Integrating the Healthcare Enterprise

IHE Cardiology
Technical Framework

Volume 1
(CARD TF-1)
Integration Profiles

Revision 3.0 - Final Text

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Contents

Foreword

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

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

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the American College of Cardiology (ACC), the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Society of Cardiology (ESC), European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Française de Radiologie (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 MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (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. They are expanded annually, after a period of public review, and maintained regularly through the identification and correction of errors. The current version for these Technical Frameworks may be found at www.ihe.net.

The IHE Technical Frameworks identify a subset of the functional components of the healthcare enterprise, called IHE Actors, and specify their interactions in terms of a set of coordinated, standards-based transactions. They describe this body of transactions in progressively greater depth. This volume 1 provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. The subsequent volumes provide detailed technical descriptions of each IHE transaction.

1 Introduction

1.1 Overview of Technical Framework

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

The CARD-TF is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errors. The latest version of the document is always available via the Internet at www.ihe.net.

The CARD-TF identifies a subset of the functional components of the healthcare enterprise, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. The present Volume 1 provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. Volume 2 provides detailed technical descriptions of each cardiology-specific IHE transaction.

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

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

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

1.2 Overview of Volume 1

The remainder of section 1 further describes the general nature, purpose and function of the Technical Framework. Section 2 introduces the concept of IHE Integration Profiles that make up the Technical Framework.

Section 3 and the subsequent sections of this volume provide detailed documentation on each Integration Profile, including the clinical problem it is intended to address and the IHE Actors and Transactions it comprises.

The appendices following the main body of the document provide detailed discussion of specific issues related to the Integration Profiles and a glossary of terms and acronyms used.

1.3 Audience

The intended audience of this document is:

- Clinicians interested in the technical aspects of integrating healthcare information systems
- Technical staff of vendors participating in the IHE initiative
- IT departments of healthcare institutions
- Experts involved in standards development

1.4 Relationship to Standards

The IHE Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE Actors), solely from the point of view of their interactions in the healthcare enterprise. At its current level of development, it defines a coordinated set of transactions based on the HL7, DICOM, and various Web standards. As the scope of the IHE initiative expands, transactions based on other standards will be included as required.

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

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

1.5 Relationship to Real-world Architectures

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, Electronic Patient Record, RIS,

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

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

1.6 Conventions

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

1.6.1 Actor and Transaction Diagrams and Tables

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

The tables of Actors and Transactions given in sections 3 – 5 indicate which Transactions each Actor in a given profile must support.

In some cases, a profile is dependent on a pre-requisite profile in order to function properly and be useful. For example, Cath Workflow depends on the Consistent Time Profile (from the IHE IT Infrastructure framework) being implemented as a pre-requisite. These dependencies can be found by locating the desired profile in Table 2-1 and seeing which profiles are listed as required pre-requisites. An Actor must implement all required transactions in the pre-requisite profiles in addition to those in the desired profile.

1.6.2 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 a "big picture" so the transactions can be seen in the context of the overall workflow. Certain transactions and activities not defined in detail by IHE are shown in these diagrams in *italics* to provide additional context on where the relevant IHE transactions fit into the broader scheme of healthcare information systems.

These diagrams are not intended to present the only possible scenario. Often other actor groupings are possible, and complementary transactions from other profiles may be interspersed.

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

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

1.6.3 Normative versus informative contents of the Technical Framework

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

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

1.6.4 Technical Framework Referencing

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

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

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

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

<section number> is the applicable section number.

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

1.6.5 Transaction Referencing

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

<domain designator>-<transaction number>, where

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

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

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

1.7 IHE Cardiology Current Year Scope

The current IHE Cardiology Technical Framework addresses the following primary features:

- The Cardiac Catheterization Workflow Integration Profile describes mechanisms to manage and distribute the workflow within the cardiology department catheterization labs across the several types of equipment in a synchronized manner, including production of procedure logs and measurements such as quantitative coronography or ventriculography.

- The Echocardiography Workflow Integration Profile describes mechanisms to manage and distribute the workflow within the cardiology department echocardiography function, including stress echo and measurements.

- The Retrieve ECG for Display Integration Profile describes interoperable ways for ECG waveforms and analyses to be retrieved and presented by display systems both inside and outside the cardiology department.

- The Evidence Documents Integration Profile, included by reference to its definition in the Radiology Technical Framework with further cardiology-specific options, describes management of observations, measurements, and peri-procedural results (i.e., evidence documents).

1.8 Comments

The ACC welcomes 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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Material drawn from these documents is credited where used.

1.10 IHE Technical Framework Development and Maintenance Process

The Technical Framework is continuously extended and maintained by the IHE Cardiology Technical Committee, in cooperation with the other domain-specific Technical Committees. The Development and Maintenance Process of the Framework follows a number of principles to ensure stability of the specification both vendors and users may rely upon in specifying, developing and acquiring IHE compatible products.

