during Antepartum care.
- **Cancer Registry Pathology Report (CPR) -** describes the content and format of summary documents used during Antepartum care.

2.8 Product Implementations

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

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

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

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

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

When multiple actors are grouped in a single product implementation, all transactions originating or terminating with each of the supported actors shall be supported (i.e., the IHE transactions shall be offered on an external product interface). The following examples describe which actors typical systems might be expected to support. This is not intended to be a requirement, but rather to provide illustrative examples.

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

2.9 Profile Abstract

The Care Management Profile (CM) provides a mechanism for EHR and other HIT systems to communicate information to Care Management systems in support of specialized care programs through the use of evidence based guidelines.

2.10 Issue Log

2.10.1 Open Issues

1. In the case of HL7 V2 transactions, how does one indicate where the response goes, since it is not a normal HL7 V3 response?
2. How well does Volume I explain the concept of the guideline based care orientation of this profile? Is there more it could do?
3. Should the the guideline or parts of it be folded into the TF as individual "content" components referenced by the transaction, or kept in-line in the transaction as is done now?
4. How does the Clinical Data Source check for consent to share data as part of its responsibilities? How is this reflected in the actor groupings in Volume I, and in the transaction details in volume II.
5. We will need an example or two for PCC-7. I propose developing one using SNOMED, LOINC, RxNORM, and CPT codes to show how a diabetes chronic disease implementation would work, using an international guideline. Are there others more appropriate that would have "more" impact?

2.10.2 Closed Issues

6. Is PCC-9 really a "query" transaction with a delayed response, or a notification transaction? The former has the advantage that it has an actor to respond to built in, whereas the latter does not. In the latter case, how would one indicate where to send the response to?
    - PCC-9 uses the HL7 V3 Query transactions.

Add the following bullet to the list of profiles

- Care Management - The Care Management Profile provides a mechanism for EHR and other HIT systems to communicate information to Care Management systems in support of specialized care programs through the use of evidence based guidelines.

2.11 Dependencies

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

Integration Profile	Dependency	Dependency Type	Purpose
Care Management	CT	Implementors of the Care Management profile must implement the Time Client Actor of the CT profile.	Ensures that messages sent to the Care Management use consistent time reporting.
Care Management	ATNA	Implementors of the Care Management profile must implement the Secure Node or Secure Application actor of the ATNA profile.	Ensures that transmissions and changes to patient health information are logged in an audit repository, and that communication is secured between nodes.

2.12 Overview

The Care Management Profile (CM) supports the exchange of information between HIT systems and applications used to manage care for specific conditions. More and more, special purpose care management systems are used to support wellness programs, public health monitoring, tracking of immunizations and infectious diseases, and to manage the care of patients with chronic diseases such as diabetes and cancer. Care management systems collect data used to manage care, provide decision support, communicate with patients and providers, and supply other tools to assist in the delivery of care. The successful management of care resulting from the use of these technologies results in improved patient outcomes, reducing the overall cost of care provided to patients. Examples of these systems include Chronic Disease Management Systems, Cancer and other Disease Registries and Immunization Information Systems.

These systems are often remarkably state of the art, including decision support capabilities and using evidence-based guidelines for the treatment and care of patients. Unfortunately, the data used by the care management system is often gathered by applying traditional interfacing practices with the many different information sources. Information can be provided to these systems from a number of sources, including:

- Physician Offices
- Imaging Centers
- Laboratories
- Surgery Centers
- Inpatient Settings
- Insurance Providers

In order to manage patient care using these systems, hundreds of data points are routinely monitored and gathered for a patient, covering a wide variety of clinical data. Furthermore, the data needed varies based upon the condition being managed. This data may include:

- Current and Past Medical History
- Family History and other Risk Factors (commonly called Social History)
- Medications (Current and prior)
- Allergies and Adverse Reactions
- Vital Signs and other common observations
- Laboratory and Diagnostic Study Results
- Immunizations
- Health Visits (planned and prior)
- Procedures
- Surgical History

Current practice involves the creation of ad hoc interfaces to pass this information from each health care application to the care management system. Given the large number of applications involved, conditions which can be managed in this fashion and number of data points nececssary to manage each condition, it is not practical or cost effective to design one-off interfaces for the many conditions that could benefit from the application of a care management system.

The economic impact of chronic and preventable diseases is measured in hundreds of billions of dollars worldwide. Over half of North Americans live with chronic disease and over 60% of deaths worldwide are due to a chronic disease[5]. A significant percentage of emergency department visits are the result of poor management of chronic conditions, with one study citing almost 30% of ambulatory visits being a result of preventable chronic disease[6]. In some areas, chronic disease patients account for almost 80% of healthcare costs, and over 90% of prescriptions filled.[7] Controlling chronic disease will result in a diversion of patients from costly acute care, resulting in significant savings. For example, after implementing a chronic care program, the Veterans Administration in the United States saw their per patient health care costs decrease by 25%. [7] It should be noted that this is strictly the change in health care costs, and does not include the further economic benefit of a reduction in lost productivity and wages, lower insurance rates, and other secondary benefits.

Automation of the data gathering can dramatically reduce the implementation costs for care management systems. Estimates for the cost of annual maintenance of an interface vary from $10,000 to as much as $30,000 annually. Given the numerous care settings and applications where care management data is obtained, automation of the interfacing can amount to a large cost savings. This savings can substantially increase the return on investment in implementation of care management applications, allowing them to be applied to more conditions.

Another desirable outcome from this profile is the elimination of duplicated clinical analysis in the development of each interface. Developing an interface using the current approach requires employing clinical experts to determine the proper clinical vocabularies and codes for the data elements of interest, and mapping of existing data into standard value sets and units of measure. The approach under this profile is to move that analysis away from interface development into the guideline development, where the

necessary clinical expertise already resides. The data elements of interest to a guideline need only be encoded once, and all users of it can benefit from the added value. This results in greater conformity to the guideline and reduced risk of misinterpretation.

Having established the need to easily and automatically configure health care IT systems to transmit information to these Care Management systems, we next examine how this is accomplished by the CM profile.

The main difficulty in automating the interfaces comes from the lack of standardization in the expression of the data requirements of, and the results provided to a care management system. If care management systems were able to define the data that they need rigourously, applications could interpret those requirements, and automatically send the necessary data when it changes. This does not require the application of advanced clincial decision support capabilities. Instead, what is needed is a simple mechanism for a care management system to identify the data that is of interest to it to a source of clinical data. That clinical data source can then monitor data changes occuring within its control and report the changes of interest to the care management system.

The IHE Query for Existing Data (QED) profile describes a mechanism to issue a query from a Clinical Data Consumer to a Clinical Data Source. That query uses standardized objects defined by the HL7 Care Record and HL7 Care Record Query Draft Standards for Trial Use (DSTU), using templates described in this PCC Technical Framework. Many of the PCC templates are derived from other HL7 standards and implementation guides, such as the HL7 Continuity of Care Document. These standards provide the rigour needed by the Care Management system in obtaining the results, and a selection criteria that is sufficiently rigourous to identify the data needs of the care management system.

The Care Management (CM) profile works in a very similar fashion to QED, but with a twist. The service described by the QED profile sends a query and gets a response back immediately on all data that currently matches the criteria, and then the query is discarded. The CM profile sends the same query, but the source system sends back anything new that it recieves that matches the criteria. This query is maintained indefinately and the source system continues to send anything that comes in until the requesting system cancels it. This is known in technical circles as a publish/subscribe design pattern. The care management system can reuse the same technical infrastructure[1] supported by the QED profile for sending the query critiera and matching against it.

Note	The IHE IT Infrastructure Technical Committee is currently developing a white paper on publish subscribe as it applies to the XDS infrastructure. The CM profile will be updated based upon the outcomes of that work.

Dynamic queries do not express why and how data is be used to manage care, or how to distribute it. The how and why are generally contained in guidelines for care provided by

[1] There are few differences in the WSDLs supplied in the transactions used in the CM and QED profiles. This allows for the same infrastructures to be used to process both. The HL7 schemas used with these WSDLs are identical.

medical professionals using evidence-based medicine. There are numerous examples of repositories of clinical guidelines, including those managed by professional societies, institutions, regional, national and international organizations and governments. These guideline repositories use a variety of manual and automatic mechanisms for distribution. Guidelines are distributed using a variety of formats that are little better than digital paper; they can be displayed. Updates to application behavior still require manual intervention and complex development.

Most existing evidence-based guidelines for care do not describe the data requirements in a rigorous fashion. Many sources provide evidence-based guidelines, but these guidelines often do not supply mappings to clinical vocabularies to identify the data elements of interest. For example, many guidelines for care of diabetic patients refer to patients with a "diagnoses of diabetes", but do not indicate the particular codes in a clinical vocabulary that explicitly identify this diagnosis. Does that include both diabetes type I and type II? Is gestational diabetes excluded? What other diagnoses may be of interest? The answers to many of these questions are often obvious to developers of the guidelines, but they are not often available to answer these questions when the guidelines are applied.

If guidelines included rigorous definitions, and were represented in a form that could be interpreted by an an application:

- Clinicians could more readily use up to date guidelines in their care
- Care would be provided in a more consistent fashion across institutions
- Patients would benefit from the latest and most appropriate best practices in care

This profile defines the Guideline Manager as the actor that supports the distribution of guidelines in a standard format. The standard format includes a way to represent the guideline and the rigorous definition of the data needed for its implementation.

The Guideline manager is also supported by the HL7 Care Record DSTU. This standard supplies a guideline class that provides many of the necessary features to complete the care management picture. The guideline class supports the definition of a guideline in a text format, and includes the definition of the various acts, observations, substance administrations, procedures and encounters that are of interest within the guideline.

Due to the current lack of rigourously coded guidelines, we have developed this profile so that it can be used in their absense. The care management system need not identify data items of interest from an electronically represented guideline. Instead, it may determine those data items via application configuration, which we have left unspecified. When rigourously coded guidelines become available, this profile does support their use within both the care management application, and also in the clinical data source.

Finally, we recognize that there is still a significant legacy installed base of applications which support HL7 Version 2 messaging. We have provided within this profile a means to exchange information with a care manager using HL7 Version 2 messages. Applications can be preconfigured to send information to a care manager without being triggered by a query. This is the "traditional interfacing" supported by care management systems today. In addition, there is a way to send an HL7 Version 3 query that tells the

application which HL7 Version 2 message to send. Applications can be preconfigured to support a number of HL7 Version 2 message payloads which are described in what HL7 calls a "message conformance profile". They can then be asked to use one of these preconfigured payloads through information passed into them by the HL7 Version 3 query message. In this way existing systems can be retrofitted to perform in a care management environment in a way that will simplify their integration.

2.13 Scope

A guideline based approach to Care Management can address the overall coordination of patient care as described below.

1. Specialist groups, using an evidence based approach, define a current “best practice” protocol for management of the disease, including the enrollment criteria, and all of the assessments, treatments and medications that define high quaility care.
2. Patients are identified for potential enrollment in a disease management program, either automatically through clinical decision support, or when seen by a clinician during a routine visit. The clinician may order tests to be performed to evaluate the patient for enrollment in the program. It may also be necessary to obtain the patient's consent for evaluation and participation in the program.
3. Patient demographics and clinical data, as defined by the guideline, is collected for evaluation.
4. Patients matching the guideline criteria are enrolled in a disease management program. This may be initiated by the provider, or the patient may self-enroll.
5. The care management program may include home monitoring. A care coordinator within the clinician’s office or elsewhere may assist with the home monitoring program. 6. Disease management data for the patient is gathered from health care IT systems during routine patient care. This can include data obtained by the patient using a self monitoring device.
6. The care management system monitors the information provided by the clinical data sources and recommends actions to support the care of the patient. Recommendations may include a follow-up office visit, urgent care, tests, or a discussion with the patient about following the recommended care plan (e.g. medications, diet, activity).
7. The clinician may need to modify the patient’s care plan based upon information received and evaluation of the patient.
8. Changes to care plan and patient data are fed back to the organization defining disease protocol for continuing research and refinement of protocols.

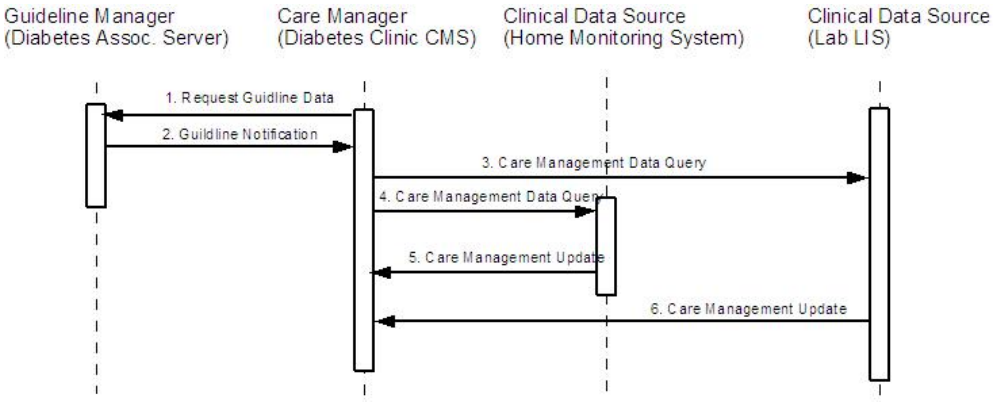

Figure 2.13-1 Figure 1. Process Flow for Guideling Notification and Care Data Query

The complete use case for Care Management is extensive and very complex. It has been necessary to limit the scope for this years development to a small subset of the desired functionality. The focus for this year is:

1. The definition and communication of the data variables needed to support guideline oriented care.
2. The exchange of this information to and from health care IT systems.
3. Association of guidelines used for care with patients needing care under those guidelines, through a query mechanism.
4. Communication of information from the patient record meeting the guideline criteria to the system used to manage the care for a specific condition or conditions
5. Support for communications using traditional HL7 Version 2 messaging, and HL7 Version 3 messages over web services.

It is hoped that future work by IHE Patient Care Coordination will expand this functionality to provide further transactions covering:

6. Use of decision support to locate patients that qualify for care management programs.
7. Administrative activities involving the enrollment of patients in care management programs.
8. Use of decision support to activate workflow in care management programs and support clinical decision making.
9. Communication of guidelines in electronic format to support clinical decision support.
10. Use of aggregated data collected by the care management programs to inform the revision of care guidelines.

The present level of support for guideline definition in this profile is sufficient to identify the variables needed for decision support to the care management system and its sources of clinical data, but is not intended to convey the complete guideline definition.

IHE Patient Care Coordination will continue to work with relevant standards organizations with respect to the development of appropriate standards in the areas of guideline definition and clinical decision support to enable these future activities.

Diabetes Patient Care Management Example

The story begins when Mabel Jones visits her Primary Care Practitioner (PCP) , Dr. Martin, and is diagnosed as having Type II Diabetes mellitus. He counsels her about lifestyle changes, and refers her to the diabetes clinic in the local hospital.

A week later, Mabel is seen at the diabetes clinic. The diabetes clinic that she is referred to has a Care Management System, which provides a care plan for the patient and monitors their progress, both through home monitoring and through continuing routine visits with the clinic and her PCP. The clinic has a working relationship with a National Diabetes Association, which publishes updated treatment guidelines twice yearly, and makes them available electronically, ensuring that their subscribers are always providing care in accordance with the latest recommendations. (Step 1 and 2 in Figure 1. above)

She is assessed by an internist and meets with a registered nurse, dietician and pharmacist, who enroll her in their program, and a care plan is created for her, using the association's guidelines, which specifies all of the medical tests, medications and recommended follow-up appointments recommended for care of her condition. Her care plan includes blood glucose measurements four times daily, as well as a regimen of oral drugs, so Mabel is supplied with a home monitoring system with a blood glucose monitor, and a prescription for glipizide. When her enrollment is completed, a query for relevant results is sent from the Care Management System to the EMR at her PCPs office, the HIS at the hospital, and the LIS at the local lab, and her home monitoring system. (Step 3 and 4 in Figure 1. above)

Six months pass and Mabel is fairly compliant with her diabetes management. Mabel checks her sugars daily and puts the results in her home monitoring system. She has purchased additional equipment and is now able to do the same for her blood pressure and weight. These measurements, as well as the results from the followup appointments she has had with her PCP, have been sent to the Care Management System (Step 5 in Figure 1. above), which has been monitoring her status. The Care Management Systems clinical decision support software initially detected the fact that her blood glucose levels were not being optimally controlled and suggested adjustments to her medications, which were accepted by the specialist and Mabel’s prescription changed. Soon her measurements were within the acceptable range.

At her next appointment with her PCP, Mabel’s standard physical exam reveals that she is pregnant. The results of this test are also sent to the Care Management System (Step 6 in Figure 1. above) and the clinical decision support rules indicate the need for an appointment with a perinatologist and an opthamologist, a change in medication from oral to insulin injections, and bi-weekly urine ketone tests, which she arranges to have done at her local lab. The Care Management System sends out an updated query, requesting the results of these tests. The test results are returned to the Care Management System as they are completed and, with continual monitoring keeping her diabetes under control, Mabel has an uneventful and healthy pregnancy.

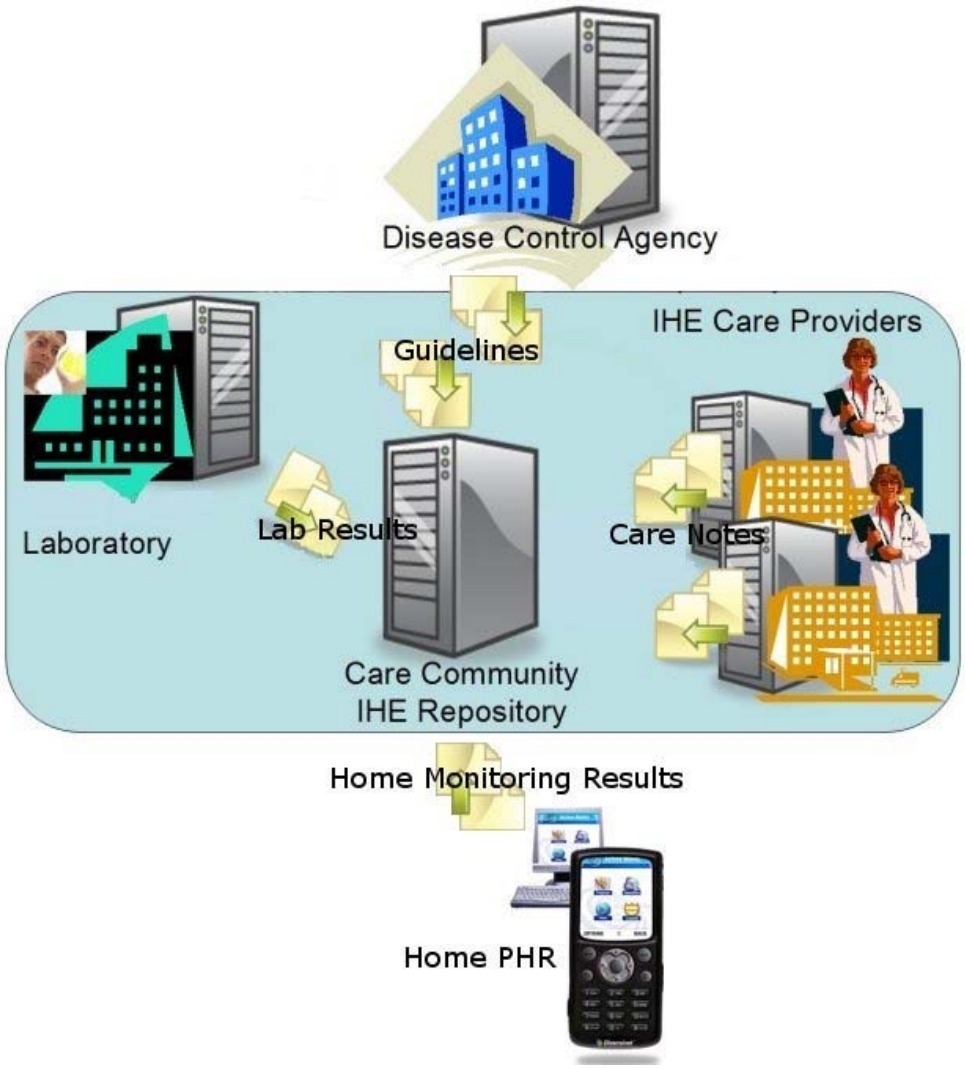

Figure 2.13-2 Figure 2. Care Management Architecture Overview

890 Several existing IHE Profiles support the communication of information collected and produced by a care management system. Rather than reproduce these actors and transactions in this profile, we have simply referenced the uses of these profiles in the Grouping section below.

2.14 Use Cases

In the uses cases below, we describe the before and after effects of implementing the Care Management profile.

2.14.1 Before Care Management

Preconditions

A Care Management protocol is defined.

Use Case

1. Using the defined care management protocol, a set of data variables are collected in report form.
2. A Clinical Analyst reviews the data variables with the protocol designers, to establish criteria and mappings from health care information sources.
3. An interface engineer creates appropriate interface messages and integrates them with the HIT application.
4. Patients are somehow enrolled in the program
5. When a health care application updates information from a patient, and that patient is determined to be enrolled with the appropriate care management program, one or more messages are sent to the care management system from the HIT application containing information specific to that program.

Postconditions

The Care management system is supported by **one** HIT system.
Repeat at step 2 above for the next HIT system.

When you've done one interface, you've done one interface.

2.14.2 After Care Management

Precondition

A care management protocol is defined by clinical experts.

Use Case

1. Using the defined care management guideline, a set of data variables are defined in an electronic format using established vocabularies and defined units and measures, in conjunction with clinical analysts and informatics experts. This electronic format is stored in a Guideline management system, and reported to the care management system.
2. Data variables used for care management are allocated automatically by care management systems reading the electronic specification.

3. Care management systems enable reporting for enrolled patients by issuing queries to the clinical data sources reporting the guideline being used.
4. [Option] Reporting is enabled for a patient by an "out-of-band" communication not specified in this profile.
5. Clinical Data Sources configure the outbound interfaces for reporting the data variables by locating the guideline definition, and reading the electronic specification of the data variables needed from it.
6. [Option] The Clinical Data Source is configured to handle the reporting of data using traditional interfacing methods, and uses the query to simply indicate which preconfigured interface to use.
7. When a health care application updates information from a patient, and that patient is determined to be enrolled with the appropriate care management program, one or more messages are sent to the care management system from the HIT application containing information specific to that program.

Postcondition

The care mangement system is updated with patient data from multiple clinical data sources.

Note: While enrollment is out of scope for this profile, the "enrollment" of a patient in a program can be enabled in the Clinical Data Source by reciept of the query specified in step 3 above.

2.15 Actors/Transaction

The diagram below shows the actors of the Care Management profile.

The Guideline Manager keeps track of guidelines and responds to requests for information about guidelines using PCC-8. When new guidelines are received, or existing guidelines are updated, it notifies the Care Manager actor using PCC-7.

The Care Manager is responsible for receiving notifications of new or updated guidelines using PCC-8. Upon receipt of these guidelines, it can analyze them in detail, and then, using PCC-9, issues queries to various Clinical Data Sources.

The Clinical Data Sources will then pass back information to the Care Manager, using either PCC-10 or PCC-11, enabling the Care Manager to evaluate next steps for the management of the patients' condition(s).

The Care Management profile is implemented using parallel HL7 V2 and V3 transactions. The Care Manager is required to support both sets of transactions. The Clinical Data Source may choose HL7 V2 messaging (updates only) or HL7 V3 messaging (updates and queries).

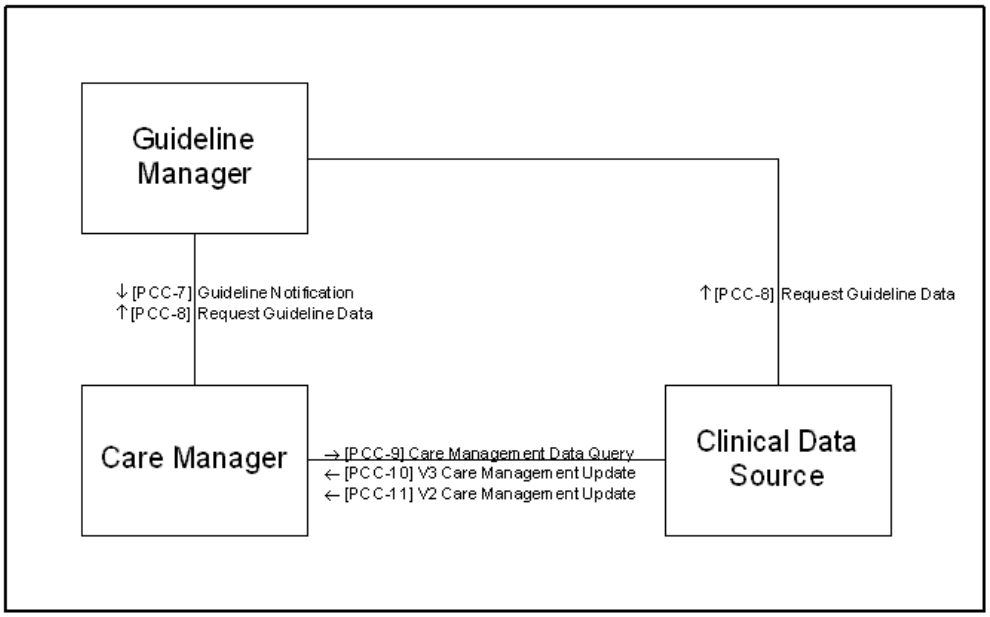

Figure 2.15-1 Care Management Actor Diagram

Actor	Transaction	Opt.	Section
Guideline Manager	Guideline Notification	R	PCC-7
	Request Guideline Data	R	PCC-8
Care Manager	Guideline Notification	O	PCC-7
	Request Guideline Data	O	PCC-8
	Care Management Data Query	R	PCC-9
	V3 Care Management Update	R	PCC-10
	V2 Care Management Update	R	PCC-11
Clinical Data Source	Request Guideline Data	O	PCC-8
	Care Management Data Query	CSee note 2	PCC-9
	V3 Care Management Update	C See note 1	PCC-10
	V2 Care Management Update	C See note 1	PCC-11

Note 1

At least one of these transactions must be supported.

965 Note 2

A Clinical Data source that implements the Care Record option shall implement this transaction.

2.16 Options

Actor	Option
Clinical Data Source	Care Record Option
	HL7 Version 2 Option
Care Manager	Guideline Management Option

970

2.16.1 Care Record Option

2.16.2 A Clinical Data Source implementing the Care Record Option shall report care activities that meet the definitions in the guideline to the Care Manager using the clinical statement templates specified in PCC-10, and must support receipt of the PCC-9 transaction. HL7 Version 2 Option

975

A Clinical Data Source implementing the HL7 Version 2 Option shall report care activities that meet the definitions in the guideline to the Care Manager using the clinical statement templates specified in PCC-11.

980

2.16.3 Guideline Management Option

A Care Manager that implements the Guideline Manager Option supports the receipt of PCC-7 transaction.

2.17 Grouping

985

2.17.1 ATNA and CT

The actors of this profile must implement the ATNA Secure Node or Secure Application Actor, and the CT Time Client Actor. Specific details on the logging requirements are given for each transaction in volume II.

2.17.2 QED

990

The Care Manager may be grouped with the Clinical Data Source actors of the QED profile to facilitate communication of care management trends or other information to PHR or EHR systems.

2.17.3 XDS

995

The Care Manager may be grouped with the Document Source actor of the XDS profile to facilitate communication of care summaries from the Care Management system to an XDS Repository, for subsequent access by a Care Provider or the patient.

The Care Manager may also be grouped with the Document Consumer actor of the XDS profile to obtain information from clinical documents of interest.

2.17.4 Analyzer / Aggregator

The the Care Manager actor may be grouped with Analyzer / Aggregator actor of the PEQD profile to support aggregation of quality reporting data to measure conformance to evidence-based guidelines.

2.17.5 BPPC

The Clinical Data Source actor may be grouped with the Content Consumer Actor of the BPPC profile to obtain information about consents to share data.

2.18 Coded Terminologies

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

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

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

2.19 Process Flow

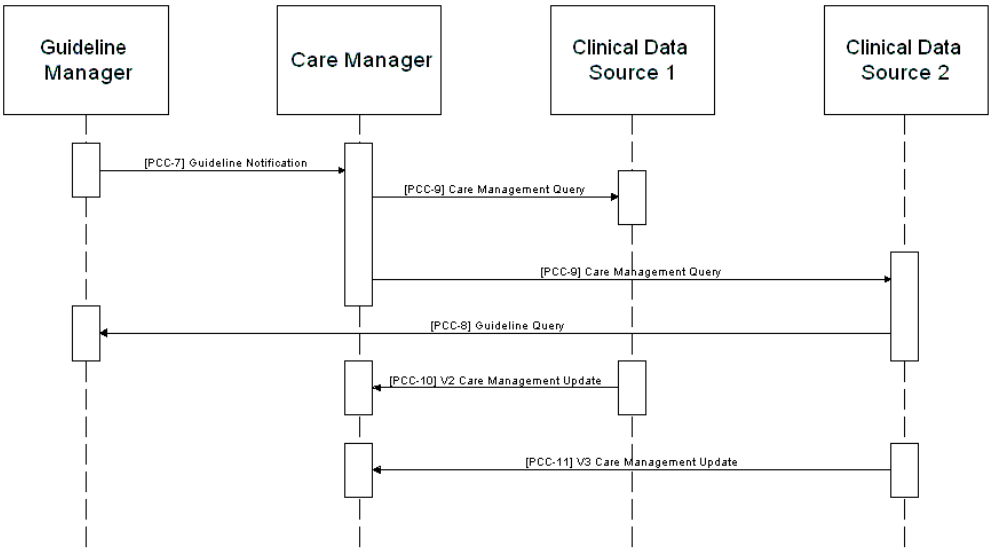

Figure 2.19-1 Care Management Process Flow

1. A guideline manager is preconfigured to notify systems that need updates to the guidelines it manages. When a guideline is defined and activated in the Guideline Manager, the set of data variables are communicated in electronic format to the Care Management System.
2. The Care Manager sends a query for the clinical data identified by the guideline to Clinical Data Source 1 and Clinical Data Source 2. The query contains a data element indicating the endpoint address to which these clinical data sources shall send their results. See the respondTo data element described in PCC TF-2:3.9.4.3.5.
3. Clinical Data Source 1 is configured out of band to respond appropriately to the query identified by the guideline manager.
4. Clinical Data Source 2 queries the Care Manager for the Guideline identified in the query, and configures itself to respond appropriately based on the data variables identified in the guideline.
5. Upon updating applicable patient data, Clinical Data Source 1 sends an HL7 Version 2 message specified by the guideline to the Care Manager.
6. Upon updating applicable patient data, Clinical Data Source 2 sends an HL7 Version 3 Care Record Update to the Care Manager, based on the configuration computed in step 4.

2.20 Configuration Considerations

2.20.1 Guideline Manager

Guideline managers must be configured to identify the Care Managers that they will notify of guideline updates.

2.20.2 Care Manager

Care Managers interpret guidelines and determine the appropriate queries to issue. Care managers are configured to send queries to specific clinical data sources. How the care manager determines what queries to issue to a clinical data source is not specified by this profile, as this may be determined clinical decision support rules or application logic that is outside the scope of this profile.

Comment [KWB1]: Page: 2
Consider moving to an appendix like ITI Affinity Domain Configuration.

2.21 Security Considerations

This profile communicates patient identifiable health information between the Clinical Data Source and Care Manager Actors. To secure this information, this profile requires the use of the IHE ATNA and CT profiles found in ITI TF-1. Consent to communicate this information may also be required according to local policies and regulations. Consents may be communicated using the BPPC profile supplement also described by ITI TF-1.

Clinical Data Source actors must log the export of patient information to, and reciept of any queries for that information from the Care Manager actors.

Care Manager actors must log the import of patient identifiable information, and sending of any queries to the Clinical Data Source actor.

Interactions between the Guideline Manager and Care Manager or Clinical Data Source Actors do not contain patient identifiable health information under this profile.

2.22 Resources and References

[1] American College of Physicians Diabetes Portal, 2000-2008, American College of Physicians

[2] Priority Areas for National Action, Transforming Healthcare Quality, 2003, Institute of Medicine

[3] Using Computerised Registries in Chronic Disease Care, February 2004, California HealthCare Foundation

[4] Global Guideline for Type 2 Diabetes, 2005, International Diabetes Federation, ISBN 2-930229-43-8

[5] Preventing Chronic Diseases: a vital investment, 2008, World Health Organization

[6] Ambulatory Medical Care Utilization Estimates for 2005, 2007, The Centers for Disease Control and Prevention

[7]Prescription for Pennsylvania: Right State, Right Plan, Right Now, 2008, Chronic Care Management, Reimbursement and Cost Reduction Commission

Actor Definitions

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

Content Creator

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

Content Consumer

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

Clinical Data Consumer

A clinical data consumer makes use of clinical patient data.

Clinical Data Source

A Clinical Data Sources maintains patient information about vital signs, problem and allergies, results from diagnostic tests (e.g., Lab, Imaging, or other test results), medications, immunizations or historical or planned visits and procedures.

Guideline Manager

The guideline manager actor is responsible for managing the guidelines used to create care plans, and for communicating those guidelines to other systems.

Care Manager

The care manager actor is responsible for supporting the management of the care of patients with respect to a specific health condition. It gathers information about the care provided and current health status of the patient. A Care Manager actor may be designed for management of a single condition, such as management of Diabetes, or may be a general purpose system supporting management of multiple conditions.

Transaction Definitions

Query Existing Data

Request information about recent patient information, used to obtain vital signs measurements, problems and allergies, diagnostic results, medications, immunizations, or procedures or visits relevant for a patient. The query may request information about some or all of the above topics, or may request information on a specific topic, or one entered for a specific encounter or date range.

Guideline Notification

The Guideline Notification transaction reports a the content of new and/or updated guidelines to interested parties. The purpose of this transaction is to alert systems that need to act on clinical guidelines of the availability of new guidelines.

Request Guideline Data

The Request Guideline Data transaction supports the capability of systems to query for the contents of an identified guideline.

Care Management Data Query

The Care Management Data Query transaction supports the capability for systems responsible for monitoring the health status and care provided to one or more patients to request that information from systems that may have it.

V3 Care Management Update

The V3 Care Management Update transaction supports the capability for systems that have information about the health status and care provided to one or more patients to share that information with external systems that need to monitor that information using profiles of HL7 V3 Care Record standard messages.