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

To maintain stability of the IHE Technical Framework, modifications occur in a regular annual cycle (Figure 1.10-1) according to one of two controlled paths: new development, and maintenance.
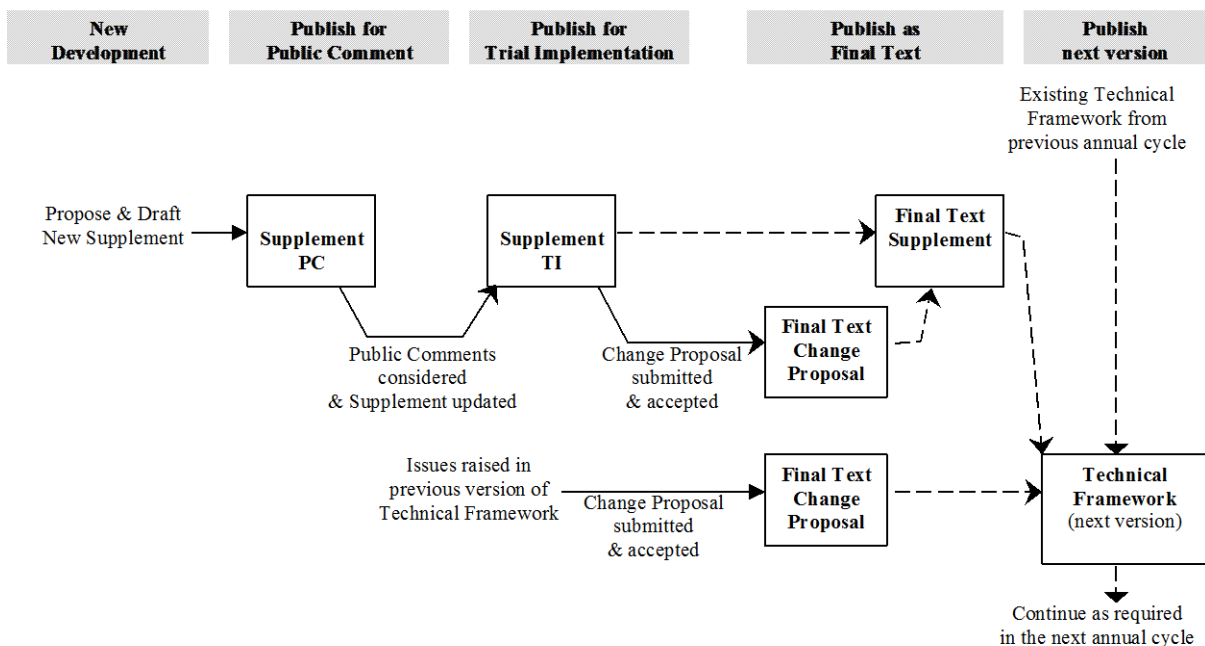
Figure 1.10-1.

The figure shows the process of developing and maintaining the Technical Framework during an annual cycle. Dashed arrows indicate the assembly (merging) of text.

1.10.1 New Development – Extending the Existing Technical Framework

Each year, new functionality to be developed is identified by the IHE Cardiology Planning Committee. The Technical Committee performs the necessary analysis and design work and generates new text for the Technical Framework.

Generally, new functionality is published in the form of a Supplement. The scope of a Supplement is to make one of the following additions to the Technical Framework:

- A new Integration Profile, usually including the introduction of new Actors and Transactions.
- New Actors in an existing Integration Profile: These may be either Actors previously defined elsewhere in the Technical Framework, or new ones not yet defined. Transactions identifying the new actors responsibilities in this profile are identified or defined and may be designated as required or optional. To avoid causing compatibility problems for systems that have already implemented that profile, no new required Transactions are added for existing Actors in the profile.
- New Options in an existing Integration Profile: These usually add optional Transactions for existing actors in the profiles, or add optional features within existing Transactions.
- Major conceptual changes: They do not change the behavior of existing Integration Profiles but may imply changes or additions to Actors or Transactions in the future.

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

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

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

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

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

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

1.10.2 Maintenance of existing Technical Framework content

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

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

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

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

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

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

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

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

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

1.10.3 Use of Technical Framework

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

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

- Product Implementations
  Products implemented based on Trial Implementation text are expected to review the subsequent Final Text and update their products as necessary. Further, it is expected that vendors will monitor Final Text Change Proposals and make any corrections relevant to their product in a timely fashion.

- Connectathon Implementations
  Testing at the Connect-a-thon will be based on the current version of the Technical Framework for the appropriate IHE Domain, plus any relevant Supplements for Trial Implementation and Final Text Change Proposals.

2   Integration Profiles

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

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

2.1   Dependencies between Integration Profiles

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

Figure 2-1 provides a graphical view of the dependencies between Integration Profiles. The arrows in the diagram point from the dependent profile to the profile(s) on which it relies. The solid arrow indicates an implementation dependency – the actors of the dependent profile must implement the supporting profile. The open arrows indicate a definitional dependency – the transactions of the dependent profile are based on the transactions of the supporting profile; this is for information purposes only, since the supporting profile is not itself used, only some subset of it.

Note especially that the supporting profiles come from other IHE domains.
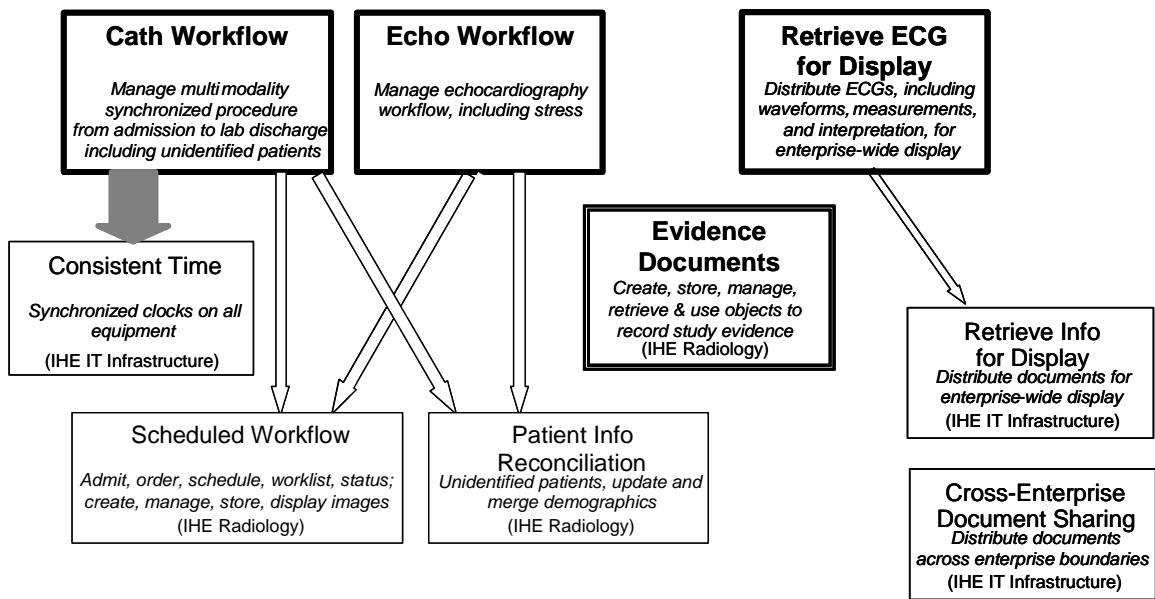
Figure 2-1. IHE Cardiology Integration Profiles and Dependencies

Table 2-1 defines the required dependencies between the Integration Profiles in a tabular form.

There are of course other useful synergies that occur when different combinations of profiles are implemented, but those are not described in the table below. For instance, actors of the various Cardiology profiles may implement profiles of the IT Infrastructure domain for user or node authentication, audit trails, patient identifier cross-referencing, etc.

Table 2-1. Cardiology Integration Profiles Dependencies

Integration Profile	Depends on	Dependency Type	Comments
Cath Workflow	ITI-TF Consistent Time	The DSS/Order Filler and all Acquisition Modality actors are required to be grouped with Time Client actor	
	RAD-TF Scheduled Workflow RAD-TF Patient Information Reconciliation	*Definitional*	
Echo Workflow	RAD-TF Scheduled Workflow RAD-TF Patient Information Reconciliation	*Definitional*	
Retrieve ECG for Display	ITI-TF Retrieve Info for Display	*Definitional*	

Vendor products support an Integration Profile by implementing the appropriate actor-transactions as outlined in the Integration Profile in sections 3 through 5. A product may implement more than one actor and more than one Integration Profile.

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

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

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

2.2 Integration Profiles Overview

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

- The IHE Actors involved
- The specific set of IHE Transactions required for each IHE Actor.

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

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

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

2.2.1 Cardiac Catheterization Workflow (CATH)

Cardiac Catheterization is complex, especially from a workflow perspective. Evidence-gathering activities may begin before an order is placed; in fact, orders are often not created for a cardiac catheterization procedure due to its frequent emergency nature. There may be a variety of imaging, measurement, and reporting systems that need to coordinate to use the same patient identifier, and to assure that the evidence produced is all associated with the same procedure. Further, the procedure itself may include both diagnostic and interventional or therapeutic aspects, and may extend over a long time period (several hours).

The Cardiac Catheterization Workflow Integration Profile establishes the continuity and integrity of basic patient data in the context of the cardiac catheterization procedure. This profile deals specifically with consistent handling of patient identifiers and demographic data, including that

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of emergency patient presentation where the actual patient identity may not be established until after the beginning of the procedure, or even a significant time after the completion of the procedure. It also specifies the scheduling and coordination of procedure data across a variety of imaging, measurement, and analysis systems, and its reliable storage in an archive from where it is available to support subsequent workflow steps, such as reporting. It also provides central coordination of the completion status of steps of a potentially multi-phase (diagnostic and interventional) procedure.

2.2.2 Echocardiography Workflow (ECHO)

The Echocardiography Workflow Integration Profile describes the workflow associated with digital echocardiography, specifically that of transthoracic echo (TTE), transesophageal echo (TEE), and stress echo. As does the Cath Workflow Integration Profile, this profile deals with patient identifiers, orders, scheduling, status reporting, multi-stage exams (especially stress echo), and data storage. It also specifically addresses the issues of acquisition modality devices that are only intermittently connected to the network, such as portable echo machines, and addresses echo-specific data requirements.

Intravascular ultrasound (IVUS) and intracardiac echocardiography (ICE) are used in cardiac catheterization procedures, and are supported as modalities in the Cath Workflow, and not in the Echo Workflow.

2.2.3 Retrieve ECG for Display (ECG)

The Retrieve ECG for Display Integration Profile specifies a mechanism for broad access throughout the enterprise to electrocardiogram (ECG) documents for review purposes. The ECG documents may include "diagnostic quality" waveforms, measurements and interpretations. This Integration Profile allows the display of this information without requiring specialized cardiology software or workstations, but with general purpose computer applications such as a Web browser.

This Integration Profile is intended primarily for retrieving resting 12-lead ECGs, but may also retrieve ECG waveforms gathered during stress, Holter, and other diagnostic tests. This Integration Profile only addresses ECGs that are already stored in an information system. It does not address the process of ordering, acquiring, storing, or interpreting the ECGs.