V2 Care Management Update

The Care Management Updagte transaction supports the capability for systems that have information about the health status and care provided to one or more patients to share that information with external systems that need to monitor that information using specific profiles of HL7 V2 standard messages.

A.1 How to Prepare an IHE Integration Statement

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

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

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

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

A.2 Structure and Content of an IHE Integration Statement

An IHE Integration Statement for a product shall include:

1. The Vendor Name
2. The Product Name (as used in the commercial context) to which the IHE Integration Statement applies.
3. The Product Version to which the IHE Integration Statement applies.
4. A publication date and optionally a revision designation for the IHE Integration Statement.
5. The following statement: "This product implements all transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors and Options listed below:"

6. A list of IHE Integration Profiles supported by the product and, for each Integration Profile, a list of IHE Actors supported. For each integration profile/actor combination, one or more of the options defined in the IHE Technical Framework may also be stated. Profiles, Actors and Options shall use the names defined by the IHE Technical Framework Volume I. (Note: The vendor may also elect to indicate the version number of the Technical Framework referenced for each Integration Profile.)

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

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

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

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

A.3 Format of an IHE Integration Statement

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

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

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

Volume II

1 Preface to Volume 2

1.1 Intended Audience

The intended audience of this document is:

- Technical staff of vendors planning to participate in the IHE initiative
- IT departments of healthcare institutions
- Experts involved in standards development
- Anyone interested in the technical aspects of integrating healthcare information systems

1.2 Related Information for the Reader

The reader of Volume 2 should read or be familiar with the following documents:

- Volume 1 of the Cross-Enterprise Document Sharing (XDS) Integration Profile documented in the ITI Infrastructure Technical Framework (See http://www.ihe.net/Technical_Framework/index.cfm).
- Volume 1 of the Notification of Document Availability (NAV) Integration Profile documented in the ITI Infrastructure Technical Framework (See http://www.ihe.net/Technical_Framework/index.cfm).
- Volume 1 of the Audit Trail and Node Authentication (ATNA) Integration Profile documented in the ITI Infrastructure Technical Framework (See http://www.ihe.net/Technical_Framework/index.cfm).
- HL7 Clinical Document Architecture Release 2: Section 1, CDA Overview.
- Care Record Summary – Implementation Guide for CDA Release 2 (US Realm): Section 1
- Presentations from IHE Workshop: Effective Integration of the Enterprise and the Health System - June 28–29, 2005: http://www.ihe.net/Participation/workshop_2005.cfm, June 2005:
- For a RHIO-3.ppt Leveraging IHE to Build RHIO Interoperability
- Cross-Enterprise Document Sharing (XDS)
- Notification of Document Availability (NAV)
- Educ.ppt Patient Care Coordination
- Use Cases for Medical Summaries
- Ovrw.ppt Patient Care Coordination - Overview of Profiles

1.2.1 How this Document is Organized

Section 1 is the preface, describing the intended audience, related resources, and organizations and conventions used within this document.

Section 2 provides an overview of the concepts of IHE actors and transactions used in IHE to define the functional components of a distributed healthcare environment.

Section 3 defines transactions in detail, specifying the roles for each actor, the standards employed, the information exchanged, and in some cases, implementation options for the transaction.

Section 4 defines a set of payload bindings with transactions.

Section 5 defines the content modules that may be used in transactions.

1.2.2 Conventions Used in this Volume

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.

1.2.2.1 The Generic IHE Transaction Model

Transaction descriptions are provided in section 4. In each transaction description, the actors, the roles they play, and the transactions between them are presented as use cases.

The generic IHE transaction description includes the following components:

- Scope: a brief description of the transaction.
- Use case roles: textual definitions of the actors and their roles, with a simple diagram relating them, e.g.:

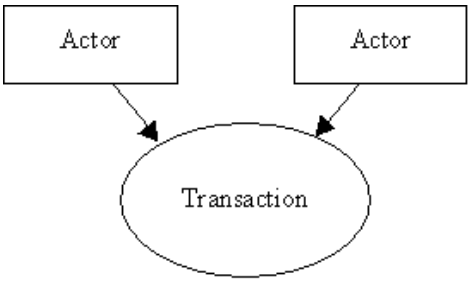

Figure 1.2-1 Use Case Role Diagram

- *Referenced Standards*: the standards (stating the specific parts, chapters or sections thereof) to be used for the transaction.
- *Interaction Diagram*: a graphical depiction of the actors and transactions, with related processing within an actor shown as a rectangle and time progressing downward, similar to:

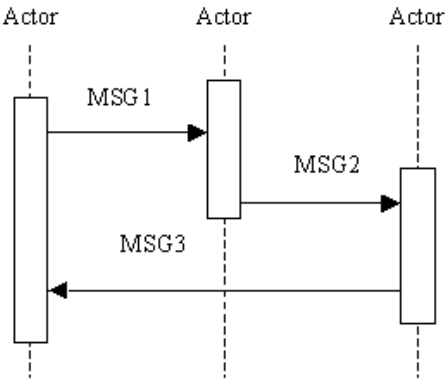

Figure 1.2-2 Interaction Diagram

The interaction diagrams used in the IHE Technical Framework are modeled after those described in Grady Booch, James Rumbaugh, and Ivar Jacobson, *The Unified Modeling Language User Guide*, ISBN 0-201-57168-4. Simple acknowledgment messages are omitted from the diagrams for brevity.

- *Message definitions*: descriptions of each message involved in the transaction, the events that trigger the message, its semantics, and the actions that the message triggers in the receiver.

1.3 Copyright Permissions

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

1.4 How to Contact Us

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

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Senior Director of Integrating the Healthcare Enterprise
230 East Ohio St., Suite 500
Chicago, IL 60611
Email: ihe@himss.org

2 Introduction

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

The IHE Patient Care Coordination Technical Framework identifies a subset of the functional components of the healthcare enterprises and health information networks, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions.

The other domains within the IHE initiative also produce Technical Frameworks within their respective areas that together form the IHE Technical Framework. Currently, the following IHE Technical Framework(s) are available:

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

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

2.1 Relationship to Standards

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

Each transaction may have as its payload one or more forms of content, as well as specific metadata describing that content within the transaction. The specification of the payload and metadata about it are the components of a Content Integration Profile. The payload is specified in a Content Module, and the impacts of any particular payload on a transaction are described within a content binding. The payloads of each transaction are also based on standards (such as HL7, IETF, ASTM, DICOM, ISO, OASIS, etc.), again, in order to meet the needs of a specific use case.

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

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

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

2.2 Relationship to Product Implementations

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

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

2.3 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.

2.3.1 Content Modules

The Patient Care Coordination Technical Framework organizes content modules categorically by the base standard. At present, the PCC 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 PCC 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 PCC 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 PCC 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 PCC 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.

For example, there is a Referral Summary content module defined in this framework. In later years an ED Referral content module can be created that inherits the constraints of the Referral Summary content module, with a few more use case specific constraints added. Systems that do not understand the ED Referral content module but do understand the Referral Summary content module will be able to interoperate with systems that send instances of documents that conform to the ED Referral content module. This interoperability, albeit at a reduced level of functionality, is by virtue of the fact that ED Referrals are simply a refinement of the Referral Summary.

In order to retain this capability, there are a few rules about how the PCC 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.

2.3.1.1 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. 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. A simplified example is shown below.

1485

Sample Document Specification SampleDocumentOID

Sample Document has one required section, and one entry that is required if known

2.3.1.1.1 Specification

Data Element Name	Opt	Template ID
Sample Section Comment on section	R	SampleSectionOID
Sample Entry Comment on entry	R2	SampleEntryOID

Table 2.3-1

2.3.1.1.2 Conformance

CDA Release 2.0 documents that conform to the requirements of this content module shall indicate their conformance by the inclusion of the appropriate <templateId> elements in the header of the document. This is shown in the sample document below.


```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root='SampleDocumentOID'/>
  <id root=' ' extension=' '/>
  <code code=' ' displayName=' '
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <title>Sample Document</title>
  <effectiveTime value='20080601012005'/>
  <confidentialityCode code='N' displayName='Normal'
    codeSystem='2.16.840.1.113883.5.25'
codeSystemName='Confidentiality' />
  <languageCode code='en-US'/>
     :
  <component><structuredBody>
    <component>
      <section>
        <templateId root='SampleSectionOID'/>
        <!-- Required Sample Section Section content -->
      </section>
    </component>

  </strucuredBody></component>
</ClinicalDocument>
```

2.3.1.1.3 Schematron

```
<pattern name='Template_SampleDocumentOID'>
 <rule context='*[cda:templateId/@root="SampleDocumentOID"]'>
   <!-- Verify that the template id is used on the appropriate
type of object -->
   <assert test='../cda:ClinicalDocument'>
     Error: The Sample Document can only be used on Clinical
Documents.
   </assert>
   <!-- Verify the document type code -->
   <assert test='cda:code[@code = "{{{LOINC}}}"]'>
     Error: The document type code of a Sample Document must be
{{{LOINC}}}
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The document type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "SampleSectionOID"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) Sample Document must contain Sample Section.
     See http://wiki.ihe.net/index.php?title=SampleDocumentOID
   </assert>
   <assert test='.//cda:templateId[@root = "SampleEntryOID"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Sample Document should contain Sample Entry.
     See http://wiki.ihe.net/index.php?title=SampleDocumentOID
   </assert>
 </rule>
</pattern>
```

2.3.1.2 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.

Sample Section

Template ID	SampleSectionOID	
Parent Template	foo (SampleParentOID)	
General Description	Desription of this section	
LOINC Codes	**Opt**	**Description**
XXXXX-X	R	SECTION NAME
Entries	**Opt**	**Description**
OID	R	Sample Entry
Subsections	**Opt**	**Description**
OID	R	Sample Subsection

2.3.1.2.1 Parent Template

The parent of this template is foo.


```
<component>
  <section>
    <templateId root='SampleParentOID'/>
    <templateId root='SampleSectionOID'/>
    <id root=' ' extension=' '/>
    <code code=' ' displayName=' '
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
      Required and optional entries as described above
    </entry>

    <component>
      Required and optional subsections as described above
    </component>

  </section>
```

2.3.1.3 Entry and Header Content Modules Constraints

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.

An example is shown below:

Sample Entry

Some text describing the entry.

```
<observation classCode='OBS' moodCode='EVN'>
   <templateId root='foo'/>
</observation>
```

2.3.1.4 <observation classCode='OBS' moodCode='EVN'>

Some details about the observation element

2.3.1.5 <templateId root='foo'/>

Some details about the template id element

3 IHE Transactions

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

3.7 Guideline Notification

This section corresponds to Transaction PCC-7 of the IHE Patient Care Coordination Technical Framework. Transaction PCC-7 is used by the Guideline Manager and Care Manager Actors.

3.7.1 Use Case Roles

Guideline Notification

Actor

Guideline Manager

Role

Notifies the Care Manager of new and/or updated guidelines for care

Cooresponding HL7 Version 3 Application Roles

Care Provision Informer (REPC_AR004010UV)

Actor

Care Manager

Role

Recieves notification of new and/or updated guidelines for care

Cooresponding HL7 Version 3 Application Roles

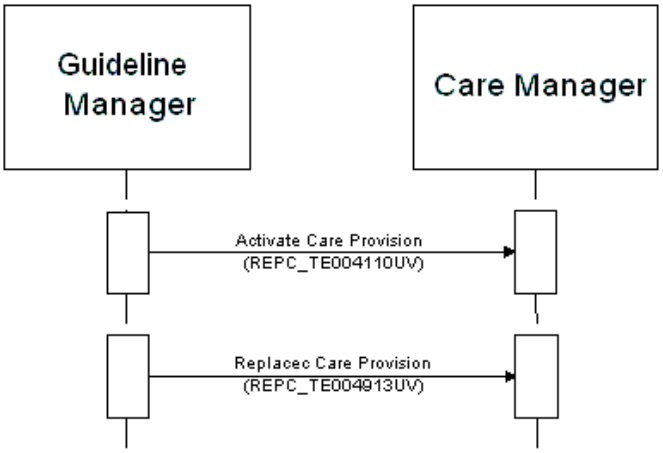
Care Provision Tracker (REPC_AR004020UV)

Note: Implementors of a Guideline Manager Actor, or a Clinical Data Source Actor shall publish an HL7 Conformance Profile that indicates the vocabularies and code sets that they support for this transaction.

3.7.2 Referenced Standards

CareRecord	HL7 Care Provision Care Record (DSTU)
HL7QI	HL7 Version 3 Standard: Infrastructure Management – Query Infrastrucure
HL7WS	HL7 Version 3 Standard: Transport Specification - Web Services Profile, Release
SOAP	Simple Object Access Protocol Version 1.1 (SOAP 1.1)
SOAP12	Simple Object Access Protocol Version 1.2 (SOAP 1.2)

3.7.3 Interaction Diagrams



3.7.4 Guideline Notification

3.7.4.1 Trigger Events

When a new or updated guideline is released, the Guideline Manager uses this transaction to notify the Care Manager of the new and/or updated guideline. This cooresponds to the HL7 trigger events:

- Activate Care Provision (REPC_TE004110UV)
- Replace Care Provision (REPC_TE004913UV)

3.7.4.2 Message Semantics

This interaction cooresponds to the HL7 Interactions:

- Activate Care Provision (REPC_IN004110UV) {Schema: [5]}
- Replace Care Provision (REPC_IN004913UV) {Schema: [6]}

The schema for these interactions can be found at the links above, and include:

- the transmission wrapper MCCI_MT000100UV01,
- the control act wrapper MCAI_MT700201UV01, and
- the message payload REPC_MT004000UV.

These components of the interaction are specified in the HL7 standards described above.

3.7.4.3 Transmission Wrapper

The transmission wrapper MCCI_MT000100UV01 provides information about the message transmission and routing. Transmission wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.


```
<REPC_IN004110UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0"
                 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
 <id root=' ' extension=' '/>
 <creationTime value=' '/>
 <interactionId
   extension='REPC_IN004110UV|REPC_IN004913UV' root='2.16.840.1.113883.5'/>
 <processingCode code='D|P|T'/>
 <processingModeCode code='T'/>
 <acceptAckCode code='AL'/>
 <receiver typeCode="RCV">
   <device classCode="DEV" determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </receiver>
 <sender typeCode="SND">
   <device classCode="DEV" determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </sender>
 <controlActProcess classCode="CACT" moodCode="EVN">
  See Control Act Wrapper below
 </controlActProcess>
</REPC_IN004110UV>
```

3.7.4.4 <REPC_IN004110UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">

The HL7 Interaction being sent will control the name of the root element in the message. The namespace of this message shall be urn:hl7-org:v3, and the ITSVersion attribute shall be "XML_1.0".

To indicate that this interaction is notification of activation of a guideline, the element shall be named: REPC_IN004110UV To indicate that this interaction is notification of replacement of a guideline, the element shall be named: REPC_IN004913UV

```
 <rule context='/'>
   <assert test='/hl7:REPC_IN004110UV|/hl7:REPC_IN004913UV'>
     The root element of a PCC-7 transaction shall be REPC_IN004110UV or
REPC_IN004913UV from the HL7 namespace (urn:hl7-org:v3).
   </assert>
 </rule>
```

3.7.4.4.1 <interactionId extension='REPC_IN004110UV|REPC_IN004913UV' root='2.16.840.1.113883.5'/>

The identifer for the interaction shall be sent using either the value REPC_IN004110UV or REPC_IN004913UV depending upon whether this interaction describes activation or replacement respectively. This value must be the same as the name of the interaction element being sent.


```
 <rule context='/hl7:REPC_IN004110UV|/hl7:REPC_IN004913UV'>
   <assert test='hl7:interactionId/@extension = local-name()'>
     The interaction of a PCC-7 transaction shall be REPC_IN004110UV or
REPC_IN004913UV and shall coorespond to the interaction being used in the
message.
   </assert>
 </rule>
```

3.7.4.4.2 <processingModeCode code='T'/>

The processingModeCode distinguishes the type of processing being performed. This element shall be present and have the value shown above to indicate that this message is for current processing.

```
<rule context='/hl7:REPC_IN004110UV|/hl7:REPC_IN004913UV'>
   <assert test='hl7:processingModeCode/@code = "T"'>
     The processingModeCode shall use the code value "T" for this message.
   </assert>
</rule>
```

3.7.4.4.3 <acceptAckCode code='AL'/>

The acceptAckCode indicates whether the sender wants to recieve an acknowledgement, and shall be sent as shown above.

```
<rule context='/hl7:REPC_IN004110UV|/hl7:REPC_IN004913UV'>
   <assert test='hl7:acceptAckCode/@code = "AL"'>
     The acceptAckCode shall use the code "AL" to indicate that the reciever
must always acknowledge the message.
   </assert>
</rule>
```

3.7.4.5 Control Act Wrapper

The control act wrapper MCAI_MT700201UV01 provides information about the business actors related to the transaction, including the author or performer of the act. Control act wrappers are further described in ITI TF-2: Appendix O.

An example control act wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

```
<controlActProcess classCode="CACT" moodCode="EVN">
  <id root=' ' extension=' '/>
  <code code='REPC_TE004110UV|REPC_TE004913UV'/>
  <effectiveTime><low value=' '/><high value=' '/></effectiveTime>
  <languageCode code=' '/>
  <authorOrPerformer typeCode=' '></authorOrPerformer>
  <subject typeCode='SUBJ' contextConductionInd='false'>
  </subject>
</controlActProcess>
```

3.7.4.5.1 <controlActProcess classCode="CACT" moodCode="EVN">

The controlActProcess element is where information about the business act being performed is recorded. The moodCode is set to "EVN" by the sender to indicate notification of a guideline activation or change event.


```
 <rule context='//hl7:controlActProcess'>
   <assert test='@classCode="CACT"'>
     The controlActProcess of a PCC-7 transaction shall have classCode="CACT".
   </assert>
   <assert test='@moodCode="EVN"'>
     The controlActProcess of a PCC-7 transaction shall have moodCode="EVN".
   </assert>
 </rule>
```

3.7.4.5.2 <code code='REPC_TE004110UV|REPC_TE004913UV'/>

The trigger event which caused the act to be transmitted is recorded in the code element is recorded. The value of the code attribute shall be REPC_TE004110UV to record an activation event, or REPC_TE004913UV to record a replacement. The code attribute shall coorespond to the correct interaction.

```
 <rule context='//hl7:controlActProcess'>
   <assert test='hl7:code'>
     The code element shall be present in a PCC-7 transaction.
   </assert>
 </rule>
 <rule context='//hl7:controlActProcess/hl7:code'>
   <assert test='(@code="REPC_TE004110UV" or @code="REPC_TE004913UV) and
substring(@code,8,8) = substring(local-name(/),8,8)"'>
     The trigger event in a PCC-7 transaction shall be REPC_TE004110UV or
REPC_TE004913UV, and shall coorespond to the interaction.
   </assert>
 </rule>
```

3.7.4.5.3 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>

The effectiveTime element shall be present. The low component shall be present and indicates the effective start date for the set of guidelines described in the subject element. The high component may be present, and if present, indicates the stop date for the guidelines. If not present, the guidelines are effective for an indefinate time period until explicitely changed or removed from the system.

```
<rule context='//hl7:controlActProcess'>
   <assert test='hl7:effectiveTime'>
     The effectiveTime element shall be present in a PCC-7 transaction.
   </assert>
 </rule>
 <rule context='//hl7:controlActProcess/hl7:effectiveTime'>
   <assert test='hl7:low and hl7:low/@value'>
     A low element shall be present in the effectiveTime and the value
attribute shall indicate the date upon which the guidelines become effective.
   </assert>
 </rule>
```

3.7.4.5.4 <subject typeCode='SUBJ' contextConductionInd='false'>

The subject element shall be present and shall be recorded as shown above. The subject element shall contain a <careProvisionEvent> element describing the guideline being activated.

3.7.4.6 Message Body

3.7.4.6.1 <careProvisionEvent classCode='PCPR' moodCode='EVN'>

An example <careProvisionEvent> element is shown below.


```
 <careProvisionEvent classCode='PCPR' moodCode='EVN'>
   <replacementOf typeCode='RPLC' contextControlCode='OP'
contextConductionInd='false'>
     <careProvisionEvent classCode='PCPR' moodCode='EVN'>
       <id root=' ' extension=' '/>
     </careProvisionEvent>
   </replacementOf>
   <component typeCode='COMP'>
     <carePlan classCode='PCPR' moodCode='INT'>
       <definition typeCode='INST' contextControlCode='OP'
contextConductionInd='false'>
         <guideline classCode='PCPR' moodCode='DEF'>
           <id root=' ' extension=' '/>
           <title></title>
           <text></text>
           <statusCode code='active|obsolete'/>
           <effectiveTime>
             <low value=' '/>
             <high value=' '/>
           </effectiveTime>
           <!-- zero or more components containing acts of care to be monitored
-->
           <component2 typeCode='COMP'>
             <!-- One of the following elements -->
             <observationDefinition classCode='OBS' moodCode='DEF'>
               <templateId root=' ' extension=' '/>
               <id root=' ' extension=' '/>
               <code code=' ' displayName=' ' codeSystem=' '
codeSystemName=' '/>
             </observationDefinition>
             <substanceAdministrationDefinition classCode='SBADM'
moodCode='DEF'>
               <templateId root=' ' extension=' '/>
               <id root=' ' extension=' '/>
               <code code=' ' displayName=' ' codeSystem=' '
codeSystemName=' '/>
             </substanceAdministrationDefinition>
             <procedureDefinition classCode='PROC' moodCode='DEF'>
               <templateId root=' ' extension=' '/>
               <id root=' ' extension=' '/>
               <code code=' ' displayName=' ' codeSystem=' '
codeSystemName=' '/>
             </procedureDefinition>
             <encounterDefinition classCode='ENC' moodCode='DEF'>
               <templateId root=' ' extension=' '/>
               <id root=' ' extension=' '/>
               <code code=' ' displayName=' ' codeSystem=' '
codeSystemName=' '/>
             </encounterDefinition>
             <actDefinition classCode='ACT' moodCode='DEF'>
               <templateId root=' ' extension=' '/>
               <id root=' ' extension=' '/>
               <code code=' ' displayName=' ' codeSystem=' '
codeSystemName=' '/>
             </actDefinition>
           </component2>
           <!-- zero or more components containing "sub-guidelines" that make
up this guideline -->
           <component3 typeCode='COMP'>
             <!-- The content model for "sub-guidelines" is as for a guideline,
with the exception
             that it need not contain an id, title, text, statusCode, or
effectiveTime element.  -->
```



```
            </component3>
          </guideline>
        </definition>
      </carePlan>
    </component>
  </careProvisionEvent>
```

The <careProvisionEvent> elements sent by a Guideline Notification transaction, or returned in a Request Guideline Data transaction represent activations or replacements of guidelines. As such these elements shall not contain any of the following participants:

- The <careProvisionEvent> element SHALL NOT contain a <recordTarget>, as guidelines are not specific to a single patient record.
- The <careProvisionEvent> element SHALL NOT contain a <subject> element, as guidelines are not specific to a device being maintained.

The <careProvisionEvent> may contain other participants not otherwise prohibited above. Furthermore, these elements shall not contain any of the following relationships which would be only relevant to a single patient:

- The <careProvisionEvent> element SHALL NOT contain a <pertinentInformation2> element.
- The <careProvisionEvent> element SHALL NOT contain a <pertinentInformation3> element.

Furthermore, the <careProvisionEvent> element SHOULD NOT contain a <pertinentInformation1> element, as this information is not directly relevant to the guideline being retrieved.

The <careProvisionEvent> may contain other relationships not otherwise prohibited above, but the use of these elements is not described in this profile.

```
<rule context='hl7:careProvisionEvent[not(../hl7:replacementOf)]'>
  <assert test='count(hl7:component) = 1'>
    A careProvisionEvent shall have only one component containing the
guideline.
  </assert>
  <assert test='not(hl7:recordTarget)'>
    The careProvisionEvent shall not contain a recordTarget element.
  </assert>
  <assert test='not(hl7:subject)'>
    The careProvisionEvent shall not contain a subject element.
  </assert>
  <assert test='not(hl7:pertinentInformation1)'>
    Warning: The careProvisionEvent should not contain a pertinentInformation1
element.
  </assert>
  <assert test='not(hl7:pertinentInformation2)'>
    The careProvisionEvent shall not contain a pertinentInformation2 element.
  </assert>
  <assert test='not(hl7:pertinentInformation3)'>
    The careProvisionEvent shall not contain a pertinentInformation3 element.
  </assert>
</rule>
```

3.7.4.6.2 <replacementOf typeCode='RPLC' contextControlCode='OP' contextConductionInd='false'>

<careProvisionEvent classCode='PCPR' moodCode='EVN'>
<id root=' ' extension=' '/>

When a Guideline Notification transaction sends a replacement notification, the <careProvisionEvent> that references the guideline being replaced shall be identified in the <replacementOf> element. The <replacementOf> element shall contain a single <careProvisionEvent> element that shall contain the an <id> element giving the unique identifier of the <careProvisionElement> that was replaced, and which should not contain any other elements.

```
<rule context='/hl7:REPC_IN004913UV'>
  <assert test='hl7:careProvisionEvent/hl7:replacementOf'>
    A replacement transaction shall contain a replacementOf element identifying
    the careProvisionEvent being replaced.
  </assert>
</rule>
<rule context='hl7:replacementOf/hl7:careProvisionEvent'>
  <assert test='hl7:id'>
    The careProvisionEvent that is being replaced shall contain an id element.
  </assert>
  <assert test='not(hl7:*[local-name() != "id"])'>
    Warning: The careProvisionEvent that is being replaced should not contain
anything other than an id element.
  </assert>
</rule>
```

3.7.4.6.3 <component typeCode='COMP'> <carePlan classCode='PCPR' moodCode='INT'>

A <careProvisionEvent> shall have only one <component> element, containing only one <carePlan>, represented exactly as shown above.

```
<rule context='hl7:careProvisionEvent/hl7:component'>
  <assert test='count(hl7:carePlan) = 1'>
    The component of the careProvisionEven shall have one and only one carePlan
element.
  </assert>
</rule>
```

3.7.4.6.4 <definition typeCode='INST' contextControlCode='OP' contextConductionInd='false'> <guideline classCode='PCPR' moodCode='DEF'>

The <carePlan> element shall be empty of all participants and relations with the exception of the <definition> of the <carePlan>. The <definition> element contains one and only one <guideline>.


```
<rule context='hl7:carePlan'>
  <assert test='not(*[local-name() != "definition"])'>
    The carePlan element shall be empty of all participants and relations with
the exception of the definition element.
  </assert>
  <assert test='count(hl7:definition) = 1'>
    The carePlan element shall have one and only one definition element.
  </assert>
</rule>
<rule context='hl7:definition'>
  <assert test='count(hl7:guideline) = 1'>
    The definition element shall have one and only one guideline element.
  </assert>
</rule>
```

3.7.4.6.5 <id root=' ' extension=' '/>

Top level guidelines shall have a unique identifier.

```
<rule context='hl7:definition/hl7:guideline'>
  <assert test='hl7:id'>
    A top level guideline shall have an id element.
  </assert>
</rule>
```

3.7.4.6.6 <title></title>

Top level guidelines shall have a title.

```
<rule context='hl7:definition/hl7:guideline'>
  <assert test='hl7:title'>
    A top level guideline shall have a title element.
  </assert>
</rule>
```

3.7.4.6.7 <text></text>

All guidelines may contain narrative text describing the guideline.

3.7.4.6.8 <statusCode code='active|obsolete'/>

Top level guidelines shall have a statusCode value that is either "active" or "obsolete".

```
<rule context='hl7:definition/hl7:guideline'>
  <assert test='hl7:statusCode'>
    A top level guideline shall have a statusCode element.
  </assert>
</rule>
<rule context='hl7:guideline/hl7:statusCode'>
  <assert test='@code="active" or @code="obsolete"'>
    The statusCode/@code attribute shall be either "active" or "obsolete".
  </assert>
<rule>
```

3.7.4.6.9 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>

Top level guidelines shall contain an <effectiveTime> element that records the time period over which the guideline is effective. It shall contain a <low> element recording at

the very least the date upon which the guideline was activated. An obsolete guideline shall contain a <high> element recording the last date upon which the guideline was effective. An active guideline may record the date upon which the guideline is expected to be revised.

```
<rule context='hl7:definition/hl7:guideline'>
  <assert test='hl7:effectiveTime'>
    A top level guideline shall have a effectiveTime element.
  </assert>
</rule>
<rule context='hl7:guideline/hl7:effectiveTime'>
  <assert test='hl7:low and hl7:low/@value'>
    The effectiveTime element shall contain a low element containing a value
attribute indicating the time at which
    the guideline became effective.
  </assert>
<rule>
<rule
context='hl7:guideline[hl7:statusCode/@code="obsolete"]/hl7:effectiveTime'>
  <assert test='hl7:high and hl7:high/@value'>
    The effectiveTime element in an obsolete guideline shall contain a high
element containing a value attribute
    indicating the time at which the guideline became ineffective.
  </assert>
<rule>
```

3.7.4.6.10<component2 typeCode='COMP'>

All guidelines are composed (at some level) of one or more definitions for acts of care which are to be monitored by a Care Manager and reported upon by a Clinical Data Source during the provision of care. These may include various observations performed (e.g., Hemoglobin A1C tests), medications or immunizations given or prescribed, procedures performed (e.g., foot care), encounters performed (e.g., eye exam), or other acts of care not elsewhere described above.

```
<rule context='hl7:guideline'>
  <assert test='count(.//hl7:component2/hl7:*[@moodCode='DEF']) > 0'>
    At least one act of care must be defined at some level beneath a guideline
element.
  </assert>
</rule>
```

3.7.4.6.11<observationDefinition classCode='OBS' moodCode='DEF'>

3.7.4.6.12<substanceAdministrationDefinition classCode='SBADM' moodCode='DEF'>

3.7.4.6.13<procedureDefinition classCode='PROC' moodCode='DEF'>

3.7.4.6.14<encounterDefinition classCode='ENC' moodCode='DEF'>

3.7.4.6.15<actDefinition classCode='ACT' moodCode='DEF'>

One of the above definitions of an act of care shall be present in a <component2> element.

3.7.4.6.16<templateId root=' ' extension=' '/>

Each act of care to be monitored shall indicate the identifier of the template used to report information on that act.

```
<rule context='hl7:component2/hl7:*[@moodCode='DEF']'>
  <assert test='hl7:templateId'>
    A templateId element must appear in the definition.
  </assert>
</rule>
```

A Guideline Manager actor shall use one the IHE Template identifiers specified for PCC-1 under careProvisionCode to request information profiled in an IHE template to be returned in a PCC-10 transaction. A Clincial Data Source implementing the Care Record option shall report activites to the Care Manager using the Care Record Query Response message using the template identified.

A Guideline Manager actor may include an ActDefinition in the <guideline> to identify the HL7 Version 2 Message Profile to describe the data to be monitored by a Care Manager. A Clinical Data Source implementing the HL7 Version 2 option shall report activities to the Care Manager using the HL7 Version 2 message identified by those ActDefinition elements.

3.7.4.6.17<id root=' ' extension=' '/> <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

Each act of care to be monitored shall contain an identifier for the definition of the act. It shall also contain a code element describing the specific act of care to be monitored. Other features of the specific act allowed by the standard may be provided by the Guideline Manager to further identify the specific acts of care that a Care Manager wants to recieve (e.g., routeCode, targetSiteCode). A Clinical Data Source may use these additional features to limit the number of items it reports, but is not required to review any feature other than the "code" element when making its reports. The Care Manager is expected to use its decision support capabilities to ignore reports that are not relevant to its decision making processes.

```
<rule context='hl7:component2/hl7:*[@moodCode='DEF']'>
  <assert test='hl7:id'>
    An id element must appear in the definition.
  </assert>
  <assert test='hl7:code'>
    An code element must appear in the definition.
  </assert>
</rule>
```

3.7.4.6.18 <component3 typeCode='COMP'>

Guidelines may cover different phases (e.g., pre-operative, post-operative) or perspectives of care (e.g., patient education, diet, medications). A guideline can therefore

be constructed of other guideline components, which follow the same pattern as for the top level guideline in the careProvisionEvent, except that these subcomponents need not have a unique identity, a title, a status, or effective time.

3.7.4.7 Expected Actions -- Guideline Manager

The Guideline Manager shall send notifications as specified in the REPC_IN004110UV and REPC_IN004913UV interactions. The message shall be sent using web services as specified in the ITI-TF: Appendix V.