2.2.4 Displayable Reports (DRPT)

This section reserved.

2.2.5 Evidence Documents (ED)

The Evidence Documents Profile defines ways for data recorded in the course of carrying out a procedure step, such as observations, measurements, and results (i.e., evidence documents), to be output by devices, such as acquisition systems and other workstations; to be stored and managed by archival systems; and to be retrieved and presented or used by display and reporting systems.

This allows detailed non-image information, such as measurements, CAD results, procedure logs, etc. to be made available as input to the process of generating a clinical Report, either as additional evidence for the reporting physician, or in some cases for selected items in the Evidence Document to be included in the report.

2.3 Actor Descriptions

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

It is acknowledged that some of the terms used as modifiers for the actor names are not used consistently (e.g., Image Manager, which also manages non-image objects). At this point, the benefit in doing extensive renaming to gain consistency is outweighed by the risk of introducing significant confusion that would result from renaming many of the existing actors that are shared across multiple domains. Therefore the actor names will remain as defined below.

Acquisition Modality – A system that acquires and creates medical images or waveforms while a patient is present, e.g., an X-ray angiography or hemodynamic measurement system. A modality may also create other evidence objects such as Structured Report Documents containing measurements.

ADT – A system responsible for adding and/or updating patient demographic and encounter information (Admission/Discharge/Transfer). In particular, it registers a new patient with the Order Placer and Department System.

Department System Scheduler/Order Filler – A department-based (for instance, Cardiology or Radiology) information system that provides functions related to the management of orders received from external systems or through the department system's user interface.

Evidence Creator – A system that creates additional evidence objects such as derived images or measurements (Evidence Documents), and transmits them to an Image Archive.

Image Archive – A system that provides long term storage of evidence objects such as images, presentation states, Key Image Notes and Evidence Documents.

Image Display – A system that offers browsing of patients' studies. In addition, it may support the retrieval and display of selected evidence objects including sets of images, presentation states, Key Image Notes, and/or Evidence Documents.

Image Manager – A system that provides functions related to safe storage and management of evidence objects. It supplies availability information for those objects to the Department System Scheduler.

Order Placer – A hospital or enterprise-wide system that generates orders for various departments and distributes those orders to the correct department.

Performed Procedure Step Manager – A system that re-distributes the Modality Performed Procedure Step information from the Acquisition Modality to the Department System Scheduler/Order Filler and Image Manager.

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

Time Client – A system unit that synchronizes its time of day clock to the correct time provided by a time server

Display – A system that can request and display preformatted ("presentation-ready") data using Web technologies.

Information Source – A system that responds to requests for patient-related data by encoding it in a presentation-ready format using Web technologies.

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

Table 2.3-1. Integration Profile Actors

Integration Profile ⟍ Actor	CATH	ECHO	ECG	ED
Acquisition Modality	X	X		X
ADT Patient Registration	X	X		
Department System Scheduler/Order Filler	X	X		
Evidence Creator	X	X		X
Image Archive	X	X		X
Image Display	X	X		X
Image Manager	X	X		X
Order Placer	X	X		
Performed Procedure Step Manager	X	X		
Report Creator				X
Time Client	(note 1)			
Display			X	
Information Source			X	

Notes: 1. The Time Client actor is not formally part of the Cath Workflow Profile, but it must be grouped with certain actors in that Profile.

2. The Information Source actor is not formally part of the Displayable Reports Profile, but must be grouped with the Report Repository actor in that Profile.

2.4 Transaction Descriptions

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

Patient Registration – The ADT system registers and/or admits a patient and forwards the information to other information systems. [RAD-1]

Placer Order Management – The Order Placer informs the Order Filler of the initiation or cancellation of an order. The Placer/Filler Order Management transaction will sometimes be referred to as "-New" when a new order is being initiated, or as "-Cancel" when an existing order is canceled. [RAD-2]

Filler Order Management – The Order Filler informs the Order Placer of the initiation, cancellation, or change in the status of an order. The Placer/Filler Order Management transaction will sometimes be referred to as "-New" when a new order is being initiated, or as "-Cancel" when an existing order is canceled. [RAD-3]

Procedure Scheduled – Schedule information is sent from the Department System Scheduler/Order Filler to the Image Manager. [RAD-4]

Query Modality Worklist – Based on a query entered at the Acquisition Modality, a modality worklist is generated listing all the items that satisfy the query. This list of Scheduled Procedure Steps with selected demographic information is returned to the Acquisition Modality [RAD-5].

Modality Procedure Step In Progress – An Acquisition Modality notifies the Performed Procedure Step Manager of the start of a new Procedure Step and the PPS Manager informs the Department System Scheduler/Order Filler and Image Manager. [CARD-1, derived from RAD-6]

Modality Procedure Step Completed – An Acquisition Modality notifies the Performed Procedure Step Manager of the completion of a Procedure Step and the PPS Manager informs the Department System Scheduler/Order Filler and Image Manager. [RAD-7]

Modality Images/Evidence Stored – An Acquisition Modality sends acquired or generated images, waveforms, or other evidence documents to the Image Archive. [CARD-2, derived from RAD-8 and RAD-43]

Storage Commitment – A requestor (Acquisition Modality) requests that the Image Manager confirm ownership for the specified DICOM objects (images, waveforms, evidence documents, or any combination thereof) that the requestor stored in the Image Archive, thus allowing the sender to delete those objects now owned by the Image Manager. [CARD-3, derived from RAD-10]