The name of the messages in the WSDL shall be REPC_IN004110UV_Message for activitation notifications, and REPC_IN004913UV_Message for replacement notifications. The following WSDL snippet defines the types for these messages:

```
<types>
   <xsd:schema elementFormDefault="qualified"
      targetNamespace="urn:hl7-org:v3" xmlns:hl7="urn:hl7-org:v3">
    <!-- Include the message schema -->
    <xsd:import namespace="urn:hl7-org:v3"
      schemaLocation="REPC_IN004110UV.xsd"/>
    <xsd:element name="REPC_IN004110UV"/>
    <xsd:import namespace="urn:hl7-org:v3"
      schemaLocation="REPC_IN004913UV.xsd"/>
    <xsd:element name="REPC_IN004913UV"/>
  </xsd:schema>
</types>
```

The message types are declared to be of the appropriate type by the following WSDL snippet:

```
<message name='REPC_IN004110UV_Message'>
  <part element='hl7:REPC_IN004110UV' name="Body"/>
</message>
<message name='REPC_IN004913UV_Message'>
  <part element='hl7:REPC_IN004913UV' name="Body"/>
</message>
```

3.7.4.8 Expected Actions -- Care Manager

The Care Manager shall send an acknowledgement response as specified in the MCCI_IN000002UV01 interaction. The message shall be sent using web services as specified in the ITI-TF: Appendix V. An acknowledgement response is structured almost identically to a transmission wrapper, but includes an acknowledgement element in the response. The example structure below uses the same values as the transmission wrapper, with the exceptions noted in bold black text below.


```
<MCCI_IN000002UV01 xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0"
                  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
 <id root=' ' extension=' '/>
 <creationTime value=' '/>
 <interactionId extension='MCCI_IN000002UV01' root='2.16.840.1.113883.5'/>
 <processingCode code='D|P|T'/>
 <processingModeCode code='T'/>
 <acceptAckCode code='NE'/>
 <receiver typeCode="RCV">
   <device determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </receiver>
 <sender typeCode="SND">
   <device determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </sender>
 <acknowledgement>
  <typeCode code='AA|AE|AR'/>
  <acknowledgementDetail>
    <typeCode='E|I|W'/>
    <code code=' ' displayName=' '
       codeSystem='2.16.840.1.113883.5.1100'
       codeSystemName='AcknowledgementDetailCode'/>
    <text></text>
    <location></location>
  </acknowledgementDetail>
 </acknowledgement>
</MCCI_IN000002UV01>
```

3.7.4.8.1 <MCCI_IN000002UV01 xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">

The name of the acknowledgement message element shall be MCCI_IN000002UV01 from the HL7 namespace.

```
<rule context='/'>
 <assert test='/hl7:MCCI_IN000002UV01'>
  The name of the acknowledgement message element shall be MCCI_IN000002UV01
from the HL7 namespace.
 </assert>
<rule>
```

3.7.4.8.2 <interactionId extension='MCCI_IN000002UV01' root='2.16.840.1.113883.5'/>

The interactionId element shall be recorded exactly as specified above.


```
<rule context='/hl7:MCCI_IN000002UV01'>
 <assert test='hl7:interactionId/@extension = "MCCI_IN000002UV01" and
interactionId/@root = "2.16.840.1.113883.5"'>
   The extension attribute of the interaction Id element shall be
MCCI_IN000002UV01.
 </assert>
<rule>
```

3.7.4.8.3 <processingModeCode code='T'/>

The code attribute of the processingModeCode element shall be T to indicate current processing.

```
<rule context='/hl7:MCCI_IN000002UV01'>
 <assert test='hl7:processingModeCode/@code = "T"'>
   The code attribute of the processingModeCode element shall be T to indicate
current processing.
 </assert>
<rule>
```

3.7.4.8.4 <acceptAckCode code='NE'/>

The code attribute of the acceptAckCode element shall be NE to indicate that acknowledgments are never acknowledged by the reciever.

```
<rule context='/hl7:MCCI_IN000002UV01'>
 <assert test='hl7:acceptAckCode/@code = "NE"'>
   The code attribute of the acceptAckCode element shall be NE.
 </assert>
<rule>
```


3.7.4.8.5 <acknowledgement>

One and only one acknowledgement element shall be present.

```
<rule context='/hl7:MCCI_IN000002UV01'>
 <assert test='count(hl7:acknowledgement) = 1'>
   One and only one acknowledgement element shall be present.
 </assert>
<rule>
```

3.7.4.8.6 <typeCode code='AA|AE|AR'/>

The typeCode element shall be present. It shall use only the values AA, AE, or AR to describe whether the application accepted it (AA), found an error in it (AE), or rejected it (AR).

```
<rule context='/hl7:MCCI_IN000002UV01/hl7:acknowledgement'>
 <assert test='hl7:typeCode/@code = "AA" or hl7:typeCode/@code = "AE" or
hl7:typeCode/@code = "AR"'>
   Only the values AA, AE and AR are acceptable.
 </assert>
<rule>
```

3.7.4.8.7 <acknowledgementDetail>

The acknowledgementDetail element shall be present when a message is rejected, or when an error is found. It may be present even when an application has accepted the message to convey information and warnings.

```
<rule context='/hl7:MCCI_IN000002UV01/hl7:acknowledgement'>
 <assert test='hl7:typeCode/@code = "AA" or hl7:acknowledgementDetail'>
   The acknowledgementDetail element is required when the acknowedgement
reports an error (AE) or rejects a message (AR).
 </assert>
<rule>
```

3.7.4.8.8 <typeCode code='E|I|W'/>

The typeCode element shll be present in the acknowledgementDetail element. It shall have a value of E, I or W to indicate errors, information or warnings. A detail message sent with the acknowledgement type of AA shall not contain a value of E in the detailed type code.


```
<rule
context='/hl7:MCCI_IN000002UV01/hl7:acknowledgement/hl7:acknowledgementDetail'>
 <assert test='hl7:typeCode/@code = "E" or hl7:typeCode/@code = "I" or
hl7:typeCode/@code = "W"'>
   Only the values E, I or W are acceptable.
 </assert>
 <assert test='hl7:typeCode/@code != "E" or ../../hl7:typeCode != "AA"'>
   Acknowledgement details cannot indicate an error when the acknowledgment is
of type AA.
 </assert>
<rule>
```

3.7.4.8.9 <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.1100' codeSystemName='AcknowledgementDetailCode'/>

The code element may be present in the acknowledgementDetail element to further describe the error.

3.7.4.8.10<text></text>

The text element may be present in the acknowledgementDetail element to further describe the error in human readable form.

3.7.4.8.11<location></location>

The location element may be present in the acknowledgementDetail element to indicate the location of the error. The location shall be reported as an XPath expression indicating the position of the error in the source message content.

The name of the acknowledgement response message shall be MCCI_IN000002UV01_Message in the WSDL. The following WSDL snippet defines the type for this message:

```
<types>
   <xsd:schema elementFormDefault="qualified"
     targetNamespace="urn:hl7-org:v3" xmlns:hl7="urn:hl7-org:v3">
     <xsd:import namespace="urn:hl7-org:v3"
       schemaLocation="MCCI_IN000002UV01.xsd"/>
     <xsd:element name="MCCI_IN000002UV01"/>
   </xsd:schema>
 </types>
```

The message type is declared to be of the appropriate type by the following WSDL snippet:

```
<message name='MCCI_IN000002UV01_Message'>
   <part element='hl7:MCCI_IN000002UV01' name="Body"/>
 </message>
```


3.7.5 WSDL Declarations

The following WSDL naming conventions SHALL apply for this transaction:

WSDL Item	Value
wsdl:definitions/@name	GuidelineManger
Activate Care Provision	REPC_IN004110UV_Message
Replace Care Provision	REPC_IN004913UV_Message
Acknowlegement	MCCI_IN000002UV01_Message
portType	GuidelineManger_PortType
Activate Guideline Operation	GuidelineManger_REPC_IN004110UV
Activate Guideline Operation	GuidelineManger_REPC_IN004913UV
SOAP 1.1 binding	GuidelineManger_Binding_Soap11
SOAP 1.1 port	GuidelineManger_Port_Soap11
SOAP 1.2 binding	GuidelineManger_Binding_Soap12
SOAP 1.2 port	GuidelineManger_Port_Soap12

The following WSDL snippets specify the Port Type and Binding definitions, according to the requirements specified in ITI TF-2: Appendix V. A full WSDL example for the Guideline Manger actor can be found at ftp://ftp.ihe.net/TF_Implementation_Material/PCC/GuidelineManager.wsdl. For a general description of the WSDLs for PCC see the Appendix of the same name in this volume.

3.7.5.1 Port Type

```
<portType name="GuidelineManger_PortType">
 <operation name="GuidelineManger_REPC_IN004110UV">
   <input message="tns:REPC_IN004110UV_Message"
     wsaw:Action="urn:hl7-org:v3:REPC_IN004110UV"/>
   <output message="tns:MCCI_IN000002UV01_Message"
     wsaw:Action="urn:hl7-org:v3:MCCI_IN000002UV01"/>
 </operation>
 <operation name="GuidelineManger_REPC_IN004913UV">
   <input message="tns:REPC_IN004913UV_Message"
     wsaw:Action="urn:hl7-org:v3:REPC_IN004913UV"/>
   <output message="tns:MCCI_IN000002UV01_Message"
     wsaw:Action="urn:hl7-org:v3:MCCI_IN000002UV01"/>
 </operation>
</portType>
```

3.7.5.2 Bindings

```
<binding name="GuidelineManger_Binding_Soap12"
   type="GuidelineManger_PortType">
 <wsoap12:binding style="document"
   transport="http://schemas.xmlsoap.org/soap/http"/>
 <operation name="GuidelineManger_REPC_IN004110UV">
   <wsoap12:operation soapAction="urn:hl7-org:v3:REPC_IN004110UV"/>
   <input>
     <wsoap12:body use="literal"/>
   </input>
   <output>
     <wsoap12:body use="literal"/>
   </output>
 </operation>
 <operation name="GuidelineManger_REPC_IN004913UV">
   <wsoap12:operation soapAction="urn:hl7-org:v3:REPC_IN004913UV"/>
   <input>
     <wsoap12:body use="literal"/>
   </input>
   <output>
     <wsoap12:body use="literal"/>
   </output>
 </operation>
</binding>
<binding name="GuidelineManger_Binding_Soap11"
   type="GuidelineManger_PortType">
 <wsoap11:binding style="document"
   transport="http://schemas.xmlsoap.org/soap/http"/>
 <operation name="GuidelineManger_REPC_IN004110UV">
   <wsoap11:operation soapAction="urn:hl7-org:v3:REPC_IN004110UV"/>
   <input>
     <wsoap11:body use="literal"/>
   </input>
   <output>
     <wsoap11:body use="literal"/>
   </output>
 </operation>
 <operation name="GuidelineManger_REPC_IN004913UV">
   <wsoap11:operation soapAction="urn:hl7-org:v3:REPC_IN004913UV"/>
   <input>
     <wsoap11:body use="literal"/>
   </input>
   <output>
```



```
      <wsoap11:body use="literal"/>
    </output>
  </operation>
</binding>
```

3.8 Request Guideline Data

This section corresponds to Transaction PCC-8 of the IHE Patient Care Coordination Technical Framework. Transaction PCC-8 is used by the Care Manager and/or Clinical Data Source Actors to request Guideline Data from a Guideline Manager Actor. Transaction PCC-8 is similar in structure to Transaction PCC-1. The difference between PCC-8 and PCC-1 is that where PCC-1 requests clinical information matching the query parameters for a specific patient, the PCC-8 transaction requests a clinical guideline identified in the query parameters.

3.8.1 Use Case Roles

Request Guideline Data

Actor

Care Manager or Clinical Data Source

Role

Requests the data required to implement a guideline.

Cooresponding HL7 Version 3 Application Roles

Care Record Query Placer (QUPC_AR004030UV)
Query by Parameter Placer (QUQI_AR000001UV01)

Actor

Guideline Manager

Role

Returns the guideline data required to implement a guideline.

Cooresponding HL7 Version 3 Application Roles

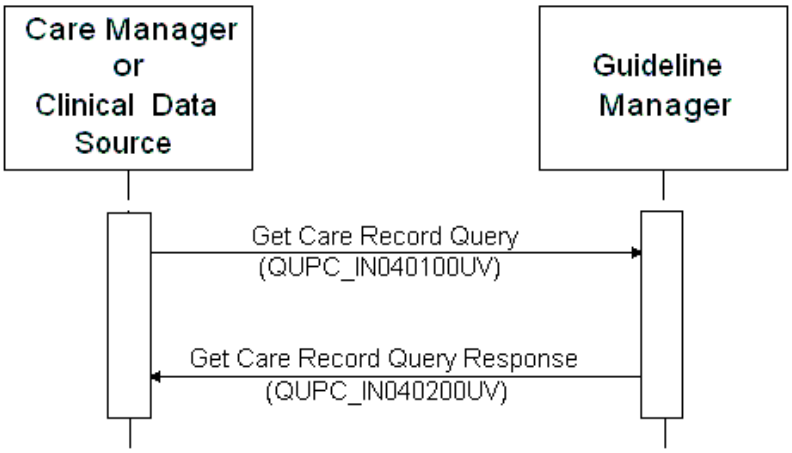
Care Record Query Fulfiller (QUPC_AR004040UV)
Query by Parameter Fulfiller (QUQI_AR000002UV01)

Note: Implementors of a Guideline Manager Actor, Care Manager Actor or a Clinical Data Source Actor shall publish an HL7 Conformance Profile that indicates the vocabularies and code sets that they support for this transaction.

3.8.2 Referenced Standards

CareRecord	HL7 Care Provision Care Record (DSTU)
CareQuery	HL7 Care Provision Care Record Query (DSTU)
HL7QI	HL7 Version 3 Standard: Infrastructure Management – Query Infrastrucure
HL7WS	HL7 Version 3 Standard: Transport Specification - Web Services Profile, Release
SOAP	Simple Object Access Protocol Version 1.1 (SOAP 1.1)
SOAP12	Simple Object Access Protocol Version 1.2 (SOAP 1.2)

3.8.3 Interaction Diagrams



3.8.4 Get Care Record Query

3.8.4.1 Trigger Events

When a Clinical Data Source actor needs to understand the data needed to respond to a query from a Care Manager, or a Care Manager actor needs to refresh its knowledge about a guideline (e.g., to determine how to update a query for a replaced guideline) it will trigger a Get Care Record Query event. This cooresponds to the HL7 trigger event: QUPC_TE040100UV

3.8.4.2 Message Semantics

The Query Care Record Event Get Query corresponds to the HL7 Interaction QUPC_IN040100UV.

A schema for this interaction can be found at: http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUPC_IN040100UV.xsd. This schema includes:

- the transmission wrapper MCCI_MT000100UV01,
- the control act wrapper QUQI_MT020001UV01, and

- the message payload QUPC_MT040100UV.

These components of the interaction are specified in the HL7 standards described above.

3.8.4.3 Transmission Wrapper

The transmission wrapper MCCI_MT000100UV01 provides information about the message transmission and routing. Transmission wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

```
<QUPC_IN040100UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0"
                 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
 <id root=' ' extension=' '/>
 <creationTime value=' '/>
 <interactionId extension='QUPC_IN040100UV' root='2.16.840.1.113883.5'/>
 <processingCode code='D|P|T'/>
 <processingModeCode code='T'/>
 <acceptAckCode code='AL'/>
 <receiver typeCode="RCV">
   <device determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </receiver>
 <sender typeCode="SND">
   <device determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </sender>
 <controlActProcess>
  See Control Act Wrapper below
 </controlActProcess>
</QUPC_IN040100UV>
```

3.8.4.3.1 <QUPC_IN040100UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">

The HL7 Interaction being sent will control the name of the root element in the message. The namespace of this message shall be urn:hl7-org:v3, and the ITSVersion attribute shall be "XML_1.0".

3.8.4.3.2 <interactionId extension='QUPC_IN040100UV' root='2.16.840.1.113883.5'/>

The identifer for the interaction shall be sent as shown above.

3.8.4.3.3 <processingModeCode code='T'/>

The processingModeCode distinguishes the type of processing being performed. This element shall be present and have the value shown above to indicate that this message is for current processing.

3.8.4.3.4 <acceptAckCode code='AL'/>

The acceptAckCode indicates whether the sender wants to recieve an acknowledgement, and shall be sent as shown above.

3.8.4.4 Control Act Wrapper

The control act wrapper QUQI_MT020001UV01 provides information about the business actors related to the transaction, including the author or performer of the act. Control act wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

```
<controlActProcess moodCode="RQO">
  <id root=' ' extension=' '/>
  <code code='QUPC_TE040100UV'/>
  <effectiveTime value=' '/>
  <languageCode code=' '/>
  <authorOrPerformer typeCode=' '></authorOrPerformer>
  <queryByParameter>
    <id root=' ' extension=' '/>
    <statusCode code='new'/>
    <responseModalityCode code='R'/>
    <responsePriorityCode code='I'/>
    <initialQuantity value=/>
    <initialQuantityCode code='REPC_RM000100UV' codeSystem='2.16.840.1.113883'>
    <parameterList>
      see Query Parameter List below
    </parameterList>
  </queryByParameter>
</controlActProcess>
```

3.8.4.4.1 <controlActProcess moodCode="RQO">

The controlActProcess element is where information about the business act being performed is recorded. The moodCode is set to "RQO" by the sender to indicate a request to perform an action, in this case, a query.

3.8.4.4.2 <code code='QUPC_TE040100UV'/>

The trigger event which caused the act to be transmitted is recorded in the code element is recorded as shown above.

3.8.4.4.3 <queryByParameter>

HL7 Version 3 messages that perform a query specify the details of it in the <queryByParameter> element.

3.8.4.4.4 <id root=' ' extension=' '/>

The sending system shall specify the identifier of the query. This is the identifier that is used in subsequent continuation or cancel messages.

3.8.4.4.5 <statusCode code='new'/>

When passing the parameter list, the <statusCode> element shall be recorded as above to indicate that this is a new query.

3.8.4.4.6 <responseModalityCode code='R'/>

The query response shall always be in real-time.

3.8.4.4.7 <responsePriorityCode code='I'/>

The query response shall always be immediate.

3.8.4.4.8 <initialQuantityCode code='REPC_RM000100UV' codeSystem='2.16.840.1.113883.5'>

The <initialQuantityCode> shall be sent when <initialQuantity> is sent. The code shall be the identifier of the HL7 artifact that is to be counted (e.g., R-MIM or C-MET identifer). In this profile what is being counted is clinical statements, so the code to use shall be REPC_RM000100UV.

3.8.4.5 Parameter List

The message supports specification of the data items listed in the table below as query parameters. The first column of this table provides the name of the parameter. The next column indicates the number of times it may occur in the query. The next column indicates the type of data expected for the query parameter. The next column indicates the vocabulary domain used for coded values. The Sender column indicates whether the message sender (a Care Manager or Clinical Data Source actor) must send this parameter. The Reciever column indicates whether the reciever (a Guideline Manager Actor) must support this parameter. If these last two columns contain the value R, then this parameter SHALL be send by actor, and if it is X, then this parameter SHALL NOT be sent by the actor. In this profile, all parameters not explicitly required are prohibited.

Parameter Name	Cardinality	Data Type	Vocabulary Domain	Sender	Reciever
careRecordId	1..1	II		R	R
patientId	0..0	CD		X	X
versionTimeStamp	0..0	TS		X	X
includeCarePlanAttachment	1..1	BL		R	R
maxHistoryClincialStatements	0..0	INT		X	X

An example of the query specification is described in the figure below.

```
<parameterList>
  <careRecordId>
    <value code='' displayName='' codeSystem='' codeSystemName=''/>
  </careRecordId>
  <includeCarePlanAttachment>
     <value value='true'/>
  </includeCarePlanAttachment>
</parameterList>
```

3.8.4.5.1 <parameterList>

The <parameterList> element shall be present, and contains the set of query parameters being used in this query.

3.8.4.5.2 <careRecordId><value root=' ' extension=' '/></careRecordId>

The identifier of the care record event that activated the guideline shall be specified in this element. The root and extension attributes shall be present.

3.8.4.5.3 <includeCarePlanAttachment><value value='true'/></includeCarePlanAttachment>

The <includeCarePlanAttachment> element shall be sent and the value shall be true. As guidelines always appear in a Care Record message under the Care Plan, the Care Plan must be present in the response.

3.8.4.6 Expected Actions -- Care Manager or Clinical Data Source

The clinical data consumer shall send a query as specified in the QUPC_IN040100UV interaction. The message shall be sent using web services as specified in the ITI-TF: Appendix V.

The name of the query response message shall be QUPC_IN040100UV_Message in the WSDL. The following WSDL snippet defines the type for this message:


```
<types>
   <xsd:schema elementFormDefault="qualified"
      targetNamespace="urn:hl7-org:v3" xmlns:hl7="urn:hl7-org:v3">
    <!-- Include the message schema -->
    <xsd:include
       namespace="urn:hl7-org:v3" schemaLocation="QUPC_IN040100UV.xsd"/>
  </xsd:schema>
</types>
```

The message type is declared to be of the appropriate type by the following WSDL snippet:

```
<message name='QUPC_IN040100UV_Message'>
  <part element='hl7:QUPC_IN040100UV' name="Body"/>
</message>
```

Other WSDL declarations required for this transaction are defined under the Domain Content section.

3.8.5 Get Care Record Profile Response

3.8.5.1 Trigger Events

This message is triggered upon reciept of a Query Care Record Event Get Query. This corresponds to HL7 trigger event: QUPC_TE043200UV

3.8.5.2 Message Semantics

The Query Care Record Event Get Query Response corresponds to the HL7 Interaction QUPC_IN040200UV. A schema for this interaction can be found at: http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUPC_IN040200UV.xsd. This schema includes:

- the transmission wrapper MCCI_MT000300UV01,
- the control act wrapper MFMI_MT700712UV01, and
- the message payload REPC_MT004000UV.

These components of the interaction are specified in the HL7 standards described above.

3.8.5.3 Transmission Wrapper

The transmission wrapper MCCI_MT000300UV01 provides information about the message transmission and routing. Transmission wrappers are further described in ITI TF-2: Appendix O.

An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.


```
<QUPC_IN040200UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0"
                 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
 <id root=' ' extension=' '/>
 <creationTime value=' '/>
 <interactionId extension='QUPC_IN040200UV' root='2.16.840.1.113883.5'/>
 <processingCode code='D|P|T'/>
 <processingModeCode code='T'/>
 <acceptAckCode code='NE'/>
 <receiver typeCode="RCV">
   <device determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </receiver>
 <sender typeCode="SND">
   <device determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </sender>
 <controlActProcess>
  See Control Act Wrapper below
 </controlActProcess>
</QUPC_IN040200UV>
```

3.8.5.3.1 <QUPC_IN040200UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">

The HL7 Interaction being sent will control the name of the root element in the message. The namespace of this message shall be urn:hl7-org:v3, and the ITSVersion attribute shall be "XML_1.0".

3.8.5.3.2 <interactionId extension='QUPC_IN040200UV' root='2.16.840.1.113883.5'/>

The identifer for the interaction shall be sent as shown above.

3.8.5.3.3 <processingModeCode code='T'/>

The processingModeCode distinguishes the type of processing being performed. This element shall be present and have the value shown above to indicate that this message is for current processing.

3.8.5.3.4 <acceptAckCode code='NE'/>

The acceptAckCode indicates whether the reciever wants to recieve an acknowledgement, and shall be sent as shown above. Query responses shall not require acknowledgements.

3.8.5.4 Control Act Wrapper

The control act wrapper MFMI_MT700712UV01 provides information about the business actors related to the transaction, including the author or performer of the act. Control act wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

```
<controlActProcess moodCode="EVN">=
  <id root=' ' extension=' '/>
  <code code='QUPC_TE040200UV'/>
  <effectiveTime value=' '/>
  <languageCode code=' '/>
  <authorOrPerformer typeCode=' '></authorOrPerformer>
  <subject>
     See Query Response below
  </subject>
  <queryAck>
    <queryId root=' ' extension=' '/>
    <statusCode code=' '/>
    <queryResponseCode code=' '/>
    <resultTotalQuantity value=' '/>
    <resultCurrentQuantity value=' '/>
    <resultRemainingQuantity value=' '/>
  </queryAck>
</controlActProcess>
```

3.8.5.4.1 <controlActProcess moodCode="EVN">

The controlActProcess element is where information about the business act being performed is recorded. The moodCode is set to "EVN" by the sender to indicate a response to a query.

3.8.5.4.2 <code code='QUPC_TE040200UV'/>

The trigger event which caused the act to be transmitted is recorded in the code element is recorded as shown above.

3.8.5.4.3 <subject>

The <subject> element shall be present to record the responses in a query request.

<queryAck>

The queryAck element is transmitted in any message that is a response to a query, query continuation or query cancellation message.

3.8.5.4.4 <queryId root=' ' extension=' '/>

The <queryId> element shall be transmitted in a queryAck element. It shall contain an identifier that was used in the original query message.

3.8.5.4.5 <statusCode code=' '/>

The statusCode element in the queryAck element indicates the status of the query. It may contain the value 'deliveredResponse' or 'aborted'.

3.8.5.4.6 <queryResponseCode code=' '/>

The queryResponseCode element indicates at a high level the results of performing the query. It may have the value 'OK' to indicate that the query was performed and has results. It may have the value 'NF' to indicate that the query was performed, but no record was found. It may have the value 'QE' to indicate that an error was detected in the incoming query message, or 'AE' to indicate some other application error occurred.

3.8.5.4.7 <resultTotalQuantity value=' '/>

The resultTotalQuantity element shall be present and enumerates the number of results found (1). This element gives the count of the total number of results located by the query.

Note: For this use of the query, the resultTotalQuantity value should always be 1

3.8.5.4.8 <resultCurrentQuantity value=' '/>

The resultCurrentQuantity element shall be present, and shall enumerate number of results returned in the current response.

Note: For this use of the query, the resultCurrentQuantity value should always be 1

3.8.5.4.9 <resultRemainingQuantity value=' '/>

This resultRemainingQuantity element shall be present. It shall enumerate the number of results that follow the results currently returned (0).

Note: For this use of the query, the resultRemainingQuantity value should always be 0

3.8.5.5 Registration Event Details

The <subject> element of the <controlActProcess> element shall appear as shown in the example below, and provides details on the event that registered the the guideline with the Guideline Manager.


```
<subject>
  <registrationEvent>
    <statusCode code='active|obsolete'/>
    <custodian>
      <assignedEntity>
        <id root='' extension=''/>
        <addr></addr>
        <telecom></telecom>
        <assignedOrganization>
          <name></name>
        </assignedOrganization>
      </assignedEntity>
    </custodian>
    <subject2>
      <careProvisionEvent classCode='PCPR' moodCode='EVN'>
        <!-- Message Body -->
      </careProvisionEvent>
      <parameterList>
      </parameterList>
    </subject2>
  </registrationEvent>
</subject>
```

3.8.5.5.1 <subject>

The <subject> element shall be present, and is where the results are returned.

3.8.5.5.2 <registrationEvent>

Only one <registrationEvent> element shall be be present.

The <registrationEvent> is used to record the information about how the <careProvisionEvent> being returned was recorded or "registered" in the custodial system (the Guideline Manager actor) .

3.8.5.5.3 <statusCode code='active|obsolete'/>

The <statusCode> element records the status of the data records. Queries return active and obsolete (replaced) records.

3.8.5.5.4 <custodian>

The <custodian> element records the custodian, or "owner", of the guideline. A Guideline Manager actor may return records from multiple custodians.

3.8.5.5.5 <assignedEntity>

The <assignedEntity> element shall be present, and provides contact and identification information about the <custodian>.

3.8.5.5.6 <id root=' ' extension=' '/>

The <id> element shall be present, and shall uniquely identify the custodian of the guideline.

3.8.5.5.7 <addr></addr>

The <addr> element shall be present, and shall provide a postal address for the custodian of the guideline.

3.8.5.5.8 <telecom></telecom>

At least one <telecom> element shall be present that provides a telephone number to contact the custodian of the guideline. A <telecom> element may be present that provides the web service end-point address of the custodian of the guideline.

For Public Comment	How might the web service end-point address be used? Is it a good idea to include it, or should we omit this from the profile?

3.8.5.5.9 <assignedOrganization> <name></name> </assignedOrganization>

The name of the organization that is the custodian of the guideline shall be provided.

3.8.5.5.10 <subject2>

The <subject2> element provides the data content requested from the query.

3.8.5.6 Query Response Content

Note:	The following content for careProvisionEvent is identical to that found in PCC-7.

3.8.5.6.1 <careProvisionEvent classCode='PCPR' moodCode='EVN'>

An example <careProvisionEvent> element is shown below.


```
<careProvisionEvent classCode='PCPR' moodCode='EVN'>
   <replacementOf typeCode='RPLC' contextControlCode='OP'
contextConductionInd='false'>
     <careProvisionEvent classCode='PCPR' moodCode='EVN'>
       <id root=' ' extension=' '/>
     </careProvisionEvent>
   </replacementOf>
   <component typeCode='COMP'>
     <carePlan classCode='PCPR' moodCode='INT'>
       <definition typeCode='INST' contextControlCode='OP'
contextConductionInd='false'>
         <guideline classCode='PCPR' moodCode='DEF'>
           <id root=' ' extension=' '/>
           <title></title>
           <text></text>
           <statusCode code='active|obsolete'/>
           <effectiveTime>
             <low value=' '/>
             <high value=' '/>
           </effectiveTime>
           <!-- zero or more components containing acts of care to be monitored
-->
           <component2 typeCode='COMP'>
             <!-- One and only one of the following elements -->
             <observationDefinition classCode='OBS' moodCode='DEF'>
               <templateId root=' ' extension=' '/>
               <id root=' ' extension=' '/>
               <code code=' ' displayName=' ' codeSystem=' '
codeSystemName=' '/>
             </observationDefinition>
             <substanceAdministrationDefinition classCode='SBADM'
moodCode='DEF'>
               <templateId root=' ' extension=' '/>
               <id root=' ' extension=' '/>
               <code code=' ' displayName=' ' codeSystem=' '
codeSystemName=' '/>
             </substanceAdministrationDefinition>
             <procedureDefinition classCode='PROC' moodCode='DEF'>
               <templateId root=' ' extension=' '/>
               <id root=' ' extension=' '/>
               <code code=' ' displayName=' ' codeSystem=' '
codeSystemName=' '/>
             </procedureDefinition>
             <encounterDefinition classCode='ENC' moodCode='DEF'>
               <templateId root=' ' extension=' '/>
               <id root=' ' extension=' '/>
               <code code=' ' displayName=' ' codeSystem=' '
codeSystemName=' '/>
             </encounterDefinition>
             <actDefinition classCode='ACT' moodCode='DEF'>
               <templateId root=' ' extension=' '/>
               <id root=' ' extension=' '/>
               <code code=' ' displayName=' ' codeSystem=' '
codeSystemName=' '/>
             </actDefinition>
           </component2>
           <!-- zero or more components containing "sub-guidelines" that make
up this guideline -->
           <component3 typeCode='COMP'>
             <!-- The content model for "sub-guidelines" is as for a guideline,
with the exception
```



```
            that it need not contain an id, title, text, statusCode, or
effectiveTime element.  -->
          </component3>
        </guideline>
      </definition>
    </carePlan>
  </component>
</careProvisionEvent>
```

The <careProvisionEvent> elements sent by a Guideline Notification transaction, or returned in a Request Guideline Data transaction represent activations or replacements of guidelines. As such these elements shall not contain any of the following participants:

- The <careProvisionEvent> element SHALL NOT contain a <recordTarget>, as guidelines are not specific to a single patient record.
- The <careProvisionEvent> element SHALL NOT contain a <subject> element, as guidelines are not specific to a device being maintained.

The <careProvisionEvent> may contain other participants not otherwise prohibited above.

Furthermore, these elements shall not contain any of the following relationships which would be only relevant to a single patient:

- The <careProvisionEvent> element SHALL NOT contain a <pertinentInformation2> element.
- The <careProvisionEvent> element SHALL NOT contain a <pertinentInformation3> element.

Furthermore, the <careProvisionEvent> element SHOULD NOT contain a <pertinentInformation1> element, as this information is not directly relevant to the guideline being retrieved.

The <careProvisionEvent> may contain other relationships not otherwise prohibited above, but the use of these elements is not described in this profile.


```
<rule context='hl7:careProvisionEvent[not(../hl7:replacementOf)]'>
  <assert test='count(hl7:component) = 1'>
    A careProvisionEvent shall have only one component containing the
guideline.
  </assert>
  <assert test='not(hl7:recordTarget)'>
    The careProvisionEvent shall not contain a recordTarget element.
  </assert>
  <assert test='not(hl7:subject)'>
    The careProvisionEvent shall not contain a subject element.
  </assert>
  <assert test='not(hl7:pertinentInformation1)'>
    Warning: The careProvisionEvent should not contain a pertinentInformation1
element.
  </assert>
  <assert test='not(hl7:pertinentInformation2)'>
    The careProvisionEvent shall not contain a pertinentInformation2 element.
  </assert>
  <assert test='not(hl7:pertinentInformation3)'>
    The careProvisionEvent shall not contain a pertinentInformation3 element.
  </assert>
</rule>
```

3.8.5.6.2 <replacementOf typeCode='RPLC' contextControlCode='OP' contextConductionInd='false'> <careProvisionEvent classCode='PCPR' moodCode='EVN'> <id root=' ' extension=' '/>

When a Guideline Notification transaction sends a replacement notification, the <careProvisionEvent> that references the guideline being replaced shall be identified in the <replacementOf> element. The <replacementOf> element shall contain a single <careProvisionEvent> element that shall contain the an <id> element giving the unique identifier of the <careProvisionElement> that was replaced, and which should not contain any other elements.

```
<rule context='/hl7:REPC_IN004913UV'>
  <assert test='hl7:careProvisionEvent/hl7:replacementOf'>
    A replacement transaction shall contain a replacementOf element identifying
    the careProvisionEvent being replaced.
  </assert>
</rule>
<rule context='hl7:replacementOf/hl7:careProvisionEvent'>
  <assert test='hl7:id'>
    The careProvisionEvent that is being replaced shall contain an id element.
  </assert>
  <assert test='not(hl7:*[local-name() != "id"])'>
    Warning: The careProvisionEvent that is being replaced should not contain
anything other than an id element.
  </assert>
</rule>
```

3.8.5.6.3 <component typeCode='COMP'> <carePlan classCode='PCPR' moodCode='INT'>

A <careProvisionEvent> shall have only one <component> element, containing only one <carePlan>, represented exactly as shown above.


```
<rule context='hl7:careProvisionEvent/hl7:component'>
  <assert test='count(hl7:carePlan) = 1'>
    The component of the careProvisionEven shall have one and only one carePlan
element.
  </assert>
</rule>
```

3.8.5.6.4 <definition typeCode='INST' contextControlCode='OP' contextConductionInd='false'> <guideline classCode='PCPR' moodCode='DEF'>

The <carePlan> element shall be empty of all participants and relations with the exception of the <definition> of the <carePlan>. The <definition> element contains one and only one <guideline>.

```
<rule context='hl7:carePlan'>
  <assert test='not(*[local-name() != "definition"])'>
    The carePlan element shall be empty of all participants and relations with
the exception of the definition element.
  </assert>
  <assert test='count(hl7:definition) = 1'>
    The carePlan element shall have one and only one definition element.
  </assert>
</rule>
<rule context='hl7:definition'>
  <assert test='count(hl7:guideline) = 1'>
    The definition element shall have one and only one guideline element.
  </assert>
</rule>
```

3.8.5.6.5 <id root=' ' extension=' '/>

Top level guidelines shall have a unique identifier.

```
<rule context='hl7:definition/hl7:guideline'>
  <assert test='hl7:id'>
    A top level guideline shall have an id element.
  </assert>
</rule>
```

3.8.5.6.6 <title></title>

Top level guidelines shall have a title.

```
<rule context='hl7:definition/hl7:guideline'>
  <assert test='hl7:title'>
    A top level guideline shall have a title element.
  </assert>
</rule>
```

3.8.5.6.7 <text></text>

All guidelines may contain narrative text describing the guideline.

3.8.5.6.8 <statusCode code='active|obsolete'/>

Top level guidelines shall have a statusCode value that is either "active" or "obsolete".


```
<rule context='hl7:definition/hl7:guideline'>
  <assert test='hl7:statusCode'>
    A top level guideline shall have a statusCode element.
  </assert>
</rule>
<rule context='hl7:guideline/hl7:statusCode'>
  <assert test='@code="active" or @code="obsolete"'>
    The statusCode/@code attribute shall be either "active" or "obsolete".
  </assert>
<rule>
```

3.8.5.6.9 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>

Top level guidelines shall contain an <effectiveTime> element that records the time period over which the guideline is effective. It shall contain a <low> element recording at the very least the date upon which the guideline was activated. An obsolete guideline shall contain a <high> element recording the last date upon which the guideline was effective. An active guideline may record the date upon which the guideline is expected to be revised.

```
<rule context='hl7:definition/hl7:guideline'>
  <assert test='hl7:effectiveTime'>
    A top level guideline shall have a effectiveTime element.
  </assert>
</rule>
<rule context='hl7:guideline/hl7:effectiveTime'>
  <assert test='hl7:low and hl7:low/@value'>
    The effectiveTime element shall contain a low element containing a value
attribute indicating the time at which
    the guideline became effective.
  </assert>
<rule>
<rule
context='hl7:guideline[hl7:statusCode/@code="obsolete"]/hl7:effectiveTime'>
  <assert test='hl7:high and hl7:high/@value'>
    The effectiveTime element in an obsolete guideline shall contain a high
element containing a value attribute
    indicating the time at which the guideline became ineffective.
  </assert>
<rule>
```

3.8.5.6.10 <component2 typeCode='COMP'>

All guidelines are composed (at some level) of one or more definitions for acts of care which are to be monitored by a Care Manager and reported upon by a Clinical Data Source during the provision of care. These may include various observations performed (e.g., Hemoglobin A1C tests), medications or immunizations given or prescribed, procedures performed (e.g., foot care), encounters performed (e.g., eye exam), or other acts of care not elsewhere described above.


```
<rule context='hl7:guideline'>
  <assert test='count(.//hl7:component2/hl7:*[@moodCode='DEF']) > 0'>
    At least one act of care must be defined at some level beneath a guideline
element.
  </assert>
</rule>
```

3.8.5.6.11 <observationDefinition classCode='OBS' moodCode='DEF'>

3.8.5.6.12 <substanceAdministrationDefinition classCode='SBADM' moodCode='DEF'>

3.8.5.6.13 <procedureDefinition classCode='PROC' moodCode='DEF'>

3.8.5.6.14 <encounterDefinition classCode='ENC' moodCode='DEF'>

3.8.5.6.15 <actDefinition classCode='ACT' moodCode='DEF'>

One of the above definitions of an act of care found in sections 3.8.5.6.11 through 3.8.5.6.15 shall be present in a <component2> element.

3.8.5.6.16 <templateId root=' ' extension=' '/>

Each act of care to be monitored shall indicate the identifier of the template used to report information on that act.

```
<rule context='hl7:component2/hl7:*[@moodCode='DEF']'>
  <assert test='hl7:templateId'>
    A templateId element must appear in the definition.
  </assert>
</rule>
```

A Guideline Manager actor shall use one the IHE Template identifiers specified for PCC-1 under careProvisionCode to request information profiled in an IHE template to be returned in a PCC-10 transaction. A Clincial Data Source implementing the Care Record option shall report activites to the Care Manager using the Care Record Query Response message using the template identified.

A Guideline Manager actor may include an ActDefinition in the <guideline> to identify the HL7 Version 2 Message Profile to describe the data to be monitored by a Care Manager. A Clinical Data Source implementing the HL7 Version 2 option shall report activities to the Care Manager using the HL7 Version 2 message identified by those ActDefinition elements.

3.8.5.6.17<id root=' ' extension=' '/> <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

Each act of care to be monitored shall contain an identifier for the definition of the act. It shall also contain a code element describing the specific act of care to be monitored. Other features of the specific act allowed by the standard may be provided by the Guideline Manager to further identify the specific acts of care that a Care Manager wants

to receive (e.g., routeCode, targetSiteCode). A Clinical Data Source may use these additional features to limit the number of items it reports, but is not required to review any feature other than the "code" element when making its reports. The Care Manager is expected to use its decision support capabilities to ignore reports that are not relevant to its decision making processes.

```
<rule context='hl7:component2/hl7:*[@moodCode='DEF']'>
  <assert test='hl7:id'>
    An id element must appear in the definition.
  </assert>
  <assert test='hl7:code'>
    An code element must appear in the definition.
  </assert>
</rule>
```

A Clinical Data Source implementing the Care Record Option shall report care activities that meet the definitions in the guideline to the Care Manager using the clinical statement templates specified in PCC-10.

A Clinical Data Source implementing the HL7 Version 2 Option shall report care activities that meet the definitions in the guideline to the Care Manager using the clinical statement templates specified in PCC-11.

3.8.5.6.18 <component3 typeCode='COMP'>

Guidelines may cover different phases (e.g., pre-operative, post-operative) or perspectives of care (e.g., patient education, diet, medications). A guideline can therefore be constructed of other guideline components, which follow the same pattern as for the top level guideline in the careProvisionEvent, except that these subcomponents need not have a unique identity, a title, a status, or effective time.

3.8.5.6.19 <parameterList>

The <parameterList> shall be present, and shall contain content that is identical to the <parameterList> passed in the query.

3.8.5.7 Expected Actions -- Data Repository

The Data Repository shall send a response as specified in the QUPC_IN043200UV interaction. The message shall be sent using web services as specified in the ITI-TF: Appendix V.

The name of the query response message shall be QUPC_IN043200UV_Message in the WSDL. The following WSDL snippet defines the type for this message:


```
<types>
   <xsd:schema elementFormDefault="qualified"
     targetNamespace="urn:hl7-org:v3" xmlns:hl7="urn:hl7-org:v3">
     <xsd:import namespace="urn:hl7-org:v3"
       schemaLocation="QUPC_IN043200UV.xsd"/>
     <xsd:element name="QUPC_IN043200UV"/>
   </xsd:schema>
 </types>
```

The message type is declared to be of the appropriate type by the following WSDL snippet:

```
<message name='QUPC_IN040200UV_Message'>
   <part element='hl7:QUPC_IN040200UV' name="Body"/>
 </message>
```

Other declarations required for this transaction are defined under the WSDL Declarations Section below.

3.8.5.7.1 Response to a New Query

The Guideline Manager, shall:

1. Recieve and validate the query message.
2. Create the response message.
3. Add an ILLEGAL detected issue alert to the response message if the content is invalid (e.g., does not pass schema validation or is otherwise malformed), and immediately return a response indicating the error, and that the query was aborted. Set the text of the alert to the name of the first data element that is not valid. The Guideline Manager may send more than one ILLEGAL detected issue alert if it is able to determine that multiple data elements in the query are not valid.
4. Add a NAT detected issue alert to the response message if the requesting party is not authorized to perform the query, and immediately return a response indicating the error, and that the query was aborted.
5. Add a ILLEGAL detected issue alert to the response message if the the data repository does not recognize the identity domain used to identify the guideline. Set the text value on the alert to careRecordId.
6. If any issues were detected, Set queryAck/statusCode/@code to aborted, and queryAct/queryResponse/@code to QE, and return the response.
7. Add an ISSUE alert to the response message if at any time during response generation, an application error occurs that prevents further processing. Set the text of the alert to the reason for the application error (e.g., a stack trace or exception message). Set queryAct/statusCode/@code to aborted, and queryAct/responseCode/@code to AE, and return the response.
8. Query for the guideline requested by the query.

9. If results are found, set queryAct/queryResponse/@code to OK, otherwise set it to NF.
10. Set queryAck/statusCode/@code to deliveredResponse.
11. Add the result to the response.

3.8.5.7.2 Raising Alerts

If the content of the request is not valid (e.g., according to the Schema or the rules of this profile), at least on ILLEGAL alert shall be raised indicating the data element that was invalid. A response will be sent indicating that the request was invalid, and no further processing shall be performed.

If the requesting party is not authorized to perform the query, the minimum response shall be sent indicating only that the requested is not authorized to perform the query.

In other cases, all possible alerts shall be accumulated before returning a response to the caller.

This enables Clinical Data Consumer actors to send a test query that will enable them to verify the vocabulary and other request parameters that are desired.

An alert is raised by sending a response containing one or more <reasonOf> elements, coded as shown below.

```
<reasonOf>
  <detectedIssueEvent>
    <code code='' displayName='' codeSystem='' codeSystemName=''/>
    <text></text>
    <mitigatedBy>
      <detectedIssueManagement moodCode="RQO">
        <code code='' displayName='' codeSystem='' codeSystemName=''/>
        <text></text>
      </detectedIssueManagement>
    </mitigatedBy>
  </detectedIssueEvent>>
</reasonOf>
```

3.8.5.7.3 <reasonOf>

The <reasonOf> element is required to indicate that an alert has occured.

3.8.5.7.4 <detectedIssueEvent>

The details of the alert shall be present in the <detectedIssueEvent> element.

3.8.5.7.5 <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode'/>

The <code> element shall contain ISSUE or one of its descendants from the HL7 ActCode vocabulary.

3.8.5.7.6 <text></text>

If a validation or other business rule error occurred, the erroneous parameter shall be identified in <text> element using the element name, and nothing else should be present.

If an application error occured, the <text> element shall contain diagnostic information (e.g., stack trace or exception message).

If the reason for the alert was an unrecognized code (CODE_INVALID), the text element shall contain the name of the erroneous parameter, and may contain a space separated list of OIDs identifying value sets which would be valid.

If the reason for the alert was an unrecognized identifier (KEY204) for the vocabulary used in the careProvisionCode or careProvisionReason element, the text element shall contain the name of the erroneous paramater, and may contain a space separated list of the OIDs for code systems which would be valid.

3.8.5.8 Expected Actions -- Clinical Data Consumer

The Care Manager or Clinical Data Source processes the query response data. No additional data other than the single requested guideline will be returned, so no provision is made in this profile for continuations or canceling the query.

3.8.6 WSDL Declarations

The following WSDL naming conventions SHALL apply for this transaction:

WSDL Item	Value
wsdl:definitions/@name	GuidelineManger
Get Care Record Query	QUPC_IN040100UV_Message
Get Care Record Query Response	QUPC_IN040200UV_Message
portType	GuidelineManger_PortType
Query Operation	GuidelineManger_QUPC_IN043100UV
SOAP 1.1 binding	GuidelineManger_Binding_Soap11
SOAP 1.1 port	GuidelineManger_Port_Soap11
SOAP 1.2 binding	GuidelineManger_Binding_Soap12
SOAP 1.2 port	GuidelineManger_Port_Soap12

The following WSDL snippets specify the Port Type and Binding definitions, according to the requirements specified in ITI TF-2: Appendix V. A full WSDL example for the Guideline Manger actor can be found at ftp://ftp.ihe.net/TF_Implementation_Material/PCC/GuidelineManager.wsdl. For a general description of the WSDLs for Care Management see the Appendix of the same name in this volume.

3.8.6.1 Port Type

```
<portType name="GuidelineManger_PortType">
 <operation name="GuidelineManger_QUPC_IN040100UV">
   <input message="tns:QUPC_IN040100UV_Message"
     wsaw:Action="urn:hl7-org:v3:QUPC_IN040100UV"/>
   <output message="tns:QUPC_IN040200UV_Message"
     wsaw:Action="urn:hl7-org:v3:QUPC_IN040200UV "/>
 </operation>
</portType>
```

3.8.6.2 Bindings

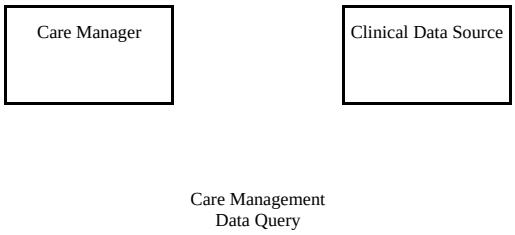
```
<binding name="GuidelineManger_Binding_Soap12"
   type="GuidelineManger_PortType">
 <wsoap12:binding style="document"
   transport="http://schemas.xmlsoap.org/soap/http"/>
 <operation name="GuidelineManger_QUPC_IN043100UV">
   <wsoap12:operation soapAction="urn:hl7-org:v3:QUPC_IN040100UV"/>
   <input>
     <wsoap12:body use="literal"/>
   </input>
   <output>
     <wsoap12:body use="literal"/>
   </output>
 </operation>
</binding>
<binding name="GuidelineManger_Binding_Soap11"
   type="GuidelineManger_PortType">
 <wsoap11:binding style="document"
   transport="http://schemas.xmlsoap.org/soap/http"/>
 <operation name="GuidelineManger_QUPC_IN040100UV">
   <wsoap11:operation soapAction="urn:hl7-org:v3:QUPC_IN040100UV"/>
   <input>
     <wsoap11:body use="literal"/>
   </input>
   <output>
     <wsoap11:body use="literal"/>
   </output>
 </operation>
</binding>
```

3.9 Care Management Data Query

This section corresponds to Transaction PCC-9 of the IHE Patient Care Coordination Technical Framework. Transaction PCC-9 is used by the Care Manager and Clinical Data Source Actors.

Transaction PCC-9 is a variation of the pattern used in transaction PCC-1 of the PCC Technical Framework. Information specific to this transaction is described in futher detail below in the section on Domain Content.

3.9.1 Use Case Roles



Actor

Care Manager

Role

Requests a collection of clinical data matching the selection criteria from the Clinical Data Source.

Cooresponding HL7 Version 3 Application Roles

Care Record Query Placer (QUPC_AR004030UV)
Query by Parameter Placer (QUQI_AR000001UV01)

Actor

Clinical Data Source

Role

Acknowledges the query. Returns clinical data subsequently matching the query selection criteria supplied by the Care Manager actor using a PCC-10 or PCC-11 transaction.

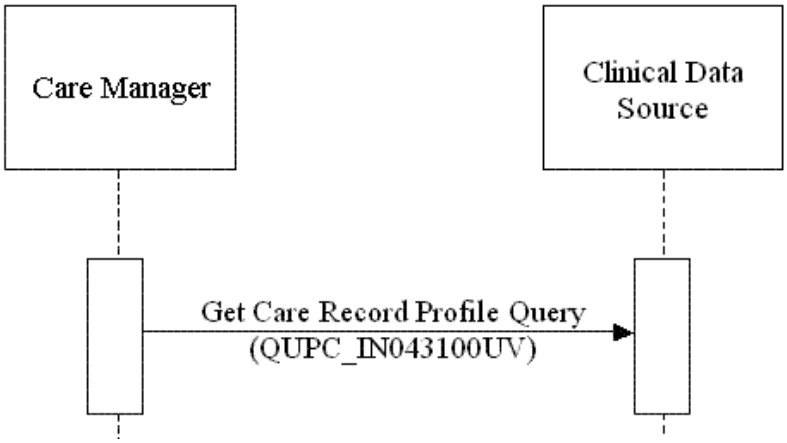
Cooresponding HL7 Version 3 Application Roles

Care Record Query Fulfiller (QUPC_AR004040UV)
Query by Parameter Fulfiller (QUQI_AR000002UV01)

3.9.2 Referenced Standards

CareRecord	HL7 Care Provision Care Record (DSTU)
CareQuery	HL7 Care Provision Care Record Query (DSTU)
HL7QI	HL7 Version 3 Standard: Infrastructure Management – Query Infrastrucure
HL7WS	HL7 Version 3 Standard: Transport Specification - Web Services Profile, Release
SOAP	Simple Object Access Protocol Version 1.1 (SOAP 1.1)
SOAP12	Simple Object Access Protocol Version 1.2 (SOAP 1.2)

3.9.3 Interaction Diagrams



3.9.4 Get Care Record Profile Query

3.9.4.1 Trigger Events

When the Care Manager needs to obtain information about a patient or population it will trigger a Get Care Record Care Profile event. This cooresponds to the HL7 trigger event: QUPC_TE043100UV

3.9.4.2 Message Semantics

The Query Care Record Event Profile Query corresponds to the HL7 Interaction QUPC_IN043100UV.

A schema for this interaction can be found at: http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUPC_IN043100UV.xsd. This schema includes:

- the transmission wrapper MCCI_MT000100UV01,
- the control act wrapper QUQI_MT020001UV01, and
- the message payload QUPC_MT040100UV.

These components of the interaction are specified in the HL7 standards described above.

3.9.4.3 Transmission Wrapper

The transmission wrapper for PCC-9 is nearly identical to the transmission wrapper used in PCC-1, and appears below.

The transmission wrapper MCCI_MT000100UV01 provides information about the message transmission and routing. Transmission wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.


```
<QUPC_IN043100UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0"
                 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
 <id root=' ' extension=' '/>
 <creationTime value=' '/>
 <interactionId extension='QUPC_IN043100UV' root='2.16.840.1.113883.5'/>
 <processingCode code='D|P|T'/>
 <processingModeCode code='T'/>
 <acceptAckCode code='AL'/>
 <receiver typeCode="RCV">
   <device determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </receiver>
 <sender typeCode="SND">
   <device determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </sender>
 <respondTo typeCode="RSP">
   <entityRsp determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' '/>
   </entityRsp>
 </respondTo><controlActProcess>
  See Control Act Wrapper below
 </controlActProcess>
</QUPC_IN043100UV>
```

3.9.4.3.1 <QUPC_IN043100UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">

The HL7 Interaction being sent will control the name of the root element in the message. The namespace of this message shall be urn:hl7-org:v3, and the ITSVersion attribute shall be "XML_1.0".

3.9.4.3.2 <interactionId extension='QUPC_IN043100UV' root='2.16.840.1.113883.5'/>

The identifer for the interaction shall be sent as shown above.

3.9.4.3.3 <processingModeCode code='T'/>

The processingModeCode distinguishes the type of processing being performed. This element shall be present and have the value shown above to indicate that this message is for current processing.

3.9.4.3.4 <acceptAckCode code='AL'/>

The acceptAckCode indicates whether the sender wants to recieve an acknowledgement, and shall be sent as shown above.

3.9.4.3.5 <respondTo typeCode="RSP"> <entityRsp determinerCode="INSTANCE"> <id/> <name/> <telecom value=' '/>

When a query is made that requires a V2 message in response, the reciever will need to know the network address and port to use for sending the V2 response to the query. This element shall be used in queries that are requesting a response in HL7 Version 2 format to indicate the destination of the response. The server and port address where the response is being sent shall appear in a URI in the value attribute of the <telecom> element. .

3.9.4.4 Control Act Wrapper

The control act wrapper QUQI_MT020001UV01 provides information about the business actors related to the transaction, including the author or performer of the act. Control act wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction. The controlActProcess element defined for this transaction nearly identical to the same element defined in PCC-1, with variations in the **responsePriorityCode**, **responseModalityCode**, and **executionAndDeliveryTime** elements.


```
<controlActProcess moodCode="RQO">
  <id root=' ' extension=' '/>
  <code code='QUPC_TE043100UV'/>
  <effectiveTime value=' '/>
  <languageCode code=' '/>
  <authorOrPerformer typeCode=' '></authorOrPerformer>

  <queryByParameter>
    <id root=' ' extension=' '/>
    <statusCode code='new'/>
    <responseModalityCode code='R'/>
    <responsePriorityCode code='D'/>
    <initialQuantity value=/>
    <initialQuantityCode code='REPC_RM000100UV'
codeSystem='2.16.840.1.113883'/>
    <parameterList>
      see Query Parameter List below
    </parameterList>
  </queryByParameter>
</controlActProcess>
```

3.9.4.4.1 <controlActProcess moodCode="RQO">

The controlActProcess element is where information about the business act being performed is recorded. The moodCode is set to "RQO" by the sender to indicate a request to perform an action, in this case, a query.

3.9.4.4.2 <code code='QUPC_TE043100UV'/>

The trigger event which caused the act to be transmitted is recorded in the code element is recorded as shown above.

3.9.4.4.3 <queryByParameter>

HL7 Version 3 messages that perform a query specify the details of it in the <queryByParameter> element.

3.9.4.4.4 <id root=' ' extension=' '/>

The sending system shall specify the identifier of the query. This is the identifierr that is used in subsequent continuation or cancel messages.

3.9.4.4.5 <statusCode code='new'/>

When passing the parameter list, the <statusCode> element shall be recorded as above to indicate that this is a new query.

3.9.4.4.6 <responseModalityCode code='R'/>

3.9.4.4.7 The query response shall be in real-time (R) <responsePriorityCode code='D'/>

The query response shall always be deferred. This means that new results shall always be sent using a separate connection when they are available.

3.9.4.4.8 <initialQuantityCode code='REPC_RM000100UV' codeSystem='2.16.840.1.113883.5'>

The <initialQuantityCode> shall be sent when <initialQuantity> is sent. The code shall be the identifier of the HL7 artifact that is to be counted (e.g., R-MIM or C-MET identifer). In this profile what is being counted is clinical statements, so the code to use shall be REPC_RM000100UV.

Please note, the initial response to this query may include a large number of clinical statements providing historical data for the patients selected by the query. The use of initialQuantityCode allows the Care Manager to control the amount of historical data that the Clinical Data Source sends.

For Public Comment	There is some question here about what to do with the acknowledgement, should it be delayed until the Care Manager has processed or stored the information. What happens with the remaining data? Is a continuation required to be sent to alert the Clinical Data Source that it can send more data?

3.9.4.5 Parameter List

The message supports specification of the data items listed in the table below as query parameters. The first column of this table provides the name of the parameter. The next column indicates the number of times it may occur in the query. The next column indicates the type of data expected for the query parameter. The next column indicates the vocabulary domain used for coded values. The Consumer column indicates whether the Care Manager must supply this parameter. The Source column indicates whether the Clinical Data Source must support this parameter.

A Care Manager may supply parameters other than those required by this profile, but must appropriately handle any detected issue alert raised by the Clinical Data Source in its response.

Parameter Name	Cardinality	Data Type	Vocabulary Domain	Consumer	Source
careProvisionCode	0..1	CD		O	R
careProvisionReason	0..*	CD		O	O
careRecordTimePeriod	0..1	IVL<TS>		O	R
clinicalStatementTimePeriod	0..1	IVL<TS>		O	R
includeCarePlanAttachment	0..1	BL		R	R
maximumHistoryStatements	0..1	INT		O	R
patientAdministrativeGender	0..1	CE	AdministrativeGender	O	R
patientBirthTime	0..1	TS		O	R
patientId	1..1	II		R	R
patientName	0..1	PN		O	R

An example of the query specification is described in the figure below.


```
<parameterList>
   <careProvisionCode>
     <value code=' ' displayName=' ' codeSystem=' ' codeSystemName=/>
   </careProvisionCode>
   <careProvisionReason>
     <value code=' ' displayName=' ' codeSystem=' ' codeSystemName=/>
   </careProvisionReason>
   <careRecordTimePeriod>
     <value><low value=' '/><high value=' '/></value>
   </careRecordTimePeriod>
   <clinicalStatementTimePeriod>
     <value><low value=' '/><high value=' '/></value>
   </clinicalStatementTimePeriod>
   <includeCarePlanAttachment><value
value='true|false'/></includeCarePlanAttachment>
   <maximumHistoryStatements><value value=' '/></maximumHistoryStatements>
   <patientAdministrativeGender>
     <value code=' ' displayName=' '
       codeSystem='2.16.840.1.113883.5.1'
codeSystemName='AdministrativeGender'/>
   </patientAdministrativeGender>
   <patientBirthTime><value value=' '/></patientBirthTime>
   <patientId><value root=' ' extension=' '/></patientId>
   <patientName><value></value></patientName>
 </parameterList>
```

3.9.4.5.1 <parameterList>

The <parameterList> element shall be present, and contains the set of query parameters being used in this query.

3.9.4.5.2 <careProvisionCode><value code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/></careProvisionCode>

This <careProvisionCode> may be present. This element describes the information that is being looked for in the <value> element. When the <careProvisionCode> element is not present, it indicates that all relevant results are to be reported up to the maximum number specified in maximumHistoryStatements for each result. To obtain results that have not been coded, the <value> element may be specified with a nullFlavor attribute. There are various *flavors* of NULL defined in the HL7 NullFlavor vocabulary. A query for results coded using a specific flavor of null shall return all flavors of null that are equal to, or subordinate to that flavor of null within the HL7 hierarchy of null flavors.

A Care Manager can restrict the results returned in the query by setting the value attribute of <value> element in the <careProvisionCode> element to a code identifying the clinical data to be returned. A Clinical Data Source can use the codes specified in the sections below to obtain different kinds of clinical data. A Care Manager shall be able to issue queries using at least those codes listed in the table below. A Clinical Data Source must support all codes listed in the table below.

Information Category	Code	Returns	Template Id
Vital Signs	COBSCAT	All Vital Signs	Vital Signs Observation

	Any Code from the Vital Signs Table in the Vital Signs Observation	The vital sign identified by the code	Vital Signs Observation
Problems and Allergies	MEDCCAT	All problem entries	Problem Entry
	CONDLIST	All Concern Entries	Concern Entry
	PROBLIST	All Problem Concerns	Problem Concern
	INTOLIST	All Allergy Concerns	Allergy and Intolerance Concern
	RISKLIST	All Risks[1]	Concern Entry
Diagnostic Results	LABCAT	All Lab Results	Simple Observations
	DICAT	All Imaging Results	Simple Observations
Medications	RXCAT	All Medications	Medications
	MEDLIST	All Medications	Medications
	CURMEDLIST	All active medications	Medications
	DISCHMEDLIST	Discharge Medications	Medications
	HISTMEDLIST	All Historical Medications	Medications
Immunizations	IMMUCAT	All Immunizations	Immunizations
Professional Services	PSVCCAT	All professional service entries	Encounters Procedures Entry

A Care Manager Actor may make requests using other codes not specified above to obtain other clinical data, but these are not guaranteed to be supported by the Clinical Data Source actor.

Note: Implementors of a Care Manager or Clinical Data Source actors shall publish an HL7 Conformance Profile that indicates the vocabularies and code sets that they support for this transaction.

Note: Clinical Data Sources that are grouped with Content Creators are required to support the vocabulary used within the templates defining the content being created!

Querying for Substances

Often, a query needs to identify a particular substance, such as in the case for a query about the use of a specific medication, immunization, or allergy to a given substance. To support these queries, IHE requires that Clinical Data Sources that can respond to queries using appropriate vocabularies for substances use the following form:

```
<value code='DRUG|IMMUNIZE|INTOL' displayName=' '
codeSystem='1.3.5.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode'>
  <qualifier>
    <name code='SUBSTANCE|SUBSTCLASS'/>
    <value code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
  </qualifier>
</value>
```

3.9.4.5.3 <value code='DRUG|IMMUNIZE|INTOL' displayName=' ' codeSystem='1.3.5.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode'>

The <value> element expresses in the code attribute whether the act being queried for is:

Code	Definition
DRUG	Treatment with a specific drug
IMMUNIZ	Immunization of a patient
INTOL	A record of an allergy or intolerance to a substance

One of the values listed above shall be used in the code attribute. The codeSystem shall be recorded as listed above.

3.9.4.5.4 <qualifier><name code='SUBSTANCE|SUBSTCLASS'/>

The <qualifier> element further qualifies the concept being requested. The <name> element indicates whether the substance is being described, or the class of substances is being described.

Code	Definition
SUBSTANCE	The substance used
SUBSTCLASS	A class of substances used

3.9.4.5.5 <value code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

The <value> element inside the <qualifier> describes the substance or class of substances of interest in the query.

3.9.4.5.6 <careProvisionReason><value code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/></careProvisionReason>

This element identifies the reason why the result was recorded. If specified, only those results which are recorded for the specified reason will be returned.

The <value> element of the <careProvisionReason> element may contain a value identifying a specific condition that was the reason for obtaining the result or prescribing the medication or immunization. A Clinical Data Source actor that chooses to honor this query parameter shall return only those results that were for the indicated reason. Should the Clinical Data Source Actor not support the use of the <careProvisionReason> element, it shall indicate this by raising the appropriate alert as decribed in the expected actions recorded in PCC-1.

For Public Comment	For immunizations, there is a desire to identify a specific immunization program that was the reason for the immunization, how might an immunization program be referenced? A code might identify the specific pathogen against which the patient is being immunized, but for public health use, a more discrete question is being asked: What program caused the patient to come in for immunization? This seems to require the ability to query for an identifier.

3.9.4.5.7 <careRecordTimePeriod><value><low value=' '/><high value=' '/></value></careRecordTimePeriod>

This element describes the time period over which the results were recorded. A query could for example, request new entries that have been processed for this patient since the last query request. If specified, only those results that were authored within the specified time period will be returned.

3.9.4.5.8 <clinicalStatementTimePeriod><value><low value=' '/><high value=' '/></value></clinicalStatementTimePeriod>

This element describes the effective time for the clinical statement. If specified, only those results that were effective within the clinical statement effective time will be returned.

The effectiveTime range of the returned clinical statements shall overlap or be wholely contained within the time range described by the <clinicalStatementTimePeriod> element. In the example below, the clinical statements with the effectiveTime values represented by time ranges B, C and D would be returned, while those with effectiveTime values represented by time ranges A and E would not, because they fall outside of the specified <clinicalStatementTimePeriod> value.

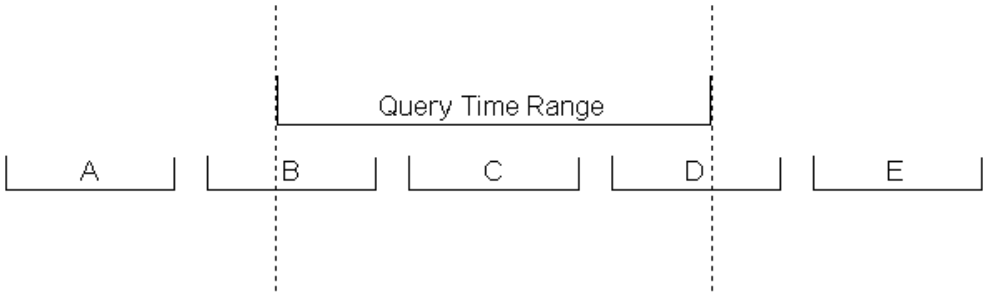


Figure 3.9-1 Effective Time and Clinical Statement Time Period

3.9.4.5.9 <includeCarePlanAttachment><value value='true|false'/></includeCarePlanAttachment>

The <includeCarePlanAttachment> element shall be sent, and must be set to either true or false depending upon whether care plans should be returned or not. A Data Source may choose not to honor this request when the value is set to true, but must then raise a BUS detected issue alert to indicate that this capability is not supported. Note that many data repositories will not associate a care plan attachment with a specific result.

3.9.4.5.10 <maximumHistoryStatements><value value=' '/></maximumHistoryStatements>

This value indicates the maximum number of each type of result that will be returned by the query. No more than the maximum number will be returned. This value is NOT the maximum number of clinical statements returned, rather it is the maximum number of clinical statements returned for individual type of clinical statement specified in the careProvisionCode. Thus, if all results are requested (e.g., all Vital Signs), and maximumHistoryStatements/value/@value = 1, you will receive the most current value for each kind of result requested (e.g., one each of the most recent value for height, weight, blood pressure, tempurature, et cetera).

For Public Comment	Does this parameter have any relevance for the Care Manager Actor?

3.9.4.5.11 <patientAdministrativeGender> <value code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.1' codeSystemName='AdministrativeGender'/>

The patient gender may be provided in the query. If provided, it serves as a verification of the patient identity. The value must match the patient gender of the patient specified in patientId. If the two values do not match, the Clinical Data Source will raise a detected issue alert.

3.9.4.5.12 <patientBirthTime><value value=' '/></patientBirthTime>

The patient birth time may be provided in the query. If provided, it serves as a verification of the patient identity. The value must match the patient birth time of the patient specified in patientId. If the two values do not match, the Clinical Data Source will raise a detected issue alert.

3.9.4.5.13 <patientId><value root=' ' extension=' '/></patientId>

The patient identifier shall be specified in this element. The root and extension attributes shall be present. When used in cross enterprise settings, the root attribute shall the affinity domain identity OID.

Sending a query with a known invalid patientId element can be used to *ping* a Clinical Data Source. For example, setting the root attribute to "0" and omitting the extension attribute should result in a response that raises an ILLEGAL detected issue alert on the patientId field, since the value "0" will never be used as the OID of a patient identity domain. This capability can be used by a Clinical Data Consumer to verify that it can connect to a Clinical Data Source when configuration parameters are modified.

The Care Manager may specify a value of * in the extension attribute of the value element to issue the query against the population of patients.

3.9.4.5.14 <patientName><value></value></patientName>

The patient name may be provided in the query. If provided, it serves as a verification of the patient identity. The value must match the patient name of the patient specified in patientId. If the two values do not match, the Clinical Data Source will raise a detected issue alert. IHE does not specify the algorithm that determines whether the two names match or not. It is expected that the Clinical Data Source will use appropriate application logic to support this capability. An implementation could, for example, use the IHE Patient Demographics Query profile (see ITI TF-1:8) to match the specified patient name and identifier against a list of names and identifiers in

3.9.4.6 Expected Actions -- Care Manager

The Care Manager shall send a query as specified in the QUPC_IN043100UV interaction. The message shall be sent using web services as specified in the ITI-TF: Appendix V. The Care Manager shall send an audit message to the audit log repository indicating that a query was initiated, and the parameters of query that were supplied (see the queryByParameter element above).

3.9.4.7 Expected Actions -- Clinical Data Source

The Clinical Data Source shall send an acknowledgement of the query as specified in the HL7 MCCI_IN000002UV01 interaction in the response to the query message, and shall trigger a QUPC_TE043200UV event to initiate the sending of historical data for all matching patients (see below).