Patient Update – The ADT Patient Registration System informs the Order Placer and the Department System Scheduler/Order Filler of new information for a particular patient. The Department System Scheduler may then further inform the Image Manager. [RAD-12]

Procedure Update – The Department System Scheduler/Order Filler sends the Image Manager updated order or procedure information. [RAD-13]

Query Images – An Image Display queries the Image Archive for a list of entries representing images by patient, study, series, or instance. [RAD-14]

Query Evidence Documents – A user of Evidence Documents queries the Image Archive for a list of entries representing Evidence Documents. [RAD-44]

Retrieve Images/Evidence – An Image Display requests and retrieves a particular image or set of images or other evidence from the Image Archive. [CARD-4, derived from RAD-16 and RAD-44]

Instance Availability Notification – The Image Manager/Image Archive notifies interested workflow actors (such as the Department System Scheduler/Order Filler and Report Manager) about the availability status of instances at specified storage locations. [RAD-49]

Maintain Time – Synchronize the local time with the time maintained by the Time Server. [ITI-1]

Retrieve Specific Info for Display – A Display queries an Information Source for a specific type information by patient and time period. [ITI-11]

Retrieve ECG List – A Display queries an Information Source for a list of entries representing ECG documents by patient and time period. [CARD-5, derived from ITI-11]

Retrieve ECG Document for Display – A Display queries an Information Source for a specific ECG document by document ID. [CARD-6, derived from ITI-12]

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

Table 2.4-1. Integration Profile Transactions

Integration Profile / Transaction	CATH	ECHO	ECG	ED
Patient Registration [RAD-1]	X	X		
Placer Order Management [RAD-2]	X	X		
Filler Order Management [RAD-3]	X	X		
Procedure Scheduled [RAD-4]	X	X		
Query Modality Worklist [RAD-5]	X	X		
Modality Procedure Step In Progress [CARD-1]	X	X		
Modality Procedure Step Completed [RAD-7]	X	X		
Modality Images/Evidence Stored [CARD-2]	X	X		X
Storage Commitment [CARD-3]	X	X		X
Patient Update [RAD-12]	X	X		
Procedure Update [RAD-13]	X	X		
Query Images [RAD-14]	X	X		

Integration Profile Transaction	CATH	ECHO	ECG	ED
Query Evidence Documents [RAD-44]				X
Retrieve Images/Evidence [CARD-4]	X	X		
Instance Availability Notification [RAD-49]	X	X		
Maintain Time [ITI-1]	(note 1)			
Retrieve Specific Info for Display [ITI-11]			X	
Retrieve ECG List [CARD-5]			X	
Retrieve ECG Document for Display [CARD-6]			X	

Notes: 1. The Maintain Time transaction is not formally part of the Cath Workflow Profile, but it is required for the Time Client actor grouped with certain actors in that Profile.

2.5 Product Implementations

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

- For a system, select which actors it will incorporate. (Multiple actors per system is acceptable.)
- For each actor, select which Integration Profiles it will participate in.
- For each actor-profile, select which optional transactions will be implemented. All required transactions must be implemented for the profile to be supported. (Refer to the Integration Profile Tables in sections 3-5.)
- Finally, for each transaction, select which optional features will be supported. (Refer to the transaction descriptions in CARD-TF Volume 2, or the appropriate domain TF)

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

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

- The Image Archive shall be grouped with the Image Manager, and the Image Manager shall be grouped with the Image Archive.
- The Image Manager participating in Cath Workflow or Echo Workflow Integration Profiles shall be grouped with a Performed Procedure Step Manager. The grouped Performed Procedure Step Manager shall be capable of being disabled via configuration.
- The Department System Scheduler/Order Filler participating in Cath Workflow or Echo Workflow shall be grouped with a Performed Procedure Step Manager. The grouped Performed Procedure Step Manager shall be capable of being disabled via configuration.

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- The DSS/Order Filler and Modality Acquisition Actors participating in Cath Workflow Integration Profile shall be grouped with the Time Client Actor of the Consistent Time Profile

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

For example, the Procedure Step In Progress/Completed transaction does not need to be supported between the Performed Procedure Step Manager and the Image Manager when these are grouped together in a single system.

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 Image Manager provides necessary information updates to the Image Archive to support its Query/Retrieve functionality. The exact mechanisms of such internal communication are outside the scope of the IHE Technical Framework.

3 Cardiac Catheterization Workflow (CATH)

The Cardiac Catheterization Workflow Integration Profile establishes the continuity and integrity of basic patient data in the context of the cardiac catheterization procedure. This profile deals specifically with consistent handling of patient identifiers and demographic data, including that of emergency patient presentation where the actual patient identity may not be established until after the beginning of the procedure, or even a significant time after the completion of the procedure. It also specifies the scheduling and coordination of procedure data across a variety of imaging, measurement, and analysis systems, and its reliable storage in an archive from where it is available to support subsequent workflow steps, such as reporting. It also provides central coordination of the completion status of steps of a potentially multi-phase (diagnostic and interventional) procedure.