In generating the acknowledgement, the Clinical Data Source shall:

1. Recieve and validate the query message.
2. Create the acknowledgement message.
3. Add an ILLEGAL detected issue alert to the acknowledgement message if the content is invalid (e.g., does not pass schema validation or is otherwise malformed), and immediately return a response indicating the error, and that the query was aborted. Set the text of the alert to the name of the first data element that is not valid. The Clincial Data Source may send more than one ILLEGAL detected issue alert if it is able to determine that multiple data elements in the query are not valid.
4. Add a NAT detected issue alert to the acknowledgement message if the requesting party is not authorized to perform the query, and immediately return a response indicating the error, and that the query was aborted.
5. Add a VALIDAT detected issue alert to the acknowledgement message for each of the patientName, patientGenderCode or patientBirthTime fields specified in the query that do not match the values known by the Clinical Data Source Actor. The text value on the alert shall be set to the name of the parameter that does not match (patientName, patientGenderCode or patientBirthTime).
6. Add a BUS detected issue alert to the acknowledgement message if includeCarePlanAttachment is true, but care plans are not associated with observation values. The text value on the alert shall be set to includeCarePlanAttachment.
7. Add a BUS detected issue alert to the acknowledgement message if a careProvisionReason value is specified, but the Clinical Data Source cannot query by this field. The text value on the alert shall be set to careProvisionReason.
8. Add a KEY204 detected issue alert to the acknowledgement message if any of the vocabulary domains are not recognized by the Clinical Data Source. The text value on the alert shall be set to the name of the query parameter that used the unrecognized vocabulary domain.
9. Add a CODE_INVALID detected issue alert to the acknowledgement message if any of the codes specified are not recognized by the Clinical Data Source. The text value on the alert shall be set to the name of the query parameter that used the unrecognized vocabulary domain.
10. Add a FORMAT detected issue alert to the acknowledgement message if any date ranges are incorrectly formed (low > high). The text value on the alert shall be set to the name of the query parameter that has the error.
11. Add a ILLEGAL detected issue alert to the acknowledgement message if the the Clinical Data Source does not recognize the identity domain used to identify the patient. Set the text value on the alert to patientId.

12. Add a KEY204 detected issue alert to the acknowledgement message if the the Clinical Data Source does not know about the patient. Set the text value on the alert to patientId. This is distinct from having nothing to report. If the patient is recognized but there is no data to report, the result returned should simply have no data. However, if information is requested for a patient that isn't known, then the KEY204 alert shall be raised.

13. Add an appropriate detected issue alert if any parameters otherwise not specified by this profile have been provided, but are not supported by the Clinical Data Source.

14. Add an ISSUE alert to the acknowledgement message if at any time during response generation, an application error occurs that prevents further processing. Set the text of the alert to the reason for the application error (e.g., a stack trace or exception message).

The Clinical Data Source shall send an audit message to the audit log repository indicating that a query was recieved, and the parameters of query that were supplied (see the queryByParameter element above).

The name of the query message shall be QUPC_IN043100UV_Message in the WSDL. The name of the acknowledgement response message shall be MCCI_IN000002UV01 in the WSDL. The following WSDL snippet defines the types used for this transaction:

```
<types>
   <xsd:schema elementFormDefault="qualified"
      targetNamespace="urn:hl7-org:v3" xmlns:hl7="urn:hl7-org:v3">
    <!-- Include the message schema -->
    <xsd:include namespace="urn:hl7-org:v3"
schemaLocation="QUPC_IN043100UV.xsd"/>
    <xsd:include namespace="urn:hl7-org:v3"
schemaLocation="MCCI_IN000002UV01.xsd"/>
  </xsd:schema>
</types>
```

The message type is declared to be of the appropriate type by the following WSDL snippet:

```
<message name='QUPC_IN043100UV_Message'>
  <part element='hl7:QUPC_IN043100UV' name="Body"/>
</message>
<message name='MCCI_IN000002UV01_Message'>
  <part element='hl7:MCCI_IN000002UV01' name="Body"/>
</message>
```

3.9.5 WSDL Declarations

The following WSDL naming conventions SHALL apply for this transaction:

WSDL Item	Value
wsdl:definitions/@name	CareManger
Get Care Record Query	QUPC_IN043100UV_Message
Message Acknowledgement	MCCI_IN000002UV01 _Message

portType	CareManger_PortType
Query Operation	CareManger_QUPC_IN043100UV
SOAP 1.1 binding	CareManger_Binding_Soap11
SOAP 1.1 port	CareManger_Port_Soap11
SOAP 1.2 binding	CareManger_Binding_Soap12
SOAP 1.2 port	CareManger_Port_Soap12

The following WSDL snippets specify the Port Type and Binding definitions, according to the requirements specified in ITI TF-2: Appendix V. A full WSDL example for the Care Manger actor can be found at ftp://ftp.ihe.net/TF_Implementation_Material/PCC/GuidelineManager.wsdl. For a general description of the WSDLs for Care Management see the Appendix of the same name in this volume.

3.9.5.1 Port Type

```
<portType name="CareManger_PortType">
 <operation name="CareManger_QUPC_IN040100UV">
   <input message="tns:QUPC_IN040100UV_Message"
     wsaw:Action="urn:hl7-org:v3:QUPC_IN040100UV"/>
   <output message="tns:QUPC_IN040200UV_Message"
     wsaw:Action="urn:hl7-org:v3:QUPC_IN040200UV "/>
 </operation>
</portType>
```

3.9.5.2 Bindings

```
<binding name="CareManger_Binding_Soap12"
   type="CareManger_PortType">
 <wsoap12:binding style="document"
   transport="http://schemas.xmlsoap.org/soap/http"/>
 <operation name="CareManger_QUPC_IN043100UV">
   <wsoap12:operation soapAction="urn:hl7-org:v3:QUPC_IN043100UV"/>
   <input>
     <wsoap12:body use="literal"/>
   </input>
   <output>
     <wsoap12:body use="literal"/>
   </output>
 </operation>
</binding>
<binding name="CareManger_Binding_Soap11"
   type="CareManger_PortType">
 <wsoap11:binding style="document"
   transport="http://schemas.xmlsoap.org/soap/http"/>
 <operation name="CareManger_QUPC_IN043100UV">
   <wsoap11:operation soapAction="urn:hl7-org:v3:QUPC_IN043100UV"/>
   <input>
     <wsoap11:body use="literal"/>
   </input>
   <output>
     <wsoap11:body use="literal"/>
   </output>
 </operation>
</binding>
```

3.10 V3 Care Management Update

This section corresponds to Transaction PCC-10 of the IHE Patient Care Coordination Technical Framework. Transaction PCC-10 is used by the Care Manager and Clinical Data Source Actors.

Transaction PCC-10 is a variation of the pattern used in transaction PCC-1 of the PCC Technical Framework. Information specific to this transaction is described in futher detail below in the section on Domain Content.

3.10.1 Use Case Roles

V3 Care Management Update

Actor

Care Manager

Role

Recieves a collection of clinical data matching the selection criteria in a prior PCC-9 transaction from the Clinical Data Source.

Cooresponding HL7 Version 3 Application Roles

Care Record Query Placer (QUPC_AR004030UV)
Query by Parameter Placer (QUQI_AR000001UV01)

Actor

Clinical Data Source

Role

Sends a collection of clinical data matching the selection criteria in a prior PCC-9 transaction from the Clinical Data Source.

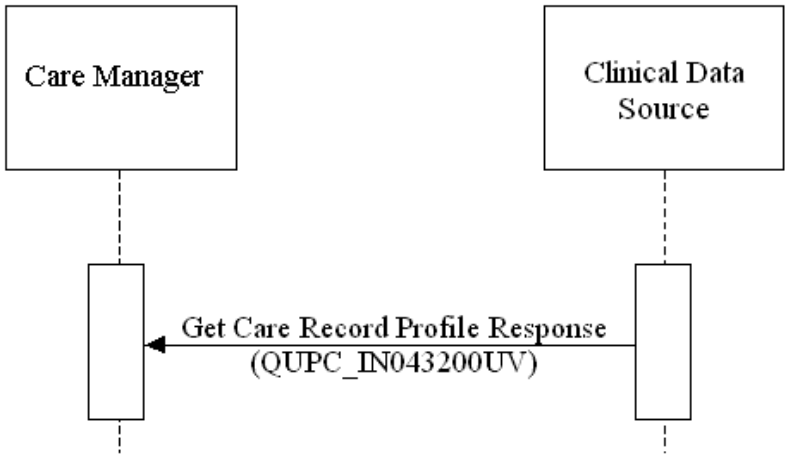
Cooresponding HL7 Version 3 Application Roles

Care Record Query Fulfiller (QUPC_AR004040UV)
Query by Parameter Fulfiller (QUQI_AR000002UV01)

3.10.2 Referenced Standards

CareRecord	HL7 Care Provision Care Record (DSTU)
CareQuery	HL7 Care Provision Care Record Query (DSTU)
HL7QI	HL7 Version 3 Standard: Infrastructure Management – Query Infrastrucure
HL7WS	HL7 Version 3 Standard: Transport Specification - Web Services Profile, Release
SOAP	Simple Object Access Protocol Version 1.1 (SOAP 1.1)
SOAP12	Simple Object Access Protocol Version 1.2 (SOAP 1.2)

3.10.3 Interaction Diagrams



3.10.4 Get Care Record Profile Response

3.10.4.1 Trigger Events

This message is triggered upon a change to data matching a query specified in a prior PCC-9 transaction. This corresponds to HL7 trigger event: QUPC_TE043200UV

3.10.4.2 Message Semantics

The Get Care Record Profile Response corresponds to the HL7 Interaction QUPC_IN043200UV. A schema for this interaction can be found at: http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUPC_IN043200UV.xsd. This schema includes:

- the transmission wrapper MCCI_MT000300UV01,
- the control act wrapper MFMI_MT700712UV01, and
- the message payload REPC_MT004000UV.

These components of the interaction are specified in the HL7 standards described above.

3.10.4.3 Transmission Wrapper

The transmission wrapper MCCI_MT000300UV01 provides information about the message transmission and routing. Transmission wrappers are further described in ITI TF-2: Appendix O.

An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction. This message wrapper is similar to the transmission wrapper used for the same interaction in PCC-1, save that the acceptAckCode is different.


```
<QUPC_IN043200UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0"
                 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
 <id root=' ' extension=' '/>
 <creationTime value=' '/>
 <interactionId extension='QUPC_IN043200UV' root='2.16.840.1.113883.5'/>
 <processingCode code='D|P|T'/>
 <processingModeCode code='T'/>
 <acceptAckCode code='AL'/>
 <receiver typeCode="RCV">
   <device determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </receiver>
 <sender typeCode="SND">
   <device determinerCode="INSTANCE">
     <id/>
     <name/>
     <telecom value=' ' />
     <manufacturerModelName/>
     <softwareName/>
   </device>
 </sender>
 <controlActProcess>
  See Control Act Wrapper below
 </controlActProcess>
</QUPC_IN043200UV>
```

3.10.4.3.1<QUPC_IN043200UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">

The HL7 Interaction being sent will control the name of the root element in the message. The namespace of this message shall be urn:hl7-org:v3, and the ITSVersion attribute shall be "XML_1.0".

3.10.4.3.2<interactionId extension='QUPC_IN043200UV' root='2.16.840.1.113883.5'/>

The identifer for the interaction shall be sent as shown above.

3.10.4.3.3<processingModeCode code='T'/>

The processingModeCode distinguishes the type of processing being performed. This element shall be present and have the value shown above to indicate that this message is for current processing.

3.10.4.3.4<acceptAckCode code='AL'/>

The acceptAckCode indicates whether the reciever wants to recieve an acknowledgement, and shall be sent as shown above. Query responses in this transaction shall require an acknowledgement.

3.10.4.4 Control Act Wrapper

The control act wrapper MFMI_MT700712UV01 provides information about the business actors related to the transaction, including the author or performer of the act. Control act wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

```
<controlActProcess moodCode="EVN">=
  <id root=' ' extension=' '/>
  <code code='QUPC_TE043200UV'/>
  <effectiveTime value=' '/>
  <languageCode code=' '/>
  <authorOrPerformer typeCode=' '></authorOrPerformer>
  <subject>
     See Query Response below
  </subject>
  <queryAck>
    <queryId root=' ' extension=' '/>
    <statusCode code=' '/>
    <queryResponseCode code=' '/>
    <resultCurrentQuantity value=' '/>
    <resultRemainingQuantity value=' '/>
  </queryAck>
</controlActProcess>
```

3.10.4.4.1<controlActProcess moodCode="EVN">

The controlActProcess element is where information about the business act being performed is recorded. The moodCode is set to "EVN" by the sender to indicate a response to a query.

3.10.4.4.2<code code='QUPC_TE043200UV'/>

The trigger event which caused the act to be transmitted is recorded in the code element is recorded as shown above.

3.10.4.4.3<subject>

The <subject> element shall be present to record the responses in a query request or continuation response.

3.10.4.4.4<queryAck>

The queryAck element is transmitted in any message that is a response to a query, query continuation or query cancellation message.

3.10.4.4.5<queryId root=' ' extension=' '/>

The <queryId> element shall be transmitted in a queryAck element. It shall contain an identifier that was used in the original query message.

3.10.4.4.6<statusCode code=' '/>

The statusCode element in the queryAck element indicates the status of the query. It may contain the value 'deliveredResponse' or 'aborted'. If the value is 'aborted', no additional messages should be sent to the Clinical Data Source for the specified query.

3.10.4.4.7<queryResponseCode code=' '/>

The queryResponseCode element indicates at a high level the results of performing the query. It may have the value 'OK' to indicate that the query was performed and has results. It may have the value 'NF' to indicate that the query was performed, but no results were located. It may have the value 'QE' to indicate that an error was detected in the incoming query message, or 'AE' to indicate some other application error occurred.

3.10.4.4.8<resultCurrentQuantity value=' '/>

The resultCurrentQuantity element shall be present, and shall enumerate number of results returned in the current response.

3.10.4.4.9<resultRemainingQuantity value=' '/>

This resultRemainingQuantity element may be present. It shall enumerate the number of additional results known to follow the results currently returned. Because these queries have long lifetimes, additional results may be added at any time.

3.10.4.5 Query Response

The <subject> element of the <controlActProcess> element shall appear as shown in the example below.


```
<subject>
  <registrationEvent>
    <statusCode code='active'/>
    <custodian>
      <assignedEntity>
        <id root='' extension=''/>
        <addr></addr>
        <telecom></telecom>
        <assignedOrganization>
          <name></name>
        </assignedOrganization>
      </assignedEntity>
    </custodian>
    <subject2>
      <careProvisionEvent>
        <recordTarget>
          <patient>
            <id root='' extension=''/>
            <addr></addr>
            <telecom value='' use=''/>
            <statusCode code='active'/>
            <patientPerson>
              <name></name>
              <administrativeGenderCode code='' displayName=''
                 codeSystem='2.16.840.1.113883.5.1'
codeSystemName='AdministrativeGender'/>
              <birthTime value=''/>
            </patientPerson>
          </patient>
        </recordTarget>
        <pertinentInformation3>
           <!-- Domain Content -->
        </pertinentInformation3>
      </careProvisionEvent>
    </subject2>
  </registrationEvent>
</subject>
```

3.10.4.5.1<subject>

The <subject> element shall be present, and is where the results are returned.

3.10.4.5.2<registrationEvent>

At least one <registrationEvent> element shall be be present for each set of records returned from a different custodial source or patient (in the case of population queries).

The <registrationEvent> is used to record the information about how the <careProvisionEvent> being returned was recorded or "registered" in the custodial system. The response to a Care Profile query is a CareProvisionEvent that is constructed in response to the query. This <careProvisionEvent> is transitory in nature, and is has limited "registration" information content.

A Data Source that aggregates information from two or more other data repositories shall separate the information into multiple <registrationEvent> elements so as to record the different custodians of the information.

3.10.4.5.3<statusCode code='active'/>

The <statusCode> element records the status of the data records. Queries always return active records, not replaced records, so the value of this element shall always be returned as 'active'. Note that an active record may reference the record that it replaces in the result. The replaced record so referenced does not count towards the number of results returned.

3.10.4.5.4<custodian>

The <custodian> element records the Data Source that is the custodian, or "owner", of the data record. A Data Source actor may return records from multiple custodians, but shall separate the data records from each custodian into different <registrationEvent> elements.

3.10.4.5.5<assignedEntity>

The <assignedEntity> element shall be present, and provides contact and identification information about the <custodian>.

3.10.4.5.6<id root=' ' extension=' '/>

The <id> element shall be present, and shall uniquely identify the custodian of the data records.

3.10.4.5.7<addr></addr>

The <addr> element shall be present, and shall provide a postal address for the custodian of the data records.

3.10.4.5.8<telecom></telecom>

At least one <telecom> element shall be present that provides a telephone number to contact the custodian of the data records. A <telecom> element may be present that provides the web service end-point address of the custodian of the data records.

For Public Comment	How might the web service end-point address be used? Is it a good idea to include it, or should we omit this from the profile?

3.10.4.5.9<assignedOrganization> <name></name> </assignedOrganization>

The name of the organization that is the custodian of the data records shall be provided.

3.10.4.5.10 <subject2>

The <subject2> element provides the data content requested from the query.

3.10.4.5.11 <careProvisionEvent>

The <careProvisionEvent> elements returned by the Care Record Profile Query are compositions based upon the information requested in the query. It is transitory in nature, and does not necessarily coorespond to a single care provision activity stored within the Data Source.

3.10.4.5.12 <recordTarget>

The <recordTarget> element records information about the patient for whom the Data Source is returning results.

3.10.4.5.13 <patient>

The <patient> element contains information identifying the patient and providing contact information.

3.10.4.5.14 <id root=' ' extension=' '/>

At least one <id> element shall be present that identifies the patient. This <id> element shall be the same as the value of the <patientId> passed in the query. Other <id> elements may be present.

3.10.4.5.15 <addr></addr>

At least one <addr> element shall be present to provide a postal address for the patient. It may have the nullFlavor attribute set to UNK if unknown (e.g., for a repository that contains pseudonomized information), or set to MSK for repositories that may contain the information, but which do not choose to divulge the information (e.g., due to access permissions, et cetera).

3.10.4.5.16 <telecom value=' ' use=' '/>

At least one <telecom> element shall be present to provide a telephone number to contact the patient. It may have the nullFlavor attribute set to UNK if unknown (e.g., for a repository that contains pseudonomized information), or set to MSK for repositories that may contain the information, but which do not choose to divulge the information (e.g., due to access permissions, et cetera). Other <telecom> elements may be present to contain other contact methods, e.g., e-mail. One cannot determine from a <telecom> element with the nullFlavor attribute whether it is supposed to contain a telephone number, e-mail address, URL, or other sort of telecommunciations address. Due to this limitation, the assumption will be made that a <telecom> element with a nullFlavor attribute represents a telephone number that is unavailable.

3.10.4.5.17 <statusCode code='normal'/>

The <statusCode> element shall be present, and shall be represented exactly as shown above. This indicates that the *role* of patient is in one of the normal states, e.g., has not been explicitly removed or "nullified".

3.10.4.5.18 <patientPerson>

The <patientPerson> element shall be present, and provides further identification information about the patient.

3.10.4.5.19 <name></name>

The <name> element shall be present, and normally provides the patient's name. The <name> element may have the nullFlavor attribute set to UNK if unknown (e.g., for a repository that contains pseudonomized information), or set to MSK for repositories that may contain the information, but which do not choose to divulge the information (e.g., due to access permissions, et cetera).

3.10.4.5.20 <administrativeGenderCode code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.1' codeSystemName='AdministrativeGender'/>

The <administrativeGenderCode> element shall be present, and normally provides the patient's gender using the HL7 AdministrativeGender vocabulary. The <administrativeGender> element may have the nullFlavor attribute set to UNK if unknown (e.g., for a repository that contains pseudonomized information), or set to MSK for repositories that may contain the information, but which do not choose to divulge the information (e.g., due to access permissions, et cetera).

3.10.4.5.21 <birthTime value=' '/>

The <birthTime> element shall be present, and normally provides the patient's birthTime. The <birthTime> element may have the nullFlavor attribute set to UNK if unknown (e.g., for a repository that contains pseudonomized information), or set to MSK for repositories that may contain the information, but which do not choose to divulge the information (e.g., due to access permissions, et cetera).

3.10.4.5.22 <pertinentInformation3> <!-- Domain Content> <pertinentInformation3>

This data element shall be present. It shall contain one of the data elements found in the Data Source that matches the specified query parameters. The content of this data element is a care statement that varies depending upon the specific transaction, and is futher defined in the section on Domain Content. Each care statement shall have at least one <author> element that indicates to whom the care statement is attributed. Each care statement may have zero or more <informant> elements that indicates who provided information related to the care statement. See the section below on Authors and Informants for more information on how this information should be recorded.

3.10.4.6 Expected Actions -- Clinical Data Source

The Clinical Data Source shall send a response as specified in the QUPC_IN043200UV interaction. The message shall be sent using web services as specified in the ITI-TF: Appendix V.

The Clinical Data Source shall populate the message with the appropriate responses using the appropriate templates specified in Care Management Data Query under the <careProvisionCode> query parameter.

3.10.4.7 Expected Actions -- Care Manager

The Care Manager processes the query response data. The Care Manager shall respond with an acknowledgement as specified in the QUPC_IN043200UV interaction. The name of the query response message shall be QUPC_IN043200UV_Message in the WSDL. The following WSDL snippet defines the type for this message:

```
<types>
   <xsd:schema elementFormDefault="qualified"
     targetNamespace="urn:hl7-org:v3" xmlns:hl7="urn:hl7-org:v3">
     <xsd:import namespace="urn:hl7-org:v3"
       schemaLocation="QUPC_IN043200UV.xsd"/>
     <xsd:import namespace="urn:hl7-org:v3"
       schemaLocation="MCCI_IN000002UV01.xsd"/>
     <xsd:element name="QUPC_IN043200UV"/>
     <xsd:element name="MCCI_IN000002UV01"/>
   </xsd:schema>
 </types>
```

The message type is declared to be of the appropriate type by the following WSDL snippet:

```
<message name='QUPC_IN043200UV_Message'>
   <part element='hl7:QUPC_IN043200UV' name="Body"/>
 </message>
 <message name='MCCI_IN000002UV01_Message'>
   <part element='hl7:MCCI_IN000002UV01' name="Body"/>
 </message>
```

The following WSDL naming conventions SHALL apply for this transaction:

WSDL Item	Value
wsdl:definitions/@name	ClinicalDataSource
Get Care Record Query Response	QUPC_IN043200UV_Message
Message Acknowledgement	MCCI_IN000002UV01 _Message
portType	ClinicalDataSource_PortType
Query Response Operation	ClinicalDataSource_QUPC_IN043200UV
SOAP 1.1 binding	ClinicalDataSource_Binding_Soap11
SOAP 1.1 port	ClinicalDataSource_Port_Soap11
SOAP 1.2 binding	ClinicalDataSource_Binding_Soap12
SOAP 1.2 port	ClinicalDataSource_Port_Soap12

The following WSDL snippets specify the Port Type and Binding definitions, according to the requirements specified in ITI TF-2: Appendix V. A full WSDL example for the Clinical Data Source actor can be found at ftp://ftp.ihe.net/TF_Implementation_Material/PCC/ClinicalDataSource.wsdl. For a general description of the WSDLs for Care Management see the Appendix of the same name in this volume.

3.10.4.8 Port Type

```
<portType name="ClinicalDataSource_PortType">
 <operation name="ClinicalDataSource_QUPC_IN043200UV">
   <input message="tns:QUPC_IN043200UV_Message"
     wsaw:Action="urn:hl7-org:v3:QUPC_IN043200UV"/>
   <output message="tns:MCCI_IN000002UV01_Message"
     wsaw:Action="urn:hl7-org:v3:MCCI_IN000002UV01"/>
 </operation>
</portType>
```

3.10.4.9 Bindings

```
<binding name="ClinicalDataSource_Binding_Soap12"
   type="ClinicalDataSource_PortType">
 <wsoap12:binding style="document"
   transport="http://schemas.xmlsoap.org/soap/http"/>
 <operation name="ClinicalDataSource_QUPC_IN043200UV">
   <wsoap12:operation soapAction="urn:hl7-org:v3:QUPC_IN043200UV"/>
   <input>
     <wsoap12:body use="literal"/>
   </input>
   <output>
     <wsoap12:body use="literal"/>
   </output>
 </operation>
</binding>
<binding name="ClinicalDataSource_Binding_Soap11"
   type="ClinicalDataSource_PortType">
 <wsoap11:binding style="document"
   transport="http://schemas.xmlsoap.org/soap/http"/>
 <operation name="ClinicalDataSource_QUPC_IN043200UV">
   <wsoap11:operation soapAction="urn:hl7-org:v3:QUPC_IN043200UV"/>
   <input>
     <wsoap11:body use="literal"/>
   </input>
   <output>
     <wsoap11:body use="literal"/>
   </output>
 </operation>
</binding>
```

3.11 V2 Care Management Update

This section corresponds to Transaction PCC-11 of the IHE Patient Care Coordination Technical Framework. Transaction PCC-11 is used by the Care Manager and Clinical Data Source Actors.

Transaction PCC-11 sends the appropriate HL7 Version 2 message defined by the guideline in the Guideline Notification transaction and that was requested in the Care Management Data Query.

The Clinical Data Source actor must be able to understand what kind of HL7 Version 2 message is being requested when interpreting the Care Management Data Query transaction issued by the Care Manager actor. How HL7 messages are described using the HL7 Version 3 act structure is now described below.

To fully describe an HL7 Version 2 message, this profile makes use of two infrastructure attributes specified on all RIM classes, and the <code> element of the act: The XML fragment below is an act, in definition mood, that describes the definition of acts of interest to a Care Manager. These acts are represented in a <guideline> element as described in the Guideline Notification transaction. An example appears below:

```
<actDefinition classCode='ACT' moodCode='DEF'>
  <typeId root='2.16.840.1.113883.12.354' extension='ADT_A01'/>
  <templateId root='2.16.840.1.113883.9.2.2'/>
     :
  <code code='A01' codeSystem='2.16.840.1.113883.12.3'
codeSystemVersion='2.4'/>
</actDefinition>
```

typeId

Describes the constraints imposed by a message type definition. In HL7 Version 2, Table 354 identifies the message structures (or types of messages) that can be sent using the HL7 Version 2 standard. This table can be found in Chapter 2 (Control/Query) of the HL7 Version 2 standard. The example above describes the message of interest as using message structure ADT_A01, which is used to convey that a patient has arrived at a facility.

templateId

Describes the constraints imposed by a template definition. Conformance profiles introduced in HL7 Version 2 are templates which further constrain a specific message structure. HL7 makes available a registry of conformance profiles that have been registered with HL7 to its members at http://www.hl7.org/memonly/conformance/. In the example given above, the profile identifer is given in the <templateId> element, and identifies the specific HL7 Conformance profile that further constrains the message.

code

Describes the specific event (or act) which is of interest in the code attribute. The value for the code attribute comes from table 3 of the HL7 Version 2 standard, which is identified using the codeSystem value 2.16.840.1.113883.12.3. In the example above, the act is the trigger event, A01 (Admit/Visit Notification). We further specify that the code (A01) used to identify that act comes from version 2.4 of the specified codeSystem.

Having demonstrated how to represent a kind of HL7 message in a guideline, we next demonstrate how it appears in a query, as shown in the example below.

```
<parameterList>
   :
  <careProvisionCode>
    <value code='A01' codeSystem='2.16.840.1.113883.12.3'
codeSystemVersion='2.4'/>
  </careProvisionCode>
</parameterList>
```

For Public Comment	As you can see, the <parameterList> element above does not completely identify the act that is of interest (the message to be returned by the Clinical Data Source). There are several approaches we have considered to address this: Create a code system whose values are the template identifiers (or Conformance profile identifiers in this example), an use those template identifiers in the code attribute of the <value> element. This is a hack that will work. Allow the meaning of templateId to be context sensitive, so that in the context of a query parameter, a templateId might simply assert that the expected response to the query would be an item matching that templateId, also a hack that will work. Leave the query for an HL7 V2 response as shown above, with the expectation that the specific conformance profile used to respond to the query will be provided out of band. Our expectation is that the V2 Care Mnaagement Update message will initially require out of band configuration in any case, as the Clinical Data Sources using the HL7 Version 2 Option are not be required to support reciept of the Care Management Data Query transaction.

3.11.1 Use Case Roles

V2 Care Management Update

Actor

Care Manager

Role

Recieves the HL7 Version 2 message matching the selection criteria in a prior PCC-9 transaction, or otherwise configured out of band with the Clinical Data Source.

Actor

Clinical Data Source

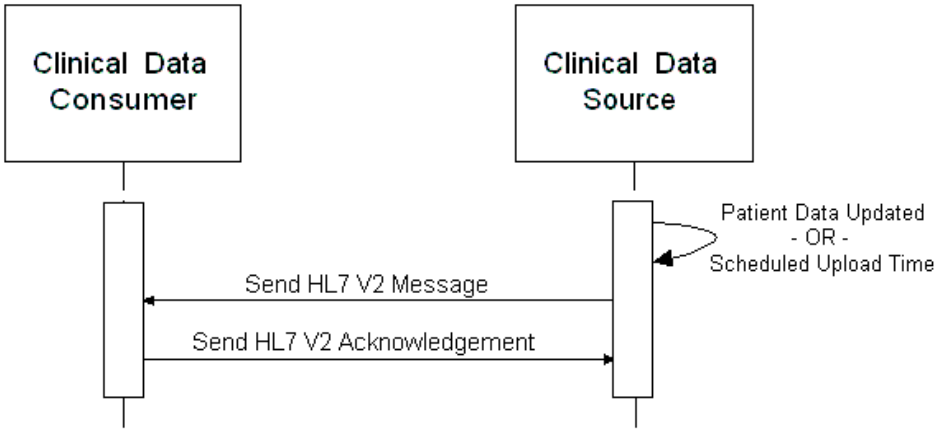
Role

Sends the HL7 Version 2 message matching the selection criteria found in a prior PCC-9 transaction from the Clinical Data Source, or preconfigured.

3.11.2 Referenced Standards

HL7V2.3	HL7 Version 2.3 Messaging Standard
HL7V2.3.1	HL7 Version 2.3.1 Messaging Standard
HL7V2.4	HL7 Version 2.4 Messaging Standard
HL7V2.5	HL7 Version 2.5 Messaging Standard
HL7V2.5.1	HL7 Version 2.5.1 Messaging Standard
CareQuery	HL7 Care Provision Care Record Query (DSTU)
MLLP	Minimal Lower Layer Message Protocol, Release 2

3.11.3 Interaction Diagrams



3.11.4 Send Message

3.11.4.1 Trigger Events

When the indicated trigger event occurs the Clinical Data Source shall send an HL7 Version 2 message to the recipient indicated in the <respondTo> element of the query.

3.11.4.2 Message Semantics

The semantics of the message are determined by the HL7 Version 2 Conformance Profile that has been specified for use in the guidelines being applied to the specific use of the Care Management profile (see http://www.hl7.org/memonly/conformance/index.cfm).

The message shall be sent using the HL7 Minimum Lower Layer Protocol (MLLP), as described in ITI TF-2:Appendix C.2 HL7 Implementation Notes

3.11.4.3 Expected Actions -- Clinical Data Source

1. Upon detection of a qualifying event, the clinical data source shall produce and send the appropriate HL7 Version 2 message for the event to the recipient indicated in the <respondTo> element of the Care Management Data Query) transaction triggering the notification.
2. The Clinical Data Source shall await an acknowledgement of the message.
3. If errors are noted in any of the messages sent in the batch, an operator will be alterted.

3.11.5 Message Acknowledgement

The Care Manager shall send an acknowledgement indicating that it has recieved the messages.

3.11.5.1 Trigger Events

The trigger event for the response is the reciept of a new real-time or batch response from the sender.

3.11.5.2 Message Semantics

A Clinical Data Source implementing the HL7 Version 2 option reports activities to the Care Manager using this transaction. The guideline and query identify the HL7 Version 2 message to use when responding to the query received. A Clinical Data Source implementing this option may simply be configured to send the appropriate message.

3.11.5.3 Expected Actions -- Care Manager

The Care Manager will validate the message content, and return an acknowledgement to the sender.

4 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.

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	This is the root OID for all IHE PCC Templates. A list of PCC templates can be found below in CDA Release 2.0 Content Modules.
1.3.6.1.4.1.19376.1.5.3.2	IHEActCode	See IHEActCode Vocabulary below
1.3.6.1.4.1.19376.1.5.3.3	IHE PCC RoleCode	See IHERoleCode Vocabulary below
1.3.6.1.4.1.19376.1.5.3.4		Namespace OID used for IHE Extensions to CDA Release 2.0
2.16.840.1.113883.10.20.1	CCD Root OID	Root OID used for by ASTM/HL7 Continuity of Care Document
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
2.16.840.1.113883.6.1	LOINC	Logical Observation Identifier Names and Codes
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.103	ICD-9CM (diagnosis codes)	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	C4	Current Procedure Terminology 4 (CPT-4) codes.
2.16.840.1.113883.6.257	Minimum Data Set for Long Term Care	The root OID for Minimum Data Set Answer Lists

4.1 IHE Format Codes

The table below lists the format codes, template identifiers and media types used by the IHE Profiles specified in the PCC Technical Framework, and also lists, for reference purposes the same values for other selected IHE Profiles from other committees.

Profile	Format Code	Media Type	Template ID
2006 Profiles			
Medical Summaries (XDS-MS)	urn:ihe:pcc:xds-ms:2007	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.3 (Referral) 1.3.6.1.4.1.19376.1.5.3.1.1.4 (Discharge Summary)
2007 Profiles			
Exchange of Personal Health Records (XPHR)	urn:ihe:pcc:xphr:2007	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.5 (Extract) 1.3.6.1.4.1.19376.1.5.3.1.1.6 (Update)
Emergency Department Referral (EDR)	urn:ihe:pcc:edr:2007	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.10
2008 Profiles			
Antepartum Summary (APS)	urn:ihe:pcc:aps:2007	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.11.2
Emergency Department Encounter Summary (EDES)	urn:ihe:pcc:edes:2007	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.13.1.1 (Triage Note) 1.3.6.1.4.1.19376.1.5.3.1.1.13.1.2 (Nursing Note) 1.3.6.1.4.1.19376.1.5.3.1.1.13.1.3 (Composite Triage and Nursing Note) 1.3.6.1.4.1.19376.1.5.3.1.1.13.1.4 (Physician Note)
2009 Profiles			
Antepartum Record (APR)	urn:ihe:pcc:apr:2008	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1 (Antepartum History and Physical) 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.2 (Antepartum Laboratory) 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.3 (Antepartum Education)
Immunization Registry Content (IRC)	urn:ihe:pcc:irc:2008	text/xml	
Cancer Registry Content (CRC)	urn:ihe:pcc:crc:2008	text/xml	
Care Management (CM)	urn:ihe:pcc:cm:2008	text/xml	
ITI Profiles			
Scanned Documents	urn:ihe:iti:sd:2007	text/xml	
Basic Patient Privacy Consents	urn:ihe:iti:bppc:2007	text/xml	
Basic Patient Privacy Consents with Scanned	urn:ihe:iti:bppc-	text/xml	

Document	sd:2007		
LAB Profiles			
CDA Laboratory Report	urn:ihe:lab:???:2007	text/xml	

4.2 IHEActCode Vocabulary

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
4140 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.
PINSTRUCT	This is the act of providing instructions to a patient regarding the use of medication.
FINSTRUCT	This is the act of providing instructions to the supplier regarding the fulfillment of the medication order.
IMMUNIZ	The act of immunization of a patient using a particular substance or class of substances identified using a specified vocabulary. Use of this vocabulary term requires the use of either the SUBSTANCE or SUBSTCLASS qualifier described below, along with an identified substance or class of substances.
DRUG	The act of treating a patient with a particular substance or class of substances identified using a specified vocabulary. Use of this vocabulary term requires the use of either the SUBSTANCE or SUBSTCLASS qualifier described below, along with an identified substance or class of substances.
INTOL	An observation that a patient is somehow intollerant of (e.g., allergic to) a particular substance or class of substances using a specified vocabulary. Use of this vocabulary term requires the use of either the SUBSTANCE or SUBSTCLASS qualifier described below, along with an identified substance or class of substances.
SUBSTANCE	A qualifier that identifies the substance used to treat a patient in an immunization or drug treatment act. The substance is expected to be identified using a vocabulary such as RxNORM, SNOMED CT or other similar vocabulary and should be specific enough to identify the ingredients of the substance used.
SUBSTCLASS	A qualifier that identifies the class of substance used to treat a patient in an immunization or drug treatment act. The class of substances is expected to be identified using a vocabulary such as NDF-RT, SNOMED CT or other similar vocabulary, and should be broad enough to classify substances by mechanism of action (e.g., Beta Blocker), intended effect (Dieuretic, antibiotic) or ...

For Public Comment	What else needs to appear above for SUBSTCLASS?

4.3 IHERoleCode Vocabulary

The IHERoleCode vocabulary is a small vocabulary of role codes that are not presently supported by the HL7 Role Code vocabulary. The root namespace (OID) for this vocabulary is 1.3.5.1.4.1.19376.1.5.3.3.

Code	Description
EMPLOYER	The employer of a person.
SCHOOL	The school in which a person is enrolled.
AFFILIATED	An organization with which a person is affiliated (e.g., a volunteer organization).
PHARMACY	The pharmacy a person uses.

5 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.

5.1 CDA and HL7 Version 3 Entry Content Modules

5.2 Authors and Informants

Each clinical statement that can be made in a CDA Document or HL7 Version 3 message shall be attributable to one or more authors. These are found in <author> elements, either directly within the clinical statement, or in one of its ancestors in the XML document or message. Each clinical statement may also contain information from zero or more informants. These are found in <informant> elements, again, either directly within the clinical statement, or in one of its ancestors in the XML document or message.

5.2.1.1 <author>

Authors shall be described in an <author> element that is either directly on the clinical statement, or which can be reached by one of its ancestors.

5.2.1.2 <time value=' '/>

The time of authorship shall be recorded in the <time> element.

5.2.1.3 <assignedAuthor> -OR- <assignedEntity1> <id root=' ' extension=' '> <addr></addr> <telecom value=' ' use=' '>

In a CDA document details about the author are provided in the <assignedAuthor> element. In Version 3 messages, they are provided in the <assignedEntity1> element. The semantics are identical even though the element names differ. The identifier of the author, and their address and telephone number shall be present inside the <id>, <addr> and <telecom> elements.

5.2.1.4 <assignedPerson><name></name></assignedPerson> <representedOrganization><name></name></representedOrganization>

The author's and/or the organization's name shall be present when the <author> element is present.

5.3 Linking Narrative and Coded Entries

This section defines a linking mechanism that allows entries or portions thereof to be connected to the text of the clinical document.

5.3.1.1 Standards

RIM	HL7 Version 3 Reference Information Model
CDAR2	HL7 Clinical Document Architecture Release 2.0

5.3.1.2 Constraints for CDA

Elements within the narrative <text> will use the ID attribute to provide a destination for links. Elements within an <entry> will be linked to the text via a URI reference using this attribute as the fragment identifier. This links the coded entry to the specific narrative text it is related to within the CDA instance, and can be traversed in either direction. This serves three purposes:

1. It supports diagnostics during software development and testing.
2. It provides a mechanism to enrich the markup that can be supported in the viewing application.
3. It eliminates the need to duplicate content in two places, which prevents a common source of error, and eliminates steps needed to validate that content that should be identical in fact is.

Each narrative content element within CDA may have an ID attribute. This attribute is of type xs:ID. This means that each ID in the document must be unique within that document. Within an XML document, an attribute of type xs:ID must start with a letter, and may be followed one or more letters, digits, hyphens or underscores . Three different examples showing the use of the ID attribute, and references to it appear below:

Use of ID	References to ID
<tr ID='foo'> <td ID='bar'>Table Cell 1</td> <td>Table Cell 2</td> </tr>	<code> <originalText><reference value='#foo'></originalText> </code> <code> <originalText><reference value='#bar'></originalText> </code>
<list> <item ID='baz'>List item 1</item> </list>	<code> <originalText><reference value='#baz'></originalText> </code>
<paragraph ID='p-1'>A paragraph <content ID='c-1'>with content</content> </paragraph>	<code> <originalText><reference value='#p-1'></originalText> </code> <code> <originalText><reference value='#c-1'></originalText> </code>

Table 5.3-1 Example Uses of ID

This allows the text to be located with a special type of URI reference, which simply contains a fragment identifier. This URI is local to the document and so just begins with a hash mark (#), and is followed by the value of the ID being referenced. Given one of

these URIs stored in a variable named theURI, the necessary text value can be found via the following XPath expression:

```
string(//*[@ID=substring-after('#',$theURI)])
```

The table below shows the result of this expression using the examples above:

$theURI	Returned Value
"#bar"	"Table Cell 1"
"#foo"	"Table Cell 1Table Cell 2" (note the spacing issue between 1 and T)
"#p-1"	"A paragraph with content"
"#c-1"	"with content"

If your XSLT processor is schema aware, even more efficient mechanisms exist to locate the element than the above expression.

Having identified the critical text in the narrative, any elements using the HL7 CD datatype (e.g., <code>) can then contain a <reference> to the <originalText> found in the narrative. That is why, although CDA allows <value> to be of any type in <entry> elements, this profile restricts them to always be of xsi:type='CD'.

Now, given an item with an ID stored in a variable named theID all <reference> elements referring to it can be found via the following XPath expression:

```
//cda:reference[@URI=concat('#',$theID)]
```

5.3.1.3 Constraints for HL7 Version 3 Messages

Unlike CDA entries, structured statements in HL7 Version 3 Messages do not have a related narrative text section. Therefore full text representations should be included in the <text> element care statement acts.

5.3.1.4 Severity 1.3.6.1.4.1.19376.1.5.3.1.4.1

Any condition or allergy may be the subject of a severity observation. This structure is included in the target act using the <entryRelationship> element defined in the CDA Schema.

The example below shows the recording the condition or allergy severity, and is used as the context for the following sections.

5.3.1.5 Standards

PatCareStruct	HL7 Care Provision Domain (DSTU)
CCD	ASTM/HL7 Continuity of Care Document

5.3.1.6 Specification

```
<observation classCode='COND' moodCode='EVN'>


  <entryRelationship typeCode='SUBJ' inversionInd='true'>
    <observation classCode='OBS' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.55'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1'/>
      <code code='SEV' displayName='Severity'
        codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode' />
      <text><reference value='#severity-2'/></text>
      <statusCode code='completed'/>
      <value xsi:type='CD' code='H|M|L'
        codeSystem='2.16.840.1.113883.5.1063'
        codeSystemName='ObservationValue' />
    </observation>
  </entryRelationship>


</observation>
```

This specification models a severity observation as a separate observation from the condition. While this model is different from work presently underway by various organizations (i.e., SNOMED, HL7, TermInfo), it is not wholly incompatible with that work. In that work, qualifiers may be used to identify severity in the coded condition observation, and a separate severity observation is no longer necessary. The use of qualifiers is not precluded by this specification. However, to support semantic interoperability between EMR systems using different vocabularies, this specification does require that severity information also be provided in a separate observation. This ensures that all EMR systems have equal access to the information, regardless of the vocabularies they support.

5.3.1.6.1 <entryRelationship typeCode='SUBJ' inversionInd='true'>

The related statement is made about the severity of the condition (or allergy). For CDA, this observation is recorded inside an <entryRelationship> element occurring in the condition, allergy or medication entry. The containing <entry> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'. For HL7 Version 3 Messages this relationship is represented with a <sourceOf> element, however the semantics, typeCode, and inversionInd is unchanged.

5.3.1.6.2 <observation moodCode='EVN' classCode='OBS'>

The related statement is another event (moodCode='EVN') observing (<observation classCode='OBS'>) the severity of the (surrounding) related entry (e.g., a condition or allergy).

5.3.1.6.3 <templateId root='2.16.840.1.113883.10.20.1.55'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1'/>

The <templateId> elements identifies this <observation> as a severity observation, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify severity observations. The templateId elements shown above must be present.

5.3.1.6.4 <code code='SEV' codeSystem='2.16.840.1.113883.5.4' displayName='Severity' codeSystemName='ActCode' />

This observation is of severity, as indicated by the <code> element listed above. This element is required. The code and codeSystem attributes shall be recorded exactly as shown above.

5.3.1.6.5 <text><reference value='#severity-2'/></text>

The <observation> element shall contain a <text> element. For CDA, the <text> elements shall contain a <reference> element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity. For HL7 Version 3 Messages, the <text> element should contain the full narrative text.

5.3.1.6.6 <statusCode code='completed'/>

The code attribute of <statusCode> for all severity observations shall be completed. While the <statusCode> element is required in all acts to record the status of the act, the only sensible value of this element in this context is completed.

5.3.1.6.7 <value xsi:type='CD' code='H|M|L' codeSystem='2.16.840.1.113883.5.1063' codeSystemName='SeverityObservation'>

The <value> element contains the level of severity. It is always represented using the CD datatype (xsi:type='CD'), even though the value may be a coded or uncoded string. If coded, it should use the HL7 SeverityObservation vocabulary (codeSystem='2.16.840.1.113883.5.1063') containing three values (H, M, and L), representing high, moderate and low severity depending upon whether the severity is life threatening, presents noticeable adverse consequences, or is unlikely substantially effect the situation of the subject.

5.3.2 Problem Status Observation 1.3.6.1.4.1.19376.1.5.3.1.4.1.1

Any problem or allergy observation may reference a problem status observation. This structure is included in the target observation using the <entryRelationship> element defined in the CDA Schema. The clinical status observation records information about the current status of the problem or allergy, for example, whether it is active, in remission, resolved, et cetera. The example below shows the recording of clinical status of a condition or allergy, and is used as the context for the following sections.

5.3.2.1 Standards

CCD ASTM/HL7 Continuity of Care Document

5.3.2.2 Specification

```
<entry>
  <observation classCode='OBS' moodCode='EVN'>

    <entryRelationship typeCode='REFR' inversionInd='false'>
      <observation classCode='OBS' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.57'/>
        <templateId root='2.16.840.1.113883.10.20.1.50'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.1'/>
        <code code='33999-4' displayName='Status'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
        <text><reference value='#cstatus-2'/></text>
        <statusCode code='completed'/>
        <value xsi:type='CE' code=' ' codeSystem='2.16.840.1.113883.6.96'
codeSystemName='SNOMED CT'/>
      </observation>
    </entryRelationship>

  </observation>
</entry>
```

This CCD models a problem status observation as a separate observation from the problem, allergy or medication observation. While this model is different from work presently underway by various organizations (i.e., SNOMED, HL7, TermInfo), it is not wholly incompatible with that work. In that work, qualifiers may be used to identify problem status in the coded condition observation, and a separate clinical status observation is no longer necessary. The use of qualifiers in the problem observation is not precluded by this specification or by CCD. However, to support semantic interoperability between EMR systems using different vocabularies, this specification does require that problem status information also be provided in a separate observation. This ensures that all EMR systems have equal access to the information, regardless of the vocabularies they support.

5.3.2.3 <entryRelationship typeCode='REFR' inversionInd='false'>

The related statement is made about the clinical status of the problem or allergy. For CDA, this observation is recorded inside an <entryRelationship> element occurring in the problem or allergy. For HL7 Version 3 Messages, the <entryRelationship> tag name is <sourceOf>, though the typeCode and inversionInd attributes and other semantics remain the same. The containing observation refers to (typeCode='REFR') this new observation.

5.3.2.4 <observation moodCode='EVN' classCode='OBS'>

The related statement is another event (moodCode='EVN') observing (<observation classCode='OBS'>) the clinical status of the (surrounding) related observation (e.g., a problem or allergy).

5.3.2.5 <templateId root='2.16.840.1.113883.10.20.1.57'/> <templateId root='2.16.840.1.113883.10.20.1.50'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.1'/>

These <templateId> elements identify this <observation> as a problem status observation, allowing for validation of the content.

5.3.2.6 <code code='33999-4' codeSystem='2.16.840.1.113883.6.1' displayName='Status' codeSystemName='LOINC' />

This observation is of clinical status, as indicated by the <code> element. This element must be present. The code and codeSystem shall be recorded exactly as shown above.

5.3.2.7 <text><reference value='#cstatus-2'/></text>

The <observation> element shall contain a <text> element that points to the narrative text describing the clinical status. For CDA, the <text> elements shall contain a <reference> element pointing to the narrative section (see Linking Narrative and Coded Entries), rather than duplicate text to avoid ambiguity. For HL7 Version 3 Messages, the <text> element SHALL contain the full narrative text.

5.3.2.8 <statusCode code='completed'/>

The code attribute of <statusCode> for all clinical status observations shall be completed. While the <statusCode> element is required in all acts to record the status of the act, the only sensible value of this element in this context is completed.

5.3.2.9 <value xsi:type='CE' code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'>

The <value> element contains the clinical status. It is always represented using the CE datatype (xsi:type='CE'). It shall contain a code from the following set of values from SNOMED CT.

Code	Description
55561003	Active
73425007	Inactive
90734009	Chronic
7087005	Intermittent
255227004	Recurrent
415684004	Rule out
410516002	Ruled out
413322009	Resolved

5.3.3 Health Status 1.3.6.1.4.1.19376.1.5.3.1.4.1.2

A problem observation may reference a health status observation. This structure is included in the target observation using the <entryRelationship> element defined in the CDA Schema. The health status observation records information about the current health status of the patient. The example below shows the recording the health status, and is used as the context for the following sections.

5.3.3.1 Specification

```
<entry>
 <observation classCode='OBS' moodCode='EVN'>

   <entryRelationship typeCode='REFR' inversionInd='false'>
     <observation classCode='OBS' moodCode='EVN'>
       <templateId root='2.16.840.1.113883.10.20.1.57'/>
       <templateId root='2.16.840.1.113883.10.20.1.51'/>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2'/>
       <code code='11323-3' displayName='Health Status'
         codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
       <text><reference value='#hstatus-2'/></text>
       <statusCode code='completed'/>
       </value>
       <value xsi:type='CE' code=' ' codeSystem='2.16.840.1.113883.6.96'
codeSystemName='SNOMED CT'/>
     </observation>
   </entryRelationship>

 </observation>
</entry>
```

This specification models a health status observation as a separate observation about the patient.

5.3.3.2 <entryRelationship typeCode='REFR'>

The related statement is made about the health status of the patient. For CDA, this observation is recorded inside an <entryRelationship> element occurring in the observation. The contained observersation is referenced (typeCode='REFR') by the observation entry. For HL7 Version 3 Messages, the entryRelationship tagName is sourceOf, though the typeCode and inversionInd attributes and other semantics remain the same.

5.3.3.3 <observation moodCode='EVN' classCode='OBS'>

The related statement is another event (moodCode='EVN') observing (<observation classCode='OBS'>) the health status of the patient.

5.3.3.4 <templateId root='2.16.840.1.113883.10.20.1.57'/> <templateId root='2.16.840.1.113883.10.20.1.51'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2'/>

The <templateId> element identifies this <observation> as a health status observation, allowing for validation of the content.

5.3.3.5 <code code='11323-3' displayName='Health Status' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />

This observation is of health status, as indicated by the <code> element. This element must be present. The code and codeSystem attributes shall be recorded exactly as shown above.

5.3.3.6 <text><reference value='#hstatus-2'/></text>

The <observation> element shall contain a <text> element that contains the narrative text describing the clinical status. For CDA, the <text> elements shall contain a <reference> element pointing to the narrative section (see Linking Narrative and Coded Entries, rather than duplicate text to avoid ambiguity. For HL7 Version 3 Messages, the <text> element shall contain the full narrative text.

5.3.3.7 <statusCode code='completed'/>

The code attribute of <statusCode> for all health status observations shall be completed. While the <statusCode> element is required in all acts to record the status of the act, the only sensible value of this element in this context is completed.

5.3.3.8 <value xsi:type='CE' code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'>

The <value> element contains the clinical status. It is always represented using the CE datatype (xsi:type='CE').

Code	Description
81323004	Alive and well
313386006	In remission
162467007	Symptom free
161901003	Chronically ill
271593001	Severely ill
21134002	Disabled
161045001	Severely disabled
419099009	Deceased

5.3.3.9 Comments 1.3.6.1.4.1.19376.1.5.3.1.4.2

This entry allows for a comment to be supplied with each entry. For CDA this structure is included in the target act using the <entryRelationship> element defined in the CDA Schema. The example below shows recording a comment for an <entry>, and is used as context for the following sections. For HL7 Version 3 Messages, this relationship is

represented with the element <sourceOf>, although the remainder of the typecodes and semantics are unchanged.

Any condition or allergy may be the subject of a comment.

5.3.3.10 Standards

CareStruct	HL7 Care Provision Care Structures (DSTU)
CCD	ASTM/HL7 Continuity of Care Document

5.3.3.11 Specification

```
<entry>
  <observation classCode='OBS' moodCode='EVN'>
        □
    <entryRelationship typeCode='SUBJ' inversionInd='true'>
      <act classCode='ACT' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.40'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.2'/>
        <code code='48767-8' displayName='Annotation Comment'
          codeSystem='2.16.840.1.113883.6.1'
          codeSystemName='LOINC' />
        <text><reference value='#comment-2'/></text>
        <statusCode code='completed' />
        <author>
          <time value=''/>
          <assignedAuthor>
            <id root='' extension=''>
            <addr></addr>
            <telecom value='' use=''>
            <assignedPerson><name></name></assignedPerson>
            <representedOrganization><name></name></representedOrganization>
          </assignedAuthor>
        </author>
      </act>
    </entryRelationship>
        □
  </observation>
</entry>
```

5.3.3.12 <entryRelationship typeCode='SUBJ' inversionInd='true'>

Again, a related statement is made about the condition, allergy or medication. In CDA this observation is recorded inside an <entryRelationship> element occurring at the end of the condition or allergy entry. The containing <observation> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'. For HL7 Version 3 Messages, the relationship element is <sourceOf>, however the typeCode and inversionInd remain the same.

5.3.3.13 <act classCode='ACT' moodCode='EVN'>

The related statement is an event (moodCode='EVN') describing the act (classCode='ACT') of making an arbitrary comment or providing instruction on the related entry.

5.3.3.14 <templateId root='2.16.840.1.113883.10.20.1.40'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.2'/>

These <templateId> elements identify this <act> as a comment, allowing for validation of the content.

5.3.3.15 <code code='48767-8' displayName='Annotation Comment' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='LOINC' />

The <code> element indicates that this is a comment and shall be recorded as shown above. The codeSystem and code attributes shall use the values specified above.

5.3.3.16 <text><reference value='#comment-2'/></text>

The <text> element provides a way to represent the <reference> to the text of the comment in the narrative portion of the document. For CDA, this SHALL be represented as a <reference> element that points to the narrative text section of the CDA. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>. For HL7 Version 3 Messages, the <text> element SHALL contain the full narrative text.

5.3.3.17 <statusCode code='completed' />

The code attribute of <statusCode> for all comments must be completed.

5.3.3.18 <author>

The comment may have an author.

5.3.3.19 <time value=' '/>

The time of the comment creation shall be recorded in the <time> element when the <author> element is present.

5.3.3.20 <assignedAuthor> <id root=' ' extension=' '> <addr></addr> <telecom value=' ' use=' '>

The identifier of the author, and their address and telephone number must be present inside the <id>, <addr> and <telecom> elements when the <author> element is present.

5.3.3.21 <assignedPerson><name></name></assignedPerson> <representedOrganization><name></name></representedOrganization>

The author's and/or the organization's name must be present when the <author> element is present.

5.3.4 Patient Medication Instructions 1.3.6.1.4.1.19376.1.5.3.1.4.3

Any medication may be the subject of further instructions to the patient, for example to indicate that it should be taken with food, et cetera.

This structure is included in the target substance administration or supply act using the <entryRelationship> element defined in the CDA Schema. The example below shows the recording of patient medication instruction for an <entry>, and is used as context for the following section.

5.3.4.1 Standards

Pharmacy HL7 Pharmacy Domain (Normative)

5.3.4.2 Specification

```
<entry>
 <substanceAdministration classCode='SBADM' moodCode='EVN'>
        □
   <entryRelationship typeCode='SUBJ' inversionInd='true'>
     <act classCode='ACT' moodCode='INT'>
       <templateId root='2.16.840.1.113883.10.20.1.49'/>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>
       <code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
         codeSystemName='IHEActCode' />
       <text><reference value='#comment-2'/></text>
       <statusCode code='completed' />
     </act>
   </entryRelationship>
        □
 </substanceAdministration>
</entry>
```

5.3.4.3 <entryRelationship typeCode='SUBJ' inversionInd='true'>

Again, a related statement is made about the medication or immunization. This observation is recorded inside an <entryRelationship> element occurring at the end of the substance administration or supply entry. The containing <entry> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'.

5.3.4.4 <act classCode='ACT' moodCode='INT'>

The related statement is the intent (moodCode='INT') on how the related entry is to be performed.

5.3.4.5 <templateId root='2.16.840.1.113883.10.20.1.49'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>

These <templateId> elements identify this <act> as a medication instruction, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify medication instructions.

5.3.4.6 <code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode' />

The <code> element indicates that this is a patient medication instruction. This element shall be recorded exactly as specified above.

Note: These values will be sent to HL7 for harmonization with the HL7 Act Vocabulary.

5.3.4.7 <text><reference value='#comment-2'/></text>

The <text> element indicates the text of the comment. For CDA, this SHALL be represented as a <reference> element that points at the narrative portion of the document. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>. For HL7 Version 3 Messages, the full text SHALL be represented here.

5.3.4.8 <statusCode code='completed' />

The code attribute of <statusCode> for all comments must be completed.

5.3.5 Medication Fulfillment Instructions 1.3.6.1.4.1.19376.1.5.3.1.4.3.1

Any medication may be the subject of further instructions to the pharmacist, for example to indicate that it should be labeled in Spanish, et cetera.

This structure is included in the target substance administration or supply act using the <entryRelationship> element defined in the CDA Schema. The figure below is an example of recording an instruction for an <entry>, and is used as context for the following sections.

5.3.5.1 Standards

Pharmacy HL7 Pharmacy Domain (Normative)

5.3.5.2 Specification


```
<entry>
 <supply classCode='SPLY' moodCode='EVN'>

   <entryRelationship typeCode='SUBJ' inversionInd='true'>
     <act classCode='ACT' moodCode='INT'>
       <templateId root='2.16.840.1.113883.10.20.1.43'/>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1'/>
       <code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
         codeSystemName='IHEActCode' />
       <text><reference value='#comment-2'/></text>
       <statusCode code='completed' />
     </act>
   </entryRelationship>
         </supply>
</entry>
```

5.3.5.3 <entryRelationship typeCode='SUBJ' inversionInd='true'>

Again, a related statement is made about the medication or immunization. In CDA, this observation is recorded inside an <entryRelationship> element occurring at the end of the substance administration or supply entry. The containing <act> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'. For HL7 Version 3 Messages, this relationship is represented with the <sourceOf> element however the semantics, typeCode, and inversionInd remain the same.

5.3.5.4 <act classCode='ACT' moodCode='INT'>

The related statement is the intent (moodCode='INT') on how the related entry is to be performed.

5.3.5.5 <templateId root='2.16.840.1.113883.10.20.1.43'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1'/>

These <templateId> elements identify this <act> as a medication fulfillment instruction, allowing for validation of the content.

5.3.5.6 <code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode' />

The <code> element indicates that this is a medication fulfillment instruction. This element shall be recorded exactly as specified above.

Note: These values will be sent to HL7 for harmonization with the HL7 Act Vocabulary.

5.3.5.7 <text><reference value='#comment-2'/></text>

The <text> element contains a free text representation of the instruction. For CDA this SHALL contain a provides a <reference>element to thelink text of the comment in the narrative portion of the document. The comment itself is not the act being coded, so it

appears in the <text> of the <observation>, not as part of the <code>. For HL7 Version 3 Messages, the full text SHALL be represented here.

5.3.5.8 <statusCode code='completed' />

The code attribute of <statusCode> for all comments must be completed.

5.3.6 External References 1.3.6.1.4.1.19376.1.5.3.1.4.4

CDA Documents may reference information contained in other documents. While CDA Release 2.0 supports references in content via the <linkHtml> element, this is insufficient for many EMR systems as the link is assumed to be accessible via a URL, which is often not the case. In order to link an external reference, one needs the document identifier, and access to the clinical system wherein the document resides. For a variety of reasons, it is desirable to refer to the document by its identity, rather than by linking through a URL.

1. The identity of a document does not change, but the URLs used to access it may vary depending upon location, implementation, or other factors.
2. Referencing clinical documents by identity does not impose any implementation specific constraints on the mechanism used to resolve these references, allowing the content to be implementation neutral. For example, in the context of an XDS Affinity domain the clinical system used to access documents would be an XDS Registry and one or more XDS Repositories where documents are stored. In other contexts, access might be through a Clincial Data Repository (CDR), or Document Content Management System (DCMS). Each of these may have different mechanisms to resolve a document identifier to the document resource.
3. The identity of a document is known before the document is published (e.g., in an XDS Repository, Clincial Data Repository, or Document Content Management System), but its URL is often not known. Using the document identity allows references to existing documents to be created before those documents have been published to a URL. This is important to document creators, as it does not impose workflow restrictions on how links are created during the authoring process.

Fortunately, CDA Release 2.0 also provides a mechanism to refer to external documents in an entry, as shown below.

5.3.6.1 Specification

```
<entry>
  <act classCode='ACT' moodCode='EVN'>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>
    <id root='' extension=''/>
    <code nullFlavor='NA' />
    <text><reference value='#study-1'/></text>
    <!-- For CDA -->
    <reference typeCode='REFR|SPRT'>
      <externalDocument classCode='DOC' moodCode='EVN'>
        <id extension='' root=''/>
        <text><reference value='http://foo..'/></text>
      </externalDocument>
    </reference>
    <!-- For HL7 Version 3 Messages
    <sourceOf typeCode='REFR|SPRT'>
       <act classCode='DOC' moodCode='EVN'>
          <id extension='' root=''/>
          <text><reference value='http://foo…'</text>
       </act>
    </sourceOf>
     -->
  </act>
</entry>
```

5.3.6.2 <act classCode='ACT' moodCode='EVN'>

The external reference is an act that refers to documentation of an <act> (classCode='ACT'), that previously occurred (moodCode='EVN').

5.3.6.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>

The <templateId> element identifies this <act> as a reference act, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify reference acts. The templateId must have root='1.3.6.1.4.1.19376.1.5.3.1.4.1.4.4'.

5.3.6.4 <id root=' ' extension=' '/>

The reference is an act of itself, and must be uniquely identified. If there is no explicit identifier for this act in the source EMR system, a GUID may be used for the root attribute, and the extension may be omitted. Although HL7 allows for multiple identifiers, this profile requires that one and only one be used.

5.3.6.5 <code nullFlavor='NA'/>

The reference act has no code associated with it.

5.3.6.6 <text><reference value='#study-1'/></text>

In order to connect this external reference to the narrative text which it refers, the value of the <reference> element in the <text> element is a URI to an element in the CDA narrative of this document.

5.3.6.7 <reference typeCode='SPRT|REFR'> <externalDocument classCode='DOC' moodCode='EVN'>

External references are listed as either supporting documentation (typeCode='SPRT') or simply reference material (typeCode='REFR') for the reader. If this distinction is not supported by the source EMR system, the value of typeCode should be REFR. For CDA, the reference is indicated by a <reference> element containing an <externalDocument> element which documents (classCode='DOC') the event (moodCode='EVN'). For HL7 Version 3 Messages, the reference is represented with the element <sourceOf> and the external document is representated with a <act> element, however semantics, and attributes remain otherwise without change.

5.3.6.8 <id extension=' ' root=' '/>

The identifier of the document is supplied in the <id> element.

5.3.6.9 <text><reference value=' '/></text>

A link to the original document may be provided here. This shall be a URL where the referenced document can be located. For CDA, the link should also be present in the narrative inside the CDA Narrative in a <linkHTML> element.

5.3.7 Internal References 1.3.6.1.4.1.19376.1.5.3.1.4.4.1

CDA and HL7 Version 3 Entries may reference (point to) information contained in other entries within the same document or message as shown below.

5.3.7.1 Specification

```
<entryRelationship typeCode='' inversionInd='true|false'>
    <act classCode='' moodCode=''>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
      <code code='' displayName='' codeSystem='' codeSystemName=''/>
    </act>
</entryRelationship>
```

5.3.7.2 <entryRelationship typeCode=' ' inversionInd='true|false'>

For CDA the act being referenced appears inside a related entryRelationship. The type (typeCode) and direction (inversionInd) attributes will be specified in the entry content module that contains the reference. For HL7 Version 3 Messages, the relationship is indicated with a <sourceOf> element, however typeCodes and semantics remain unchanged.

5.3.7.3 <act classCode=' ' moodCode=' '>

The act being referred to can be any CDA Clinical Statement element type (act, procedure, observation, substanceAdministration, supply, et cetera). For compatibility with the Clinical Statement model the internal reference shall always use the <act> class, regardless of the XML element type of the act it refers to.

5.3.7.4 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>

The <templateId> element identifies this as an internal reference that conforms to all rules specified in this section.

5.3.7.5 <id root=' ' extension=' '/>

This element shall be present. The root and extension attributes shall identify an element defined elsewhere in the same document.

5.3.7.6 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

This element shall be present. It shall be valued when the internal reference is to element that has a <code> element, and shall have the same attributes as the <code> element in the act it references. If the element it references does not have a <code> element, then the nullFlavor attribute should be set to "NA".

5.3.8 Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.1

This event (moodCode='EVN') represents an act (<act classCode='ACT') of being concerned about a problem, allergy or other issue. The <effectiveTime> element describes the period of concern. The subject of concern is one or more observations about related problems (see 1.3.6.1.4.1.19376.1.5.3.1.4.5.2) or allergies and intolerances (see 1.3.6.1.4.1.19376.1.5.3.1.4.5.3). Additional references can be provided having additional information related to the concern. The concern entry allows related acts to be grouped. This allows representing the history of a problem as a series of observation over time, for example.

5.3.8.1 Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	ClinStat HL7 Clinical Statement (DRAFT)

5.3.8.2 Specification

```
<act classCode='ACT' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.27'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
  <id root='' extension=''/>
  <code nullFlavor='NA'/>
  <statusCode code='active|suspended|aborted|completed'/>
  <effectiveTime>
    <low value=''/>
    <high value=''/>
  </effectiveTime>
  <!-- one or more entry relationships identifying problems of concern -->
  <entryRelationship typeCode='SUBJ' inversionInd='false'>
     :
  </entryRelationship>
  <!-- For HL7 Version 3 Messages
  <sourceOf typeCode='SUBJ' inversionInd='false'>
     :
  </sourceOf>
  -->
  <!-- optional entry relationship providing more information about the concern
-->
  <entryRelationship typeCode='REFR'>
     :
  </entryRelationship>
  <!-- For HL7 Version 3 Messages
  <sourceOf typeCode='REFR' inversionInd='false'>
     :
  </sourceOf>
  -->

</act>
```


5.3.8.3 <act classCode='ACT' moodCode='EVN'>

5.3.8.4 All concerns reflect the act of recording (<act classCode='ACT'>) the event (moodCode='EVN') of being concerned about a problem, allergy or other issue about the patient condition.

5.3.8.5 <templateId root='2.16.840.1.113883.10.20.1.27'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>

5.3.8.6 These template identifiers indicates this entry conforms to the concern content module. This content module inherits constraints from the HL7 CCD Template for problem acts, and so also includes that template identifier.

5.3.8.7 <id root=' ' extension=' '/>

5.3.8.8 This required element identifies the concern.

5.3.8.9 <code nullFlavor='NA'/>

5.3.8.10 The code is not applicable to a concern act, and so shall be recorded as shown above.

5.3.8.11 <statusCode code='active|suspended|aborted|completed'/>

The statusCode associated with any concern must be one of the following values:

Value	Description
active	A concern that is still being tracked.
suspended	A concern that is active, but which may be set aside. For example, this value might be used to suspend concern about a patient problem after some period of remission, but before assumption that the concern has been resolved.
aborted	A concern that is no longer actively being tracked, but for reasons other than because the problem was resolved. This value might be used to mark a concern as being aborted after a patient leaves care against medical advice.
completed	The problem, allergy or medical state has been resolved and the concern no longer needs to be tracked except for historical purposes.

Note: A concern in the "active" state represents one for which some ongoing clinical activity is expected, and that no activity is expected in other states. Specific uses of the suspended and aborted states are left to the implementation.

5.3.8.12 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>

The <effectiveTime> element records the starting and ending times during which the concern was active. The <low> element shall be present. The <high> element shall be present for concerns in the completed or aborted state, and shall not be present otherwise.

5.3.8.13 <!-- 1..* entry relationships identifying problems of concern --> <entryRelationship type='SUBJ' inversionInd='false'>

Each concern is about one or more related problems or allergies. This entry shall contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances. This is how a series of related observations can be grouped as a single concern.

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element. The typeCode SHALL be 'SUBJ' for both HL7 Version 3 and CDA. HL7 Version 3 additionally requires that inversionInd SHALL be 'false'.

Note: The Allergy and Intolerances entry is a refinement of the Problem entry.