This profile has much in common with the IHE Radiology Scheduled Workflow, Patient Information Reconciliation, and Evidence Document Integration Profiles, but deals more explicitly with the multi-modality coordination, and with cath-specific data requirements. See **Rad TF-1: 3.4** for the integrated workflow data model adopted by the IHE Technical Framework for HL7 messages and DICOM information objects. This data model offers three major levels of control for workflow:

- **Order**: A request for a Departmental Service
- **Requested Procedure**: Unit of work resulting in one or more reports, with associated codified, billable acts.
- **Scheduled and Performed Procedure Step**: the smallest unit of work in the workflow that is scheduled (work to do) or performed (work done).

A clear understanding of the workflow data model is essential to interpreting the Cath Workflow Integration Profile. Additional information may be found in Appendix B.

Although the major cases for cath workflow are described in the following subsections, it is beneficial to also see the corresponding workflows in radiology. Rad TF-1: 3.3 has a description of the "normal" scheduled workflow when all three levels of control in the data model are fully utilized for known patients, and Rad TF-1: 4.3 and 4.4 describes workflows when the patient is unknown and/or the ordering and scheduling process is short-circuited (e.g., in the emergency case). Even in this latter case, all three levels of control are present and used, although not to their full extent.

3.1 Actors/Transactions

Figure 3.1-1 diagrams the actors involved with this profile and the transactions between actors.
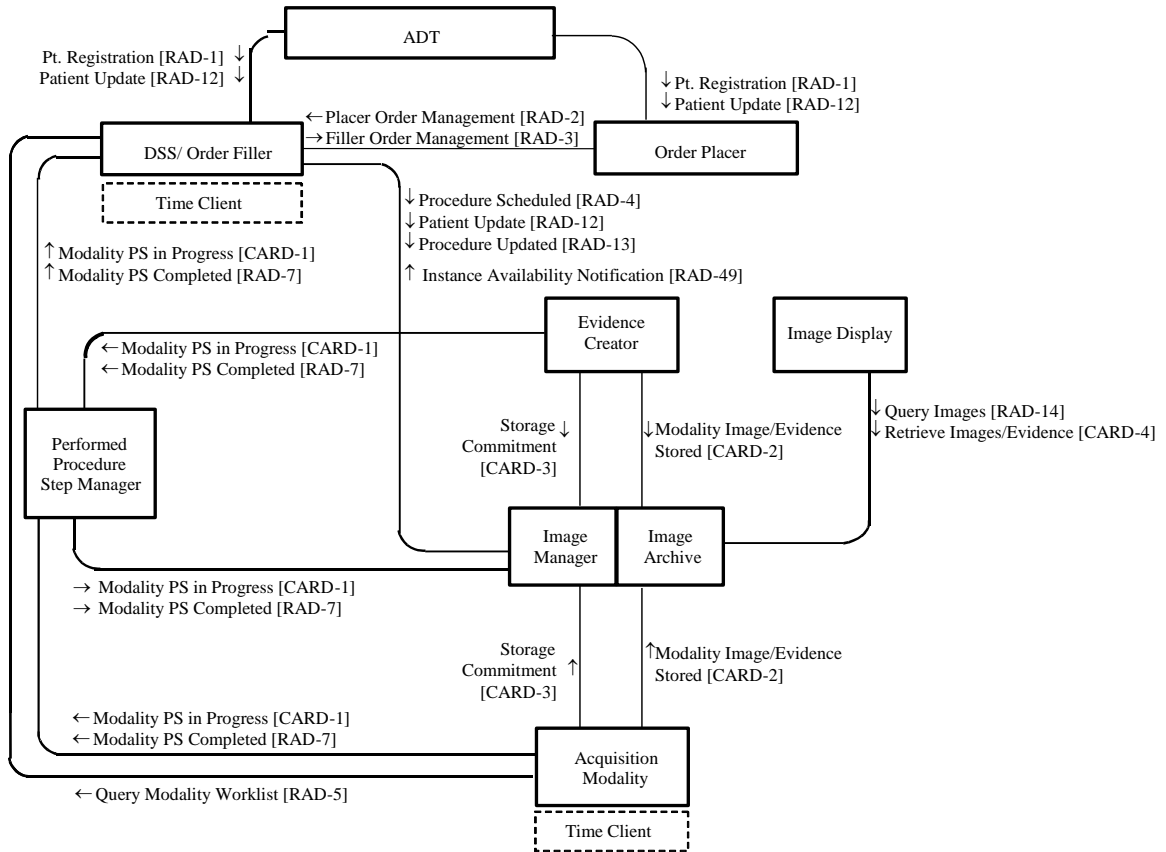
Figure 3.1-1. Cath Workflow Diagram

Note that this diagram maintains the actor and transaction names specified in the Radiology Technical Framework (RAD-TF) for consistency of definitions.

Table 3.1-1 lists the transactions for each actor directly involved in the Cath Workflow Integration Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options defined by this Integration Profile that implementations may choose to support is listed in Section 3.2.