5.3.8.14 <!-- 0..n optional entry relationship providing more information about the concern --> <entryRelationship type='REFR' inversionInd='false'>

Each concern may have 0 or more related references. These may be used to represent related statements such related visits. This may be any valid CDA clinical statement, and SHOULD be an IHE entry template. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <subjectOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'false'

5.3.9 Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on a problem. Elements shown in the example below in gray are explained in the Concern Entry.

5.3.9.1 Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	HL7 Clinical Statement Pattern (Draft)

5.3.9.2 Parent Template

The parent of this template is Concern Entry. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.27

5.3.9.3 Specification

```
<act classCode='ACT' moodCode='EVN'>
 <templateId root='2.16.840.1.113883.10.20.1.27'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
 <id root=' ' extension=' '/>
 <code nullFlavor='NA'/>
 <statusCode code='active|suspended|aborted|completed'/>
 <effectiveTime>
   <low value=' '/>
   <high value=' '/>
 </effectiveTime>
 <!-- 1..* entry relationships identifying problems of concern -->
 <entryRelationship type='SUBJ'>
   <observation classCode='OBS' moodCode='EVN'/>
      <templateID root='1.3.6.1.4.1.19376.1.5.3.1.4.5'>
        :
   </observation>
 </entryRelationship>
 <!-- optional entry relationship providing more information about the concern
-->
 <entryRelationship type='REFR'>
 </entryRelationship>
</act>
```

5.3.9.4 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.2, and is a subtype of the Concern Entry, and so must also conform to that specification, with the template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.1. These elements are required and shall be recorded exactly as shown above.

5.3.9.5 <!-- 1..* entry relationships identifying problems of concern -->

```
<observation classCode='OBS' moodCode='EVN'>
 <templateID root=' 1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
  …
 </observation>
<entryRelationship type='SUBJ'>
```

This entry shall contain one or more problem entries that conform to the Problem Entry template 1.3.6.1.4.1.19376.1.5.3.1.4.5. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <subjectOf> element. The typeCode SHALL be ‘SUBJ’ and inversionInd SHALL be ‘false’

5.3.9.6 Allergy and Intolerance Concern 1.3.6.1.4.1.19376.1.5.3.1.4.5.3

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on an allergy or intolerance. Elements shown in the example below in gray are explained in that entry.

5.3.9.7 Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	HL7 Clinical Statement Pattern (Draft)

5.3.9.8 Parent Template

The parent of this template is Concern Entry. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.27

5.3.9.9 Specification

```
<act classCode='ACT' moodCode='EVN'>
 <templateId root='2.16.840.1.113883.10.20.1.27'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
 <id root=' ' extension=' '/>
 <code nullFlavor='NA'/>
 <statusCode code='active|suspended|aborted|completed'/>
 <effectiveTime>
   <low value=' '/>
   <high value=' '/>
 </effectiveTime>
 <!-- 1..* entry relationships identifying allergies of concern -->
 <entryRelationship type='SUBJ'>
   <observation classCode='OBS' moodCode='EVN'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
        :
   </observation>
 </entryRelationship>
 <!-- optional entry relationship providing more information about the concern
-->
 <entryRelationship type='REFR'>
 </entryRelationship>
</act>
```

5.3.9.10 <templateId root='2.16.840.1.113883.10.20.1.27'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.3, and is a subtype of the Concern entry, and so must also conform to the rules of the Concern Entry. These elements are required and shall be recorded exactly as shown above.

5.3.9.11 <!-- 1..* entry relationships identifying allergies of concern -->

```
<observation classCode='OBS' moodCode='EVN'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
  :
</observation>
<entryRelationship type='SUBJ'>
```

This entry shall contain one or more allergy or intolerance entries that conform to the Allergy and Intolerance Entry. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'false'

5.3.10 Problem Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5

This section makes use of the linking, severity, clinical status and comment content specifications defined elsewhere in the technical framework. In HL7 RIM parlance, observations about a problem, complaint, symptom, finding, diagnosis, or functional limitation of a patient is the event (moodCode='EVN') of observing (<observation classCode='OBS'>) that problem. The <value> of the observation comes from a controlled vocabulary representing such things. The <code> contained within the <observation> describes the method of determination from yet another controlled vocabulary. An example appears below in the figure below.

5.3.10.1 Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	HL7 Clinical Statement Pattern (Draft)

5.3.10.2 Parent Template

This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.28

5.3.10.3 Specification


```
<observation classCode='OBS' moodCode='EVN' negationInd=' false|true '>
 <templateId root='2.16.840.1.113883.10.20.1.28'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
 <id root=' ' extension=' '/>
 <code code=' ' displayName=' '
   codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
 <statusCode code='completed'/>
 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>
 <value xsi:type='CD' code=' '
   codeSystem=' ' displayName=' ' codeSystemName=' '>
   <originalText><reference value=' '/></originalText>
 </value>
 <
 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'>
elements
      identifying the health status of concern -->
 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'>
elements
      containing clinical status -->
 <!-- zero to many <entryRelationship typeCode='REFR' inversionInd='true'>
elements
      containing comments -->
</observation>
```

5.3.10.4 <observation classCode='OBS' moodCode='EVN' negationInd='false|true'>

The basic pattern for reporting a problem uses the CDA <observation> element, setting the classCode='OBS' to represent that this is an observation of a problem, and the moodCode='EVN', to represent that this is an observation that has in fact taken place. The negationInd attribute, if true, specifies that the problem indicated was observed to not have occurred (which is subtly but importantly different from having not been observed). The value of negationInd should not normally be set to true. Instead, to record that there is "no prior history of chicken pox", one would use a coded value indicated exactly that. However, it is not always possible to record problems in this manner, especially if using a controlled vocabulary that does not supply pre-coordinated negations , or which do not allow the negation to be recorded with post-coordinated coded terminology.

5.3.10.5 <templateId root='2.16.840.1.113883.10.20.1.28'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>

These <templateId> elements identify this <observation> as a problem, under both IHE and CCD specifications. This SHALL be included as shown above.

5.3.10.6 <id root=' ' extension=' '/>

The specific observation being recorded must have an identifier (<id>) that shall be provided for tracking purposes. If the source EMR does not or cannot supply an intrinsic identifier, then a GUID shall be provided as the root, with no extension (e.g., <id root='CE1215CD-69EC-4C7B-805F-569233C5E159'/>). While CDA allows for more than one identifier element to be provided, this profile requires that only one be used.

5.3.10.7 <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'>

The <code> describes the process of establishing a problem. The code element should be used, as the process of determining the value is important to clinicians (e.g., a diagnosis is a more advanced statement than a symptom). The recommended vocabulary for describing problems is shown in the table below. Subclasses of this content module may specify other vocabularies. When the list below is used, the codeSystem is '2.16.840.1.113883.6.96' and codeSystemName is SNOMED CT.

Code	Description
64572001	Condition
418799008	Symptom
404684003	Finding
409586006	Complaint
248536006	Functional limitation
55607006	Problem
282291009	Diagnosis

5.3.10.8 <statusCode code='completed'/>

A clinical document normally records only those condition observation events that have been completed, not observations that are in any other state. Therefore, the <statusCode> shall always have code='completed'.

5.3.10.9 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>

The <effectiveTime> of this <observation> is the time interval over which the <observation> is known to be true. The <low> and <high> values should be no more precise than known, but as precise as possible. While CDA allows for multiple mechanisms to record this time interval (e.g. by low and high values, low and width, high and width, or center point and width), we are constraining Medical summaries to use only the low/high form. The <low> value is the earliest point for which the condition is known to have existed. The <high> value, when present, indicates the time at which the observation was no longer known to be true. Thus, the implication is made that if the <high> value is specified, that the observation was no longer seen after this time, and it thus represents the date of resolution of the problem. Similarly, the <low> value may seem to represent onset of the problem. Neither of these statements is necessarily precise, as the <low> and <high> values may represent only an approximation of the true onset and resolution (respectively) times. For example, it may be the case that onset occurred prior to the <low> value, but no observation may have been possible before that time to discern whether the condition existed prior to that time. The <low> value should normally be present. There are exceptions, such as for the case where the patient may be able to report that they had chicken pox, but are unsure when. In this case, the

<effectiveTime> element shall have a <low> element with a nullFlavor attribute set to 'UNK'. The <high> value need not be present when the observation is about a state of the patient that is unlikely to change (e.g., the diagnosis of an incurable disease).

5.3.10.10 <confidentialityCode code=' '/>

While CDA allows for a condition to specify a <confidentialtyCode> for an observation, in practice there is no way to enforce consistent use of this information across institutions to secure confidential patient information. Therefore, it is recommended that this element not be sent. If there are confidentiality issues that need to be addressed other mechanisms should be negotiated within the affinity domain.

5.3.10.11 <uncertaintyCode code=' '/>

CDA allows a condition to be specified with an <uncertaintyCode>. Such conditions can also be recorded as a possible condition (e.g. possible ear infection). There is no present consensus on the best use of this element; therefore, it is recommended that this element not be sent.

5.3.10.12 <value xsi:type='CD' code=' ' codeSystem=' ' codeSystemName=' ' displayName=' '>

The <value> is the condition that was found. This element is required. While the value may be a coded or an un-coded string, the type is always a coded value (xsi:type='CD'). If coded, the code and codeSystem attributes shall be present. The codeSystem should reference a controlled vocabulary describing problems, complaints, symptoms, findings, diagnoses, or functional limitations, e.g., ICD-9, SNOMED-CT or MEDCIN, or others. The table below is an incomplete listing of acceptable values for the codeSystem attribute, along with the codeSystemName.

CodeSystem	codeSystemName	Description
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.103	ICD-9CM (diagnoses)	International Classification of Diseases, Clinical Modifiers, Version 9
2.16.840.1.113883.6.26	MEDCIN	A classification system from MEDICOMP Systems.

It is recommended that the codeSystemName associated with the codeSystem, and the displayName for the code also be provided for diagnostic and human readability purposes, but this is not required by this profile.

If uncoded, all attributes other than xsi:type='CD' must be absent.

5.3.10.13 <originalText><reference value=' '/></originalText>

The <value> contains a <reference> to the <originalText> in order to link the coded value to the narrative text. The <reference> contains a URI in value attribute. This URI points to the free text description of the problem in the document that is being described.

5.3.10.14 <!-- zero or one <entryRelationship typeCode='SUBJ' inversionInd='true'> elements containing severity -->

An optional <entryRelationship> element may be present indicating the severity of the problem. When present, this <entryRelationship> element shall contain a severity observation conforming to the Severity entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1).

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <subjectOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'.

5.3.10.15 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements containing clinical status -->

An optional <entryRelationship> may be present indicating the clinical status of the problem, e.g., resolved, in remission, active. When present, this <entryRelationship> element shall contain a clinical status observation conforming to the Problem Status Observation template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1).

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element. The typeCode SHALL be 'REFR' and inversionInd SHALL be 'false'.

5.3.10.16 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements identifying the health status of concern -->

An optional <entryRelationship> may be present referencing the health status of the patient, e.g., resolved, in remission, active. When present, this <entryRelationship> element shall contain a clinical status observation conforming to the Health Status Observation template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1). The typeCode SHALL be 'REFR' and inversionInd SHALL be 'false'.

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

5.3.10.17 <!-- zero to many <entryRelationship typeCode='SUBJ' inversionInd='true'> element containing comments -->

One or more optional <entryRelationship> elements may be present providing an additional comments (annotations) for the condition. When present, this <entryRelationship> element shall contain a comment observation conforming to the Comment entry template (1.3.6.1.4.1.19376.1.5.3.1.4.2). The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'.

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

5.3.11 Allergies and Intolerances 1.3.6.1.4.1.19376.1.5.3.1.4.6

Allergies and intolerances are special kinds of problems, and so are also recorded in the CDA <observation> element, with classCode='OBS'. They follow the same pattern as the problem entry, with exceptions noted below.

5.3.11.1 Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	HL7 Clinical Statement Pattern (Draft)

5.3.11.2 Specification

```
<observation classCode='OBS' moodCode='EVN' negationInd='false'>
 <templateId root='2.16.840.1.113883.10.20.1.18'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
 <id root=' ' extension=' '/>
 <code
   code='ALG|OINT|DALG|EALG|FALG|DINT|EINT|FINT|DNAINT|ENAINT|FNAINT'
   codeSystem='2.16.840.1.113883.5.4'
   codeSystemName='ObservationIntoleranceType'/>
 <statusCode code='completed'/>
 <effectiveTime>
   <low value=' '/>
   <high value=' '/>
 </effectiveTime>
 <value xsi:type='CD' code=' ' codeSystem=' ' displayName=' ' codeSystemName='
'/>
 <participant typeCode='CSM'>
   <participantRole classCode='MANU'>
     <playingEntity classCode='MMAT'>
       <code  code=' ' codeSystem=' '>
         <originalText><reference value='#substance'/></orginalText>
       </code>
       <name></name>
     </playingEntity>
   </participantRole>
 </participant>
 <!-- zero to many <entryRelationship> elements containing reactions -->
 <!-- zero or one <entryRelationship> elements containing severity -->
 <!-- zero or one <entryRelationship> elements containing clinical status -->
 <!-- zero to many <entryRelationship> elements containing comments -->
</observation>
```

5.3.11.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.6, and is a subtype of the Problem entry, and so must also conform to the rules of the problem entry, which has the template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.5. These elements are required and shall be recorded exactly as shown above.

5.3.11.4 <code code='ALG|OINT|DINT|EINT|FINT|DALG|EALG|FALG|DNAINT|ENAINT|FNAINT' displayName=' ' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ObservationIntoleranceType'/>

The <code> element represents the kind of allergy observation made, to a drug, food or environmental agent, and whether it is an allergy, non-allergy intolerance, or unknown class of intolerance (not known to be allergy or intolerance). The <code> element of an allergy entry shall be provided, and a code and codeSystem attribute shall be present. The example above uses the HL7 ObservationIntoleranceType vocabulary domain, which does provide suitable observation codes. Other vocabularies may be used, such as SNOMED-CT or MEDCIN. The displayName and codeSystemName attributes should be present.

5.3.11.5 <value xsi:type='CD' code=' ' codeSystem=' ' codeSystemName=' ' displayName=' '>

The <value> is a description of the allergy or adverse reaction. While the value may be a coded or an uncoded string, the type is always a coded value (xsi:type='CD'). If coded, the code and codeSystem attributes must be present. The codingSystem should reference a controlled vocabulary describing allergies and adverse reactions, see Table 5.4 12Table 5.4 12 above . If uncoded, all attributes other than xsi:type='CD' must be absent. The allergy or intolerance may not be known, in which case that fact shall be recorded appropriately. This might occur in the case where a patient experiences an allergic reaction to an unknown substance.

5.3.11.6 <participant typeCode='CSM'> <participantRole classCode='MANU'> <playingEntity classCode='MMAT'>

The substance that causes the allergy or intolerance may be specified in the <participant> element.

5.3.11.7 <code code=' ' codeSystem=' '> <originalText><reference value=' '/></originalText> </code>

The <code> element shall be present. It may contain a code and codeSystem attribute to indicate the code for the substance causing the allergy or intolerance. It shall contain a <reference> to the <originalText> in the narrative where the substance is named.

5.3.11.8 <!-- zero to many <entryRelationship> elements containing reactions -->

An allergy entry can record the reactions that are manifestations of the allergy or intolerance as shown below.


```
<entryRelationship typeCode='MFST'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6.1'/>
  <!-- a problem entry  -->
  <observation classCode='OBS' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.54'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>

  </observation>
</entryRelationship>
```

5.3.11.9 <entryRelationship typeCode='MFST'>

This is a related entry (<entryRelationship>) that indicates the manifestations (typeCode='MFST') the reported allergy or intolerance. These are events that may occur, or have occurred in the past as a reaction to the allergy or intolerance.

5.3.11.10 <observation classCode='OBS' moodCode='EVN'> <templateId root='2.16.840.1.113883.10.20.1.54'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/> </observation>

The entry contained with this entry relationship is some sort of problem that is a manifestation of the allergy. It is recorded using the Problem Entry structure, with the additional template identifier (2.16.840.1.113883.10.20.1.54) indicating that this problem is a reaction.

5.3.11.11 <!-- zero or one <entryRelationship typeCode='SUBJ' inversionInd='true'> elements containing severity -->

An optional <entryRelationship> element may be present indicating the severity of the problem. When present, this <entryRelationship> element shall contain a severity observation conforming to the Severity entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1). For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'.

5.3.11.12 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements containing clinical status -->

An optional <entryRelationship> may be present indicating the clinical status of the allergy, e.g., resolved, in remission, active. When present, this <entryRelationship> element shall contain a clinical status observation conforming to the Problem Status Observation template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1). The typeCode SHALL be 'REFR' and inversionInd SHALL be 'false'. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

5.3.11.13 <!-- zero to many <entryRelationship typeCode='SUBJ' inversionInd='true'> element containing comments -->

One or more optional <entryRelationship> elements may be present providing an additional comments (annotations) for the allergy. When present, this <entryRelationship> element shall contain an entry conforming to the Comment entry template (1.3.6.1.4.1.19376.1.5.3.1.4.2). The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'.

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

5.3.12 Medications 1.3.6.1.4.1.19376.1.5.3.1.4.7

This content module describes the general structure for a medication. All medication administration acts will be derived from this content module.

5.3.12.1 Standards

Pharmacy	**HL7 Pharmacy Domain (Normative)**
CCD	ASTM/HL7 Continuity of Care Document

5.3.12.2 Specification

```
<substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.24'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
  <templateId root=''/>
  <id root='' extension=''/>
  <code code='' codeSystem='' displayName='' codeSystemName=''/>
  <text><reference value='#med-1'/></text>
  <statusCode code='completed'/>
  <effectiveTime xsi:type='IVL_TS'>
      <low value=''/>
      <high value=''/>
  </effectiveTime>
  <effectiveTime operator='A'
xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS'>
    :
  </effectiveTime>
  <routeCode code='' codeSystem='' displayName='' codeSystemName=''>
  <doseQuantity value='' unit=''/>
  <approachSiteCode code='' codeSystem='' displayName='' codeSystemName=''>
  <rateQuantity value='' unit=''/>
  <consumable>
    :
    .
  </consumable>
  <!-- 0..* entries describing the components -->
  <entryRelationship typeCode='COMP' >
      <sequenceNumber value=''/>
  </entryRelationship>
  <!-- An optional entry relationship that indicates the the reason for use -->
  <entryRelationship typeCode='RSON'>
    <act classCode='ACT' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
    </act>
  </entryRelationship>
  <!-- An optional entry relationship that provides prescription activity -->
  <entryRelationship typeCode='REFR'>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
      :
      .
  </entryRelationship>
  <precondition>
    <criterion>
      <text><reference value=''></text>
    </criterion>
  </precondition>
</substanceAdministation>
```

This section makes use of the linking, severity and instruction entries. Medications are perhaps the most difficult data elements to model due to variations in the ways that medications are prescribed.

This profile identifies the following relevant fields of a medication as being important to be able to generate in a medical summary. The table below identifies and describes these fields, and indicates the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

5.3.12.2.1 Medication Fields

Field	Opt.	CDA Tag	Description
Start and Stop Date	R2	<effectiveTime>	The date (and time if available) when the medication regimen began and is expected to finish. The first component of the <effectiveTime> encodes the lower and upper bounds over which the <substanceAdministration> occurs, and the start time is determined from the lower bound. If the medication has been known to be stopped, the high value must be present, but expressed as a flavor of null (e.g., Unknown).
Frequency	R2	<effectiveTime>	The frequency indicates how often the medication is to be administered. It is often expressed as the number of times per day, but which may also include information such as 1 hour before/after meals, or in the morning, or evening.The second <effectiveTime> element encodes the frequency. In cases where split or tapered doses are used, these may be found in subordinate <substanceAdministration> elements.
Route	R2	<routeCode>	The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
Dose	R2	<doseQuantity>	The amount of the medication given. This should be in some known and measurable unit, such as grams, milligrams, et cetera. It may be measured in "administration" units (such as tablets or each), for medications where the strength is relevant. In this case, only the unit count is specified , no units are specified. It may be a range.
Site	O	<approachSiteCode>	The site where the medication is administered, usually used with IV or topical drugs.
Rate	R2	<rateQuantity>	The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.
Product	R	<consumable> <name> </consumable>	The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information.Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text.
Strength	R2	<consumable> <code> <originalText/> </code> </consumable>	The name and strength of the medication. This information is only relevant for some medications, as the dose of the medication is often sufficient to indicate how much medication the patient receives. For example, the medication Percocet comes in a variety of strengths, which indicate specific amounts of two different medications being received in single tablet. Another example is eye-drops, where the medication is in a solution of a particular strength, and the dose quantity is some number of drops. The originalText referenced by the <code> element in the consumable should refer to the name and strength of the medication in the narrative text.Note: Due to restrictions of the CDA schema, there is no way to separately record the strength.
Code	R2	<consumable> <code/>	A code describing the product from a controlled vocabulary, such as RxNorm, First DataBank, et cetera.

		</consumable>	
Instructions	R2	<entryRelationship>	A place to put free text comments to support additional relevant information, or to deal with specialized dosing instructions. For example, "take with food", or tapered dosing.
Indication	O	<entryRelationship>	A link to supporting clinical information about the reason for providing the medication (e.g., a link to the relevant diagnosis).

5.3.12.2.2 <substanceAdministration classCode='SBADM' moodCode='INT|EVN'>

The general model is to record each prescribed medication in a <substanceAdministration> intent (moodCode='INT'). Medications that have been reported by the patient or administered (instead of prescribed), are recorded in the same element, except that this is now an event (moodCode='EVN'). The <substanceAdministration> element may contain subordinate <substanceAdministration> elements in a related component entry to deal with special cases (see the section below on Special Cases). These cases include split, tapered, or conditional dosing, or combination medications. The use of subordinate <substanceAdministration> elements to deal with these cases is optional. The comment field should always be used in these cases to provide the same information as free text in the top level <substanceAdministration> element. There are a variety of special cases for dosing that need to be accounted for. These are described below. Most of these special cases involve changing the dosage or frequency over time, or based on some measurement. When the dosage changes, then additional entries are required for each differing dosage. The last case deals with combination medications.

5.3.12.2.3 Normal Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.7.1

This template identifier is used to identify medication administration events that do not require any special processing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. Medications that use this template identifier shall not use subordinate <substanceAdministation> acts.

5.3.12.2.4 Tapered Doses 1.3.6.1.4.1.19376.1.5.3.1.4.8

This template identifier is used to identify medication administration events that require special processing to handle tapered dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A tapered dose is often used for certain medications where abrupt termination of the medication can have negative consequences. Tapered dosages may be done by adjusting the dose frequency, the dose amount, or both.

When merely the dose frequency is adjusted, (e.g., Prednisone 5mg b.i.d. for three days, then 5mg. daily for three days, and then 5mg every other day), then only one medication entry is needed, multiple frequency specifications recorded in <effectiveTime> elements. When the dose varies (eg. Prednisone 15mg daily for three days, then 10 mg daily for three days, the 5 mg daily for three days), subordinate medication entries should be created for each distinct dosage.

5.3.12.2.5 Split Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.9

This template identifier is used to identify medication administration events that require special processing to handle split dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A split dose is often used when different dosages are given at different times (e.g., at different times of day, or on different days). This may be to account for different metabolism rates at different times of day, or to simply address drug packaging deficiencies (e.g., and order for Coumadin 2mg on even days, 2.5mg on odd days is used because Coumadin does not come in a 2.25mg dose form).

In this case a subordinate <substanceAdministration> entry is required for each separate dosage.

5.3.12.2.6 Conditional Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.10

This template identifier is used to identify medication administration events that require special processing to handle conditional dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A conditional dose is often used when the dose amount differs based on some measurement (e.g., an insulin sliding scale dose based on blood sugar level). In this case a subordinate <substanceAdministration> entry is required for each different dose, and the condition should be recorded.

5.3.12.2.7 Combination Medications 1.3.6.1.4.1.19376.1.5.3.1.4.11

This template identifier is used to identify medication administration events that require special processing to handle combination medications. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A combination medication is made up of two or more other medications. These may be prepackaged, such as Percocet, which is a combination of Acetaminophen and oxycodone in predefined ratios, or prepared by a pharmacist, such as a GI cocktail.

In the case of the prepackaged combination, it is sufficient to supply the name of the combination drug product, and its strength designation in a single <substanceAdministation> entry. The dosing information should then be recorded as simply a count of administration units.

In the latter case of a prepared mixture, the description of the mixture should be provided as the product name (e.g., "GI Cocktail") , in the <substanceAdministration> entry. That entry may, but is not required, to have subordinate <substanceAdministration> entries included beneath it to record the components of the mixture.

5.3.12.3 <templateId root='2.16.840.1.113883.10.20.1.24'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7' />

All medications entries use the <templateId> elements specified above to indicate that they are medication acts. This element is required. In addition, a medication entry shall further identify itself using one of the template identifiers detailed in the next section.

5.3.12.4 <templateId root=' ' />

The <templateId> element identifies this <entry> as a particular type of medication event, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify medication events. The templateId must use one of the values in the table below for the root attribute.

root	Description
1.3.6.1.4.1.19376.1.5.3.1.4.7.1	A "normal" <substanceAdministration> act that may not contain any subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.8	A <substanceAdministration> act that records tapered dose information in subordinate <substanceAdministration> act.
1.3.6.1.4.1.19376.1.5.3.1.4.9	A <substanceAdministration> act that records split dose information in subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.10	A <substanceAdministration> act that records conditional dose information in subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.11	A <substanceAdministration> act that records combination medication component information in subordinate <substanceAdministration> acts.

5.3.12.5 <id root=' ' extension=' '/>

A top level <substanceAdministration> element must be uniquely identified. If there is no explicit identifier for this observation in the source EMR system, a GUID may be used for the root attribute, and the extension may be omitted. Although HL7 allows for multiple identifiers, this profile requires that one and only one be used. Subordinate <substanceAdministration> elements may, but need not be uniquely identified.

5.3.12.6 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '>

Do NOT code the medication here. This <code> element is used to supply a code that describes the <substanceAdminstration> act, not the medication being administered or prescribed. This may be a procedure code, such as those found in CPT-4 (and often used for billing), or may describe the method of medication administration, such as by intravenous injection. This element is optional.

5.3.12.7 <text><reference value=' '/></text>

The URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the medication. In a CDA document, the URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the medication. In an HL7 message, the content of the text element shall contain the complete text describing the medication.

5.3.12.8 <statusCode code='completed'/>

The status of all <substanceAdministration> elements must be "completed". The act has either occurred, or the request or order has been placed.

5.3.12.9 <effectiveTime xsi:type='IVL_TS'>

The first <effectiveTime> element encodes the start and stop time of the medication regimen. This an interval of time (xsi:type='IVL_TS'), and must be specified as shown. This is an additional constraint placed upon CDA Release 2.0 by this profile, and simplifies the exchange of start/stop and frequency information between EMR systems.

5.3.12.10 <low value=' '/><high value=' '/>

The <low> and <high> values of the first <effectiveTime> element represent the start and stop times for the medication. The <low> value represents the start time, and the <high> value represents the stop time. If either the <low> or the <high> value is unknown, this shall be recorded by setting the nullFlavor attribute to UNK. The <high> value records the end of the medication regime according to the information provided in the prescription or order. For example, if the prescription is for enough medication to last 30 days, then the high value should contain a date that is 30 days later then the <low> value. The rationale is that a provider, seeing an un-refilled prescription would normally assume that the medication is no longer being taken, even if the intent of the treatment plan is to continue the medication indefinitely.

5.3.12.11 <effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS' />

The second <effectiveTime> element records the frequency of administration. This <effectiveTime> element must be intersected with the previous time specification (operator='A'), producing the bounded set containing only those time specifications that fall within the start and stop time of the medication regimen. Several common frequency expressions appear in the table below, along with their XML representations.

5.3.12.11.1 Specifying Medication Frequency

Freq	Description	XML Representation
b.i.d.	Twice a day	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'> <period value='12' unit='h' /></effectiveTime>
q12h	Every 12 hours	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'> <period value='12' unit='h' /></effectiveTime>
Once	Once, on 2005-09-01 at 1:18am.	<effectiveTime xsi:type='TS' value='200509010118'/>
t.i.d.	Three times a day, at times determined by the person administering the medication .	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'> <period value='8' unit='h' /></effectiveTime>
q8h	Every 8 hours	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'> <period value='8' unit='h' /></effectiveTime>
qam	In the morning	<effectiveTime xsi:type='EIVL' operator='A'> <event code='ACM'/></effectiveTime>
	Every day at 8 in the morning for 10 minutes	<effectiveTime xsi:type='PIVL_TS' operator='A'> <phase> <low value="198701010800" inclusive="true"/> <width value="10" unit="min"/> </phase> <period value='1' unit='d'/></effectiveTime>
q4-6h	Every 4 to 6 hours.	<effectiveTime xsi:type='PIVL_PPD_TS' institutionSpecified='false' operator='A'> <period value='5' unit='h' /> <standardDeviation value='1' unit='h'></effectiveTime>

The last frequency specification is about as bad as it gets, but can still be represented accurately within the HL7 V3 datatypes. The mean (average) of the low and high values is specified for the period. The mean of 4 and 6 is 5. The standard deviation is recorded as one half the difference between the high and low values, with an unspecified distribution. The type attribute of the <effectiveTime> element describes the kind of frequency specification it contains. More detail is given for each type in the table below.

5.3.12.11.2 Data types used in Frequency Specifications

xsi:type	Description
TS	An xsi:type of TS represents a single point in time, and is the simplest of all to represent. The value attribute of the <effectiveTime> element specifies the point in time in HL7 date-time format (CCYYMMDDHHMMSS)
PIVL_TS	An xsi:type of PIVL_TS is the most commonly used, representing a periodic interval of time. The <low> element of <phase> may be present. If so it specifies the starting point, and only the lower order components of this value are relevant with respect to the <period>. The <width> element represents the duration of the dose administration (e.g., for IV administration). The <period> indicates how often the dose is given. Legal values for the unit attribute of <period> are s, min, h, d, wk and mo representing seconds, minutes, hours, days, weeks, and months respectively.
EIVL_TS	An xsi:type of EIVL_TS represents an event based time interval, where the event is not a precise time, but is often used for timing purposes (e.g. with meals, between meals, before breakfast, before sleep). Refer to the HL7 TimingEvent vocabulary for the codes to use for the <event> element. This interval may specify an <offset> which provides information about the time offset from the specified event (e.g., <offset><low value='-1' unit='h'/><width value='10'

	unit='min'/></offset> means 1 hour before the event. In that same example, the <width> element indicates the duration for the dose to be given.
PIVL_PPD_TS	An xsi:type of PIVL_PPD_TS represents an probabilistic time interval and is used to represent dosing frequencies like q4-6h. This profile requires that the distributionType of this interval be left unspecified. The <period> element specifies the average of the time interval, and the value of the <standardDeviation> shall be computed as half the width of the interval. The unit attributes of the <period> and <standardDeviation> elements shall be the same.
SXPR_TS	An xsi:type of SXPR_TS represents a parenthetical set of time expressions. This type is used when the frequency varies over time (e.g., for some cases of tapered dosing, or to handle split dosing). The <comp> elements of this <effectiveTime> element are themselves time expressions (using any of the types listed above). Each <comp> element may specify an operator (e.g. to intersect or form the union of two sets).

5.3.12.12 <routeCode code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.112' codeSystemName='RouteOfAdministration'>

The <routeCode> element specifies the route of administration using the HL7 RouteOfAdministration vocabulary. A code must be specified if the route is known, and the displayName attribute should be specified. If the route is unknown, this element shall not be sent.

5.3.12.13 <approachSiteCode code=' ' codeSystem=' '> originalText><reference value=' '/></originalText> </approachSiteCode>

The <approachSiteCode> element describes the site of medication administrion. It may be coded to a controlled vocabulary that lists such sites (e.g., SNOMED-CT). In CDA documents, this element contains a URI in the value attribute of the <reference> that points to the text in the narrative identifying the site. In a message, the <originalText> element shall contain the text identifying the site.

5.3.12.14 <doseQuantity> <low value=' ' unit=' '/><high value=' ' unit=' '/> </doseQuantity>

The dose is specified if the <doseQuantity> element. If a dose range is given (e.g., 1-2 tablets, or 325-750mg), then the <low> and <high> bounds are specified in their respective elements, otherwise both <low> and <high> have the same value. If the dose is in countable units (tablets, caplets, "eaches"), then the unit attribute is not sent. Otherwise the units are sent. The unit attribute should be derived from the HL7 UnitsOfMeasureCaseSensitive vocabulary .

5.3.12.15 <low|high value=' '> <translation> <originalText><reference value=' '/></originalText> </translation></low|high >

Any <low> and <high> elements used for <doseQuantity> or <rateQuantity> should contain a <translation> element that provides a <reference> to the <originalText> found in the narrative body of the document. In a CDA document, any <low> and <high> elements used for <doseQuantity> or <rateQuantity> should contain a <translation>

element that provides a <reference> to the <originalText> found in the narrative body of the document. In a message, the <originalText> may contain the original text used to describe dose quantity.

5.3.12.16 <rateQuantity><low value=' ' unit=' '/><high value=' ' unit=' '/></rateQuantity>

The rate is specified in the <rateQuantity> element. The rate is given in units that have measure over time. In this case, the units should be specified as a string made up of a unit of measure (see doseQuantity above), followed by a slash (/), followed by a time unit (s, min, h or d).

Again, if a range is given, then the <low> and <high> elements contain the lower and upper bound of the range, otherwise, they contain the same value.

5.3.12.17 <consumable>

The <consumable> element shall be present, and shall contain a <manufacturedProduct> entry conforming to the Product Entry template

5.3.12.18 <entryRelationship typeCode='REFR'> &nsbp;<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>

The top level <substanceAdministration> element may contain a reference (typeCode='REFR') to related prescription activity as described in section 5.4.4.16.

5.3.12.19 <entryRelationship typeCode='COMP'> <sequenceNumber value=' '>

A top level <substanceAdministration> element may contain one or more related components, either to handle split, tapered or conditional dosing, or to support combination medications.

In the first three cases, the subordinate components shall specify only the changed <frequency> and/or <doseAmount> elements. For conditional dosing, each subordinate component shall have a <precondition> element that specifies the <observation> that must be obtained before administration of the dose. The value of the <sequenceNumber> shall be an ordinal number, starting at 1 for the first component, and increasing by 1 for each subsequent component. Components shall be sent in <sequenceNumber> order.

5.3.12.20 <entryRelationship typeCode='SUBJ' inversionInd='true'/>

At most one instruction may be provided for each <substanceAdministration> entry. If provided, it shall conform to the requirements listed above under section 5.4.4.6 on medication instructions. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).

5.3.12.21 <entryRelationship typeCode='RSON'> <act classCode='ACT' moodCode='EVN'>


```
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
<id root=' ' extension=' '/>
</act>
</entryRelationship>
```

A <substanceAdministration> event may indicate one or more reasons for the use of the medication. These reasons identify the concern that was the reason for use via the Internal Reference entry content module specified in section 5.4.4.8.2. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document. A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.

5.3.12.22 <precondition><criterion>

```
<text><reference value=' '></text>
</criterion></precondition>
```

In a CDA document, the preconditions for use of the medication are recorded in the <precondition> element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.

5.3.12.23 <condition typeCode='PRCN'>

```
<criterion>
<text></text>
<value nullFlavor='UNK'/>
<interpretationCode nullFlavor='UNK'/>
</criterion>
</condition>
```

In a message, the preconditions for use of the medication are recorded in the <condition> element. The typeCode shall be PRCN. The <text> element of the criterion shall contain a text description of the precondition. The <value> element is required, and may be recorded in a structured data type if known, and if not, may be recorded using a nullFlavor as shown above. The same is true for <interpretationCode>.

5.3.13 Immunizations 1.3.6.1.4.1.19376.1.5.3.1.4.12

An immunizations entry is used to record the patient's immunization history.

5.3.13.1 Specification

```
<substanceAdministration typeCode='SBADM' moodCode='EVN'
negationInd='true{{!}}false'>
  <templateId root='2.16.840.1.113883.10.20.1.24'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>

  <id root='' extension=''/>
  <code code='IMMUNIZ' codeSystem='2.16.840.1.113883.5.4'
codeSystemName='ActCode'/>
  <text><reference value='#xxx'/><text>
  <statusCode code='completed'/>
  <effectiveTime value=''/>
  <!-- The reasonCode would normally provide a reason why the immunization was
    not performed.  It isn't supported by CDA R2, and so comments will have to
suffice.
    <reasonCode code='' codeSystem=''
codeSystemName='ActNoImmunizationReasonIndicator'/>
  -->
  <routeCode code='' codeSystem='' codeSystemName='RouteOfAdministration'/>
  <approachSiteCode code='' codeSystem=''
codeSystemName='HumanSubstanceAdministrationSite'/>
  <doseQuantity value='' units=''/>
  <consumable typeCode='CSM'>
    <manufacturedProduct classCode='MANU'>
      <manufacturedLabeledDrug classCode='MMAT' determinerCode='KIND'>
        <code code='' codeSystem='' codeSystemName=''>
          <originalText><reference value='#yyy'/></originalText>
        </code>
      </manufacturedLabeledDrug>
    </manufacturedProduct>
  </consumable>
  <!-- An optional entry relationship that provides prescription activity -->
  <entryRelationship typeCode='REFR'>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
      :
      .
  </entryRelationship>
  <!-- An optional entry relationship that identifies the immunization series
number -->
  <entryRelationship typeCode='SUBJ'>
    <observation typeCode='OBS' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.46'/>
      <code code='30973-2' displayName='Dose Number'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <statusCode code='completed'/>
      <value xsi:type='INT' value=''/>
    </observation>
  </entryRelationship>

  <entryRelationship inversionInd='true' typeCode='CAUS'>
    <observation typeCode='OBS' moodCode='EVN'>
      <id root='' extension=''/>
    </observation>
  </entryRelationship>
  <!-- Optional <entryRelationship> element containing comments -->
</substanceAdministration>
```


5.3.13.2 <substanceAdministration typeCode='SBADM' moodCode='EVN' negationInd='true|false'>

An immunization is a substance administration event. An immunization entry may be a record of why a specific immunization was not performed. In this case, negationInd shall be set to "true", otherwise, it shall be false.

5.3.13.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>

The <templateId> element identifies this <substanceAdministration> as an immunization, allowing for validation of the content. The templateId must have root='1.3.6.1.4.1.19376.1.5.3.1.4.12'.

5.3.13.4 <id root=' ' extension=' '/>

This shall be the identifier for the immunization event.

5.3.13.5 <code code='IMMUNIZ' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode'/>

This required element records that the act was an immunization. The substance administration act must have a <code> element with code and codeSystem attributes present. If no coding system is used by the source, then simply record the code exactly as shown above. Another coding system that may be used for codes for immunizations are the CPT-4 codes for immunization procedures. This <code> element shall not be used to record the type of vaccine used from a vocabulary of drug names.

codeSystem	codeSystemName	Description
2.16.840.1.113883.5.4	IMMUNIZ	The IMMUNIZ term from the HL7 ActCode vocabulary.
2.16.840.1.113883.6.12	C4	Current Procedure Terminology 4 (CPT-4) codes.

5.3.13.6 <text><reference value='#xxx'/><text>

In a CDA document, the URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the immunization activity. In an HL7 message, the content of the text element shall contain the complete text describing the immunization activity.

5.3.13.7 <statusCode code='completed'/>

The statusCode shall be set to "completed" for all immunizations.

5.3.13.8 <effectiveTime value=' '/>

The effectiveTime element shall be present and should contain a time value that indicates the date of the substance administration. If the date is unkown, this shall be recorded using the nullFlavor attribute, with the reason that the information is unknown being specified. Otherwise, the date shall be recorded, and should have precision of at least the day.

5.3.13.9 <routeCode code=' ' codeSystem=' ' codeSystemName='RouteOfAdministration'/>

See routeCode under Medications.

5.3.13.10 <approachSiteCode code=' ' codeSystem=' ' codeSystemName='HumanSubstanceAdministrationSite'/>

See approachSiteCode under Medications.

5.3.13.11 <doseQuantity value=' ' units=' '/>

See doseQuantity under Medications.

5.3.13.12 <consumable typeCode='CSM'>

See consumable under Medications.

5.3.13.13 <entryRelationship typeCode='REFR'> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>

The top level <substanceAdministration> element may contain a reference (typeCode='REFR') to related Supply entry

5.3.13.14 <entryRelationship typeCode='SUBJ'> <observation classCode='OBS' moodCode='EVN'> <templateId root='2.16.840.1.113883.10.20.1.46'/>

This optional entry relationship may be present to indicate that position of this immunization in a series of immunizations.

5.3.13.15 <code code='30973-2' displayName='Dose Number' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>

The <code> element shall be present and must be recorded with the code and codeSystem attributes shown above. This element indicates that the observation describes the dose number for the immunization.

5.3.13.16 <statusCode code='completed'/>

The <statusCode> element shall be present, and must be recorded exactly as shown above. This element indicates that the observation has been completed.

5.3.13.17 <value xsi:type='INT' value=' '/>

The <value> element shall be present, and shall indicate the immunization series number in the value attribute.

5.3.13.18 <entryRelationship inversionInd='true' typeCode='CAUS'>

This repeatable element should be used to identify adverse reactions caused by the immunization.

5.3.13.19 <observation typeCode='OBS' moodCode='EVN'>

This element is required, and provides a pointer to the the adverse reaction caused by the immunization.

5.3.13.20 <id root=' ' extension=' '/>

This element is required, and gives the identifier of the adverse reaction. The adverse reaction pointed to by this element shall be described in more detail using the Allergies entry, elsewhere in the document where this element was found.

5.3.13.21 <!-- Optional <entryRelationship> element containing comments -- >

An immunization entry can have negationInd set to true to indicate that an immunization did not occur. In this case, it shall have at least one comment that provides an explaination for why the immunization did not take place . Other comments may also be present.

5.3.14 Supply Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7.3

The supply entry describes a prescription activity.

5.3.14.1 Specification

```
<substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
    :
    .
  <entryRelationship type='REFR' inversionInd='false'>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
    <sequenceNumber value=''/>
    <supply classCode='SPLY' moodCode='INT|EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.34'/>
      <id root='' extension=''/>
      <repeatNumber value=''/>
      <quantity value='' unit=''/>
      <author>
        <time value=''/>
        <assignedAuthor>
          <id root='' extension=''/>
          <addr></addr>
          <telecom use='' value=''/>
          <assignedPerson><name></name></assignedPerson>
          <representedOrganization><name></name></representedOrganization>
        </assignedAuthor>
      </author>
      <performer typeCode='PRF'>
        <time value=''/>
        <assignedEntity>
          <id root='' extension=''/>
          <addr></addr>
          <telecom use='' value=''/>
          <assignedPerson><name></name></assignedPerson>
          <representedOrganization><name></name></representedOrganization>
        </assignedEntity>
      </performer>
      <!-- Optional Fulfillment instrctions -->
      <entryRelationship typeCode='SUBJ'>
      </entryRelationship>
    </supply>
  <entryRelationship>
</substanceAdministration>
```

5.3.14.2 <entryRelationship typeCode='REFR' inversionInd='false'>

A <substanceAdministration> act may reference (typeCode='REFR') a prescription activity in an <entryRelationship> element in a CDA document. In a message, the relationship is recorded using a <sourceOf> element instead of the <entryRelationship> element. The typeCode and inversionInd attributes, and the semantics remain identical.

5.3.14.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>

The <entryRelationship> element shall contain a <templateId> element that appears exactly as shown above. This element identifies this entry as a prescription activity.

5.3.14.4 <sequenceNumber value=' '/>

The prescription activity may have a <sequenceNumber> element to indicate the fill number. A value of 1, 2 or N indicates that it is the first, second, or Nth fill respectively

of a specific prescription. This element should be present when the embedded <supply> element has a moodCode attribute of EVN.

5.3.14.5 <supply classCode='SPLY' moodCode='INT|EVN'>

The <supply> element shall be present. The moodCode attribute shall be INT to reflect that a medication has been prescribed, or EVN to indicate that the prescription has been filled.

5.3.14.6 <templateId root='2.16.840.1.113883.10.20.1.34'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>

The <templateId> elements shown above shall be present, and identify this supply act as a Supply Entry.

5.3.14.7 <id root=' ' extension=' '/>

Each supply act shall have an identifier to uniquely identify the supply entry.

5.3.14.8 <repeatNumber value=' '/>

Each supply entry should have a <repeatNumber> element that indicates the number of times the prescription can be filled.

5.3.14.9 <quantity value=' ' unit=' '/>

The supply entry should indicate the quantity supplied. The value attribute shall be present and indicates the quantity of medication supplied. If the medication is supplied in dosing units (tablets or capsules), then the unit attribute need not be present (and should be set to 1 if present). Otherwise, the unit element shall be present to indicate the quantity (e.g., volume or mass) of medication supplied.

5.3.14.10 <author>

A supply entry that describes an intent (<supply classCode='SPLY' moodCode='INT'>) may include an <author> element to identify the prescribing provider.

5.3.14.11 <time value=' '/>

The <time> element must be present to indicate when the author created the prescription. If this information is unknown, it shall be recorded by setting the nullFlavor attribute to UNK.

5.3.14.12 <assignedAuthor>

The <assignedAuthor> element shall be present, and identifies the author.

5.3.14.13 <id root=' ' extension=' '/>

One or more <id> elements should be present. These identifiers identify the author of the act. When the author is the prescribing physician they may include local identifiers or regional identifiers necessary for prescribing.

5.3.14.14 <assignedPerson><name/></assignedPerson> <representedOrganization><name/></ representedOrganization>

An <assignedPerson> and/or <representedOriganization> element shall be present. This element shall contain a <name> element to identify the prescriber or their organization.

5.3.14.15 <performer typeCode='PRF'>

The <performer> element may be present to indicate who is intended (moodCode='INT'), or actually filled (moodCode='EVN') the prescription.

5.3.14.16 <time value=' '/>

The <time> element shall be present to indicate when the prescription was filled (moodCode='EVN'). If this information is unknown, it shall be recorded by setting the nullFlavor attribute to UNK.

The <time> element should be present to indicate when the prescription is intended to be filled (moodCode='INT').

5.3.14.17 <assignedEntity>

The < assignedEntity> element shall be present, and identifies the filler of the prescription.

5.3.14.18 <id root=' ' extension=' '/>

One or more <id> elements should be present. These identify the performer.

5.3.14.19 <assignedPerson><name/></assignedPerson> <representedOrganization><name/></ representedOrganization>

An <assignedPerson> and/or <representedOriganization> element shall be present. This element shall contain a <name> element to identify the filler or their organization.

5.3.14.20 <!-- Optional Fulfillment instrctions --> <entryRelationship typeCode='SUBJ'> </entryRelationship>

An entry relationship may be present to provide the fulfillment instructions. When present, this entry relationship shall contain a Medication Fulfillment Instructions entry.

5.3.15 Product Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7.2

The product entry describes a medication or immunization used in a <substanceAdministration> or <supply> act. It adopts the constraints of the ASTM/HL7 Continuity of Care Document.

5.3.15.1 Specification

```
<!-- Within a CDA Document -->
<manufacturedProduct>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2'/>
  <templateId root='2.16.840.1.113883.10.20.1.53'/>
  <manufacturedMaterial>
    <code code='' displayName='' codeSystem='' codeSystemName=''>
      <originalText><reference value=''/></originalText>
    </code>
    <name></name>
  </manufacturedMaterial>
</manufacturedProduct>
<!-- Within a message -->
<administerableMaterial>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2'/>
  <templateId root='2.16.840.1.113883.10.20.1.53'/>
   <administerableMaterial>
      <code></code>
   <desc></desc>
  </administerableMaterial>
</administerableMaterial>
```

5.3.15.2 <manufacturedProduct> -OR- <administerableMaterial> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2'/> <templateId root='2.16.840.1.113883.10.20.1.53'/> <manufacturedMaterial> -OR- <administerableMaterial>

In a CDA document, the name and strength of the medication are specified in the elements under the <manufacturedMaterial> element. In a message, the are contained within the <administeredMaterial> element, inside another <administerableMaterial> element[1]. The templateId elements are required and identify this as a product entry.

[1] This duplication of element names is an artifact of the standard.

5.3.15.3 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '> <originalText><reference value=' '/></originalText> </code>

The <code> element of the <manufacturedMaterial> describes the medication. This may be coded using a controlled vocabulary, such as RxNorm, First Databank, or other vocabulary system for medications, and should be the code that represents the generic medication name and strength (e.g., acetaminophen and oxycodone -5/325), or just the generic medication name alone if strength is not relevant (Acetaminophen).

In a CDA document, the <originalText> shall contain a <reference> whose URI value points to the generic name and strength of the medication, or just the generic name alone if strength is not relevant. Inside a message, the <originalText> may contain the actual text that describes the medication in similar fashion.

Note: When the text is supplied from the narrative, the implication is that if you supply the components of a combination medication in an entry, you must also display these in the narrative text, otherwise you would not be able to break the combination medication down into its component parts. This is entirely consistent with the CDA Release 2.0 requirements that the narrative supply the necessary and relevant human readable information content.

The <code> element is also used to support coding of the medication. If coded, it must provide a code and codeSystem attribute using a controlled vocabulary for medications. The displayName for the code and codeSystemName should be provided as well for diagnostic and human readability purposes, but are not required. The table below provides the codeSystem and codeSystemName for several controlled terminologies that may be used to encode medications and/or immunizations.

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.88	RxNorm	RxNorm
2.16.840.1.113883.6.69	NDC	National Drug Codes
2.16.840.1.113883.6.63	FDDC	First DataBank Drug Codes
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.59	CVX	CDC Vaccine Codes

The code used for an immunization may use code systems other than what might be used for other medications, such as the CDC maintained CVX codes. Code systems that describe vaccination *procedures* (such as CPT-4) shall not be used to describe the vaccine entry.

5.3.15.4 <name> -OR- <desc>

In a CDA document, the <name> element should contain the brand name of the medication (or active ingredient in the case of subordinate <substanceAdministration> elements used to record components of a medication). Within a message, this information shall be provided in the <desc> element.

5.3.15.5 Simple Observations 1.3.6.1.4.1.19376.1.5.3.1.4.13

The simple observation entry is meant to be an abstract representation of many of the observations used in this specification. It can be made concrete by the specification of a few additional constraints, namely the vocabulary used for codes, and the value representation. A simple observation may also inherit constraints from other specifications (e.g., ASTM/HL7 Continuity of Care Document).

5.3.15.6 Specification

```
<observation typeCode='OBS' moodCode='EVN'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
  <id root='' extension=''/>
  <code code='' displayName='' codeSystem='' codeSystemName=''/>
  <!-- for CDA -->
  <text><reference value='#xxx'/></text>
  <!-- For HL7 Version 3 Messages
  <text>text</text>
  -->
  <statusCode code='completed'/>
  <effectiveTime value=''/>
  <repeatNumber value=''/>
  <value xsi:type='' …/>
  <interpretationCode code='' codeSystem='' codeSystemName=''/>
  <methodCode code='' codeSystem='' codeSystemName=''/>
  <targetSiteCode code='' codeSystem='' codeSystemName=''/>
  <author typeCode='AUT'>
    <assignedAuthor typeCode='ASSIGNED'><id></assignedAuthor> <!-- for CDA -->
    <!-- For HL7 Version 3 Messages
    <assignedEntity typeCode='ASSIGNED'>
       <Person classCode='PSN'>
          <determinerCode root=''>
          <name>…</name>
       </Person>
    <assignedEntity>
     -->
  </author>
</observation>
```

5.3.15.7 <observation typeCode='OBS' moodCode='EVN'>

These acts are simply observations that have occurred, and so are recored using the <observation> element as shown above.

5.3.15.8 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>

The <templateId> element identifies this <observation> as a simple observation, allowing for validation of the content. The templateId must appear as shown above.

5.3.15.9 <id root=' ' extension=' '/>

Each observation shall have an identifier.

5.3.15.10 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

Observations shall have a code describing what was measured. The code system used is determined by the vocabulary constraints on the types of measurements that might be recorded in a section. Content modules that are derived from the Simple Observation content module may restrict the code system and code values used for the observation.

5.3.15.11 <text><reference value='#xxx'/></text> -OR- <text>text</text>

Each observation measurement entry may contain a <text> element providing the free text that provides the same information as the observation within the narrative portion of the document with a <text> element. For CDA based uses of Simple Observations, this element SHALL be present, and SHALL contain a <reference> element that points to the related string in the narrative portion of the document. For HL7 Version 3 based uses, the <text> element MAY be included.

5.3.15.12 <statusCode code='completed'/>

The status code of all observations shall be completed.

5.3.15.13 <effectiveTime value=' '/>

The <effectiveTime> element shall be present in standalone observations , and shall record the date and time when the measurement was taken. This element should be precise to the day. If the date and time is unknown, this element should record that using the nullFlavor attribute.

5.3.15.14 <value xsi:type=' ' …/>

The value of the observation shall be recording using a data type appropriate to the observation. Content modules derived from the Simple Observation content module may restrict the allowable data types used for the observation.

5.3.15.15 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>

If there is an interpretation that can be performed using an observation result (e.g., high, borderline, normal, low), these may be recorded within the interpretationCode element.

5.3.15.16 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>

The methodCode element may be used to record the specific method used to make an observation when this information is not already pre-coordinated with the observation code .

5.3.15.17 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>

The targetSiteCode may be used to record the target site where an observation is made when this information is not already pre-coordinated with the observation code.

5.3.15.18 <author><assignedAuthor classCode='ASSIGNED'>...<assignedAuthor></author>

In CDA uses, SimpleObservaions are assumed to be authored by the same author as the document through context conduction. However specific authorship of observation may be represented by listing the author in the header and referencing the author in a <author> relationship. If authors are explicitly listed in documents, an <id> element SHOULD reference the ID of the author in the header through an assignedAuthor Role. If the author

of the observation is not an author of the document the <person> object including a name and ID SHALL be included.

For HL7 Version 3 purposes, the <author> element SHOULD be present unless it can be determined by conduction from organizers or higher level structures. When used for HL7 Version 3 the role element name is <assignedEntity> and the author is represented a <assignedPerson> element.

5.3.16 Vital Signs Organizer 1.3.6.1.4.1.19376.1.5.3.1.4.13.1

A vital signs organizer collects vital signs observations.

5.3.16.1 Specification

```
<organizer classCode='CLUSTER' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.32'/>
  <templateId root='2.16.840.1.113883.10.20.1.35'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1'/>
  <id root='' extension=''/>
  <code code='46680005' displayName='Vital signs'
    codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
  <statusCode code='completed'/>
  <effectiveTime value=''/>
  <!-- For HL7 Version 3 Messages
  <author classCode='AUT'>
     <assignedEntity1 typeCode='ASSIGNED'>
        :
     <assignedEntity1>
  </author>
  -->
  <!-- one or more vital signs observations -->
  <component typeCode='COMP'>
    <observation classCode='OBS' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'/>
        :
    </observation>
  </component>
</organizer>
```

5.3.16.2 <organizer classCode='CLUSTER' moodCode='EVN'>

The vital signs organizer is a cluster of vital signs observations.

5.3.16.3 <templateId root='2.16.840.1.113883.10.20.1.32'/> <templateId root='2.16.840.1.113883.10.20.1.35'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1'/>

The vital signs organizer shall have the <templateId> elements shown above to indicate that it inherits constraints from the ASTM/HL7 CCD Specification for Vital signs, and the constraints of this specification.

5.3.16.4 <id root=' ' extension=' '/>

The organizer shall have an <id> element.

5.3.16.5 <code code='46680005' displayName='Vital signs' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>

The <code> element shall be recorded as shown above to indicate that this organizer captures information about patient vital signs.

5.3.16.6 <statusCode code='completed'/>

The observations have all been completed.

5.3.16.7 <effectiveTime value=' '/>

The effective time element shall be present to indicate when the measurement was taken.

5.3.16.8 <author typeCode='AUT'><assignedEntity1 typeCode='ASSIGNED'>...</assignedEntity1></author>

For use with HL7 Version 3, Vital Sign organizers SHALL contain an <author> element to represent the person or device.

5.3.16.9 <!-- one or more vital signs observations --> <component typeCode='COMP'>

The organizer shall have one or more <component> elements that are <observation> elements using the Vital Signs Observation template.

5.3.17 Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2

A vital signs observation is a simple observation that uses a specific vocabulary, and inherits constraints from CCD.

5.3.17.1 Specification

```
<observation classCode='OBS' moodCode='EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='2.16.840.1.113883.10.20.1.31'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'/>
 <id root=' ' extension=' '/>
 <code code=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
 <text><reference value='#xxx'/></text>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <repeatNumber value=' '/>
 <value xsi:type='PQ' value=' ' unit=' '/>
 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
</observation>
```


5.3.17.2 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/> <templateId root='2.16.840.1.113883.10.20.1.31'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'/>

A vital signs observation shall have the <templateId> elements shown above to indicate that it inherits constraints from the ASTM/HL7 CCD Specification for Vital signs, and the constraints of this specification.

5.3.17.3 <code code=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>

A vital signs observation entry shall use one of the following LOINC codes, with the specified data types and units.

LOINC	Description	Units	Type
9279-1	RESPIRATION RATE	/min	PQ
8867 4	HEART BEAT		
2710-2	OXYGEN SATURATION	%	
8480-6	INTRAVASCULAR SYSTOLIC	mm[Hg]	
8462-4	INTRAVASCULAR DIASTOLIC		
8310-5	BODY TEMPERATURE	Cel or [degF]	
8302-2	BODY HEIGHT (MEASURED)	m, cm,[in_us] or [in_uk]	
8306-3	BODY HEIGHT^LYING		
8287-5	CIRCUMFRENCE.OCCIPITAL-FRONTAL (TAPE MEASURE)		
3141-9	BODY WEIGHT (MEASURED)	kg, g, [lb_av] or [oz_av]	

5.3.17.4 <value xsi:type='PQ' value=' ' unit=' '/>

The <value> element shall be present, and shall be of the appropriate data type specified for measure in the table above.

5.3.17.5 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>

The interpretation code may be present to provide an interpretation of the vital signs measure (e.g., High, Normal, Low, et cetera).

5.3.17.6 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>

The <methodCode> element may be present to indicate the method used to obtain the measure. Note that method used is distinct from, but possibly related to the target site.

5.3.17.7 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>

The target site of the measure may be identified in the <targetSiteCode> element (e.g., Left arm [blood pressure], oral [temperature], et cetera).

5.3.18 Family History Organizer 1.3.6.1.4.1.19376.1.5.3.1.4.15

The family history organizer collects the problems of a patient's family member.

5.3.18.1 Specification

```
<entry>
  <organizer classCode='CLUSTER' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.23'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.15'/>
    <subject typeCode='SUBJ'>
      <relatedSubject classCode='PRS'>
        <code code='' displayName=''
          codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>
        <subject>
          <sdtc:id root='' extension=''/>
          <administrativeGenderCode code='' displayName=''
            codeSystem='' codeSystemName=''/>
        </subject>
      </relatedSubject>
    </subject>
    <!-- zero or more participants linking to other relations -->
    <participant typeCode='PART'>
      <participantRole classCode='PRS'>
        <code code='' displayName=''
          codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>
        <playingEntity classCode='PSN'>
          <sdtc:id root='' extension=''/>
        </playingEntity>
      </participantRole>
    </participant>
    <!-- one or more entry relationships for family history observations -->
    <entryRelationship typeCode='COMP'>
      <observation classCode='OBS' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.22'/>
      </observation>
    </entryRelationship>
  </organizer>
</entry>
```

5.3.18.2 <organizer classCode='CLUSTER' moodCode='EVN'>

Each family history entry is organized (classCode='CLUSTER') into a group of observations about a family member.

5.3.18.3 <templateId root='2.16.840.1.113883.10.20.1.23'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.15'/>

The organizer is identified by the <templateId> elements, which shall be present as shown above.

5.3.18.4 <subject typeCode='SUBJ'> <relatedSubject classCode='PRS'>

The <subject> element shall be present and relates the subject of the observations to the patient. It shall contain a <relatedSubject> element that is a personal relation of the patient (classCode='PRS').

5.3.18.5 <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>

The <code> element shall be present, and give the relationship of the subject to the patient. The code attribute shall be present, and shall contain a value from the HL7 FamilyMember vocabulary. The codeSystem attribute shall be present and shall use the value shown above.

5.3.18.6 <subject>

The <subject> element contains information about the relation.

5.3.18.7 <sdtc:id root=' ' extension=' '/>

The <sdtc:id> element should be present. It is used to identify the patient relation to create a pedigree graph.

5.3.18.8 <administrativeGenderCode code=' ' />

The <administrativeGenderCode> element should be present. It gives the gender of the relation.

5.3.18.9 <participant typeCode='PART'> <participantRole classCode='PRS'>

The <participant> element may be present to record the relationship of the subject to other family members to create a pedigree graph. It shall contain a <participantRole> element showing the relationship of the subject to other family members (classCode='PRS').

5.3.18.10 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

The <code> element shall be present, and gives the relationship of the participant to the subject. The code attribute shall be present, and shall contain a value from the HL7 FamilyMember vocabulary. The codeSystem attribute shall be present and shall use the value shown above.

5.3.18.11 <playingEntity classCode='PSN'>

The <playingEntity> element identifies the related person. It shall be recorded as shown above.

5.3.18.12 <sdtc:id root=' ' extension=' '/>

The <sdtc:id> element shall be present. It must have the same root and extension attributes of the <subject> of a separate family history organizer.

5.3.18.13 <entryRelationship typeCode='COMP'> <observation classCode='OBS' moodCode='EVN'> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.3'/>

The family history organizer shall contain one or more components using the <entryRelationship> element shown above. These components must conform the Family History Observation template.

5.3.19 Family History Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.3

A family history observation is a Simple Observation that uses a specific vocabulary, and inherits constraints from CCD. Family history observations are found inside Family History Organizers.

5.3.19.1 Standards

CCD ASTM/HL7 Continuity of Care Document

5.3.19.2 Parent Template

The parent of this template is Simple Observation. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.22

5.3.19.3 Specification

```
<observation typeCode='OBS' moodCode='EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='2.16.840.1.113883.10.20.1.22'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.3'/>
 <id root=' ' extension=' '/>
 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
 <text><reference value='#xxx'/></text>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <repeatNumber value=' '/>
 <value xsi:type='CD' .../>
 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
</observation>
```

5.3.19.4 <templateId root='2.16.840.1.113883.10.20.1.22'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.3'/>

The <templateId> elements identify this observation as a family history observation, and shall be present as shown above.

5.3.19.5 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

The <code> indicates the type of observation made (e.g., Diagnosis, et cetera). See the code element in the Problem Entry entry for suggested values.

5.3.19.6 <value xsi:type='CD' code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

The <value> element indicates the information (e.g., diagnosis) of the family member. See the value element in the Problem Entry for suggested values.

5.3.20 Social History Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.4

A social history observation is a simple observation that uses a specific vocabulary, and inherits constraints from CCD.

5.3.20.1 Standards

CCD ASTM/HL7 Continuity of Care Document

5.3.20.2 Parent Template

The parent of this template is Simple Observation. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.33

5.3.20.3 Specification

```
<observation typeCode='OBS' moodCode='EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='2.16.840.1.113883.10.20.1.33'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4'/>
 <id root=' ' extension=' '/>
 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
 <text><reference value='#xxx'/></text>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <repeatNumber value=' '/>
 <value xsi:type=' ' />
 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
</observation>
```

5.3.20.4 <templateId root='2.16.840.1.113883.10.20.1.33'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4'/>

These <templateId> elements identify this as a Social History observation.

5.3.20.5 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

The <code> element identifies the type social history observation.

Code	Description	Data Type	Units
229819007	Smoking	PQ	{pack}/d or {pack}/wk or {pack}/a
256235009	Exercise		{times}/wk

160573003	ETOH (Alcohol) Use		{drink}/d or {drink}/wk
364393001	Diet	CD	N/A
364703007	Employment		
425400000	Toxic Exposure		
363908000	Drug Use		
228272008	Other Social History	ANY	

~~5.3.20.6 <repeatNumber value=' '/>~~

The <repeatNumber> element should not be used in a social history observation.

5.3.20.7 <value xsi:type=' ' ... />

The <value> element reports the value associated with the social history observation. The data type to use for each observation should be drawn from the table above.

Observations in the table above using the PQ data type have a unit in the form {xxx}/d, {xxx}/wk or {xxx}/a represent the number of items per day, week or year respectively. The value attribute indicates the number of times of the act performed, and the units represent the frequency. The example below shows how to represent 1 drink per day.

```
  :
<code code='160573003' displayName='ETOH Use'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'/>
  :
<value xsi:type='PQ' value='1' unit='{drink}/d'/>
  :
```

Observations in the table using the CD data type should include coded values from an appropriate vocabulary to represent the social history item. The example below shows the encoding to indicate drug use of cannabis.

```
  :
<code code='363908000' displayName='Drug Use'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'/>
  :
<value xsi:type='CD' code='398705004' displayName='cannabis'
       codeSystem='2.16.840.1.113883.6.96'
       codeSystemName='SNOMED CT'/>
  :
```

Other social history observations may use any appropriate data type.

~~5.3.20.8 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/> <methodCode code=' ' codeSystem=' ' codeSystemName=' '/> <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>~~

The <interpretationCode>, <methodCode>, and <targetSiteCode> elements should not be used in a social history observation.

5.3.21 Procedure Entry 1.3.6.1.4.1.19376.1.5.3.1.4.19

The procedure entry is used to record procedures that have occured, or which are planned for in the future.

5.3.21.1 Standards

CCD ASTM/HL7 Continuity of Care Document

5.3.21.2 Specification

```
<procedure classCode='PROC' moodCode='EVN|INT'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.19'/>
  <templateId root='2.16.840.1.113883.10.20.1.29'/><!-- see text of section 0 -
->
  <templateId root='2.16.840.1.113883.10.20.1.25'/><!-- see text of section 0 -
->
  <id root='' extension=''/>
  <code code='' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode' />
  <text><reference value='#xxx'/></text>
  <statusCode code='completed|active|aborted|cancelled'/>
  <effectiveTime>
    <low value=''/>
    <high value=''/>
  </effectiveTime>
  <priorityCode code=''/>
  <approachSiteCode code='' displayName='' codeSystem='' codeSystemName=''/>
  <targetSiteCode code='' displayName='' codeSystem='' codeSystemName=''/>
  <author />
  <informant />
  <entryRelationship typeCode='REFR'>
    <encounter classCode='ENC' moodCode=''>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
    </encounter>
  </entryRelationship>
  <entryRelationship typeCode='RSON'>
    <act classCode='ACT' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
    </act>
  </entryRelationship>
</procedure>
```

5.3.21.3 <procedure classCode='PROC' moodCode='EVN|INT'>

This element is a procedure. The classCode shall be 'PROC'. The moodCode may be INT to indicated a planned procedure or EVN, to describe a procedure that has already occurred.

5.3.21.4 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19'/>

The templateId indicates that this <procedure> entry conforms to the constraints of this content module. NOTE: When the procedure is in event mood (moodCode='EVN'), this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.29, and when in intent mood, this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.25.

5.3.21.5 <id root=' ' extension=' '/>

This required element shall contain an identifier for the procedure. More than one procedure identifier may be present.

5.3.21.6 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' ' />

This element shall be present, and should contain a code describing the type of procedure.

5.3.21.7 <text><reference value='#xxx'/></text>

The <text> element shall contain a reference to the narrative text describing the procedure.

5.3.21.8 <statusCode code='completed|active|aborted|cancelled'/>

The <statusCode> element shall be present when used to describe a procedure event. It shall have the value 'completed' for procedures that have been completed, and 'active' for procedures that are still in progress. Procedures that were stopped prior to completion shall use the value 'aborted', and procedures that were cancelled before being started shall use the value 'cancelled'.

5.3.21.9 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>

This element should be present, and records the time at which the procedure occurred (in EVN mood), or the desired time of the procedure in INT mood.

5.3.21.10 <priorityCode code=' '/>

This element shall be present in INT mood when effectiveTime is not provided, it may be present in other moods. It indicates the priority of the procedure.

5.3.21.11 <approachSiteCode code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

This element may be present to indicate the procedure approach.

5.3.21.12 <targetSiteCode code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

This element may be present to indicate the target site of the procedure.

5.3.21.13 <entryRelationship typeCode='COMP' inversionInd='true'>

This element may be present to point the encounter in which the procedure was performed, and shall contain an internal reference to the encounter. See section 1.3.6.1.4.1.19376.1.5.3.1.4.4.1 for more details.

5.3.21.14 <entryRelationship typeCode='RSON'>

A <procedure> act may indicate one or more reasons for the procedure. These reasons identify the concern that was the reason for use via the Internal Reference entry content module specified in section 1.3.6.1.4.1.19376.1.5.3.1.4.4.1. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.