Table 3.1-1. Cath Workflow - Actors and Transactions

Actors	Transactions	Optionality	Section
ADT Patient Registration	Patient Registration [RAD-1]	R	RAD-TF 2: 4.1
	Patient Update [RAD-12]	R	RAD-TF 2: 4.12
Order Placer	Patient Registration [RAD-1]	R	RAD-TF 2: 4.1
	Patient Update [RAD-12]	R	RAD-TF 2: 4.12
	Placer Order Management [RAD-2]	R	RAD-TF 2: 4.2
	Filler Order Management [RAD-3]	R	RAD-TF 2: 4.3
Department System Scheduler/ Order Filler	Patient Registration [RAD-1]	R	RAD-TF 2: 4.1
	Patient Update [RAD-12]	R	RAD-TF 2: 4.12
	Placer Order Management [RAD-2]	R	RAD-TF 2: 4.2
	Filler Order Management [RAD-3]	R	RAD-TF 2: 4.3
	Procedure Scheduled [RAD-4]	R	RAD-TF 2: 4.4
	Query Modality Worklist [RAD-5]	R	RAD-TF 2: 4.5
	Modality Procedure Step In Progress [CARD-1]	R	CARD-TF 2: 4.1
	Modality Procedure Step Completed [RAD-7]	R	RAD-TF 2: 4.7
	Procedure Updated [RAD-13]	R	RAD-TF 2: 4.13
	Instance Availability Notification [RAD-49]	O	RAD-TF 3: 4.49
Acquisition Modality	Query Modality Worklist [RAD-5]	R	RAD-TF 2: 4.5
	Modality Procedure Step In Progress [CARD-1]	R	CARD-TF 2: 4.1
	Modality Procedure Step Completed [RAD-7]	R	RAD-TF 2: 4.7
	Modality Images/Evidence Stored [CARD-2]	R	CARD-TF 2: 4.2
	Storage Commitment [CARD-3]	R	CARD-TF 2: 4.3
Image Manager/ Image Archive	Procedure Scheduled [RAD-4]	R	RAD-TF 2: 4.4
	Modality Procedure Step In Progress [CARD-1]	R	CARD-TF 2: 4.1
	Modality Procedure Step Completed [RAD-7]	R	RAD-TF 2: 4.7
	Modality Images/Evidence Stored [CARD-2]	R	CARD-TF 2: 4.2
	Storage Commitment [CARD-3]	R	CARD-TF 2: 4.3
	Patient Update [RAD-12]	R	RAD-TF 2: 4.12
	Procedure Updated [RAD-13]	R	RAD-TF 2: 4.13
	Query Images [RAD-14]	R	RAD-TF 2: 4.14
	Retrieve Images/Evidence [CARD-4]	R	CARD-TF 2: 4.4
	Instance Availability Notification [RAD-49]	O	RAD-TF 3: 4.49
Performed Procedure Step Manager	Modality Procedure Step In Progress [CARD-1]	R	CARD-TF 2: 4.1
	Modality Procedure Step Completed [RAD-7]	R	RAD-TF 2: 4.7
Image Display	Query Images [RAD-14]	R	RAD-TF 2: 4.14
	Retrieve Images/Evidence [CARD-4]	R	CARD-TF 2: 4.4
Evidence Creator	Modality Procedure Step In Progress [CARD-1]	R	CARD-TF 2: 4.1
	Modality Procedure Step Completed [RAD-7]	R	RAD-TF 2: 4.7

Actors	Transactions	Optionality	Section
	Modality Images/Evidence Stored [CARD-2]	R	CARD-TF 2: 4.2
	Storage Commitment [CARD-3]	R	CARD-TF 2: 4.3

Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

3.2 Cath Workflow Integration Profile Options

Many Actors have Options defined in order to accommodate variations in use across domains or implementations. Options that may be selected for this Integration Profile are listed in the table 3.2-1 along with the Actors to which they apply. Certain of these Options are required for implementation by actors in this Profile (although they may be truly optional in other Profiles).

Table 3.2-1: Cath Workflow - Actors and Options

Actor	Option Name	Optionality	Vol & Section
ADT Patient Registration	*No options defined*	-	-
Order Placer	*No options defined*	-	-
Department System Scheduler/Order Filler	Multi-modality Procedure Update	R	CARD-TF 2: 4.1
	PPS Exception Management	O	RAD-TF 2: 4.7
	Availability of PPS-Referenced Instances	O	RAD-TF 3: 4.49
Acquisition Modality	Patient Based Worklist Query	O	RAD-TF 2: 4.5
	Broad Worklist Query	R (see note)	RAD-TF 2: 4.5
	PPS Exception Management	O	RAD-TF 2: 4.7
Image Manager/ Image Archive	PPS Exception Management	O	RAD-TF 2: 4.7
	Intermittently Connected Modality	R	CARD-TF 2: 4.3
	Cardiac Cath	R	CARD-TF 2: 4.2
	Availability of PPS-Referenced Instances	O	RAD-TF 3: 4.49
Image Display	*No options defined*	-	-
Performed Procedure Step Manager	*No options defined*	-	-
Evidence Creator	*No options defined*	-	-

Note: The Broad Worklist Query option is required to support Case C7, and facilitates effective workflow in the multimodality environment.

The Acquisition Modality and Image Manager/ Image Archive will likely support a variety of DICOM SOP Classes. It is expected that this level of optionality will be documented by a reference in the IHE Integration Statement (see Appendix C).

3.3 Cath Scheduled Process Flow

Each process flow is introduced with an overview of the end-user issue addressed ("Clinical Context") and the approach taken in the Technical Framework ("IHE Context").

Clinical context: This reflects the situation where a patient is admitted to the facility, and a cath procedure is ordered and scheduled, similar to a radiology procedure. The main difference is that cath is inherently multi modality so there needs to be a way for all of the participating modalities to coordinate and to share patient and procedure information. Note that while Scheduled Workflow is the normal or expected situation in radiology, it is currently the exception in Cardiac Catheterization. The procedure traditionally is rarely ordered, as it is typically preceded by a Cardiology Consultation that simply arranges for the procedure to be done. See also Appendix A which discusses the cath procedure and its relationship to the overall episode of care.

IHE Context: This section describes the "normal" scheduled workflow when all three levels of control (order, requested procedure, and scheduled/performed procedure steps) in the IHE data model are fully utilized to request a procedure for known patients. In fact, orders are often not created for a cardiac catheterization procedure due to its frequent emergency nature, but this process flow provides the basis for understanding the specific use cases described in section 3.4. In fact, this workflow, plus a patient information reconciliation step, constitutes case C1 in section 3.4

For comparison with radiology, see RAD-TF 1:3.3. To facilitate such comparison for those readers familiar with RAD-TF, the differences between the radiology Process Flow Diagrams and those in cardiology are shown in green in the figures. Note that the Order Change Flow (RAD-TF 1:3.3.3) and the Exception Management Workflow (RAD-TF 1:3.3.4) may be used as elaborated there, and are not further described in the Cardiology Technical Framework. The functionality of those data flows is specified within the specific transactions invoked by the CARD-TF.
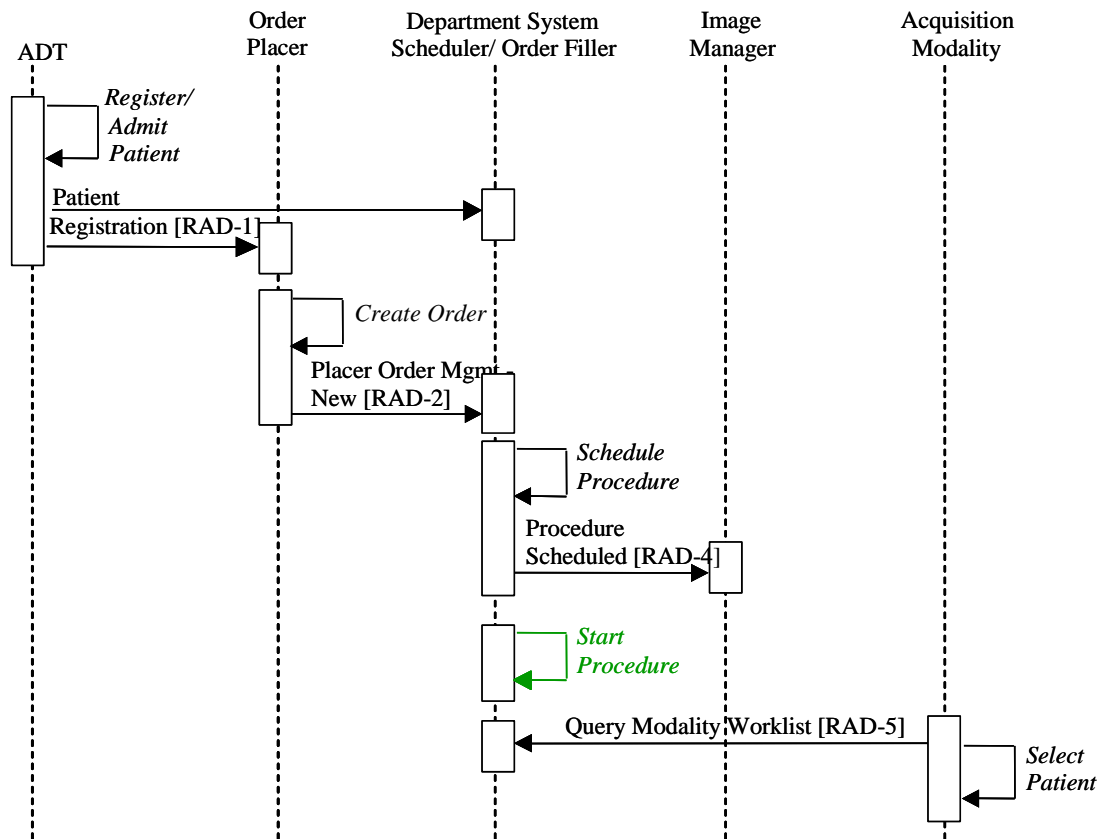
Figure 3.3-1. Scheduled Workflow: Administrative Process Flow

The following should be noted in relation to the Administrative process flow:

- *Patient Registration*: The Patient Registration data is broadcast to several systems, including the Order Placer and the Department System Scheduler/Order Filler (DSS/OF).

- *Create Order*: The Order Placer is the repository for all patient orders.

- *Schedule Procedure*: The DSS/OF associates the order with one or more Requested Procedures that have to be performed to satisfy the order. Each Requested Procedure prescribes a number of actions that have to be performed by Acquisition Modalities. Actions are specified in Scheduled Procedure Steps (SPS) based on timing and sequencing, and on modality. Scheduled Procedure Steps are scheduled, i.e., assigned a time slot and performing resource (modality), and are made available for Modality Worklist Query.

- *Start Procedure*: The DSS/OF may have an optional function to start the Cath Procedure, typically to allow the collection of patient data specifically tied to the procedure but outside the scope of any particular modality. This may result, for instance, in the "Arrived" status being set in the associated SPSs. The purpose of this action is to start a procedure from a non-modality actor.

- *Query Modality Worklist*: The Modality Worklist (MWL) query may be broad (get a list of scheduled procedures from which one will be selected), or patient-specific (provided with

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sufficient query keys to get back the scheduled procedure for a single patient). The latter case may be facilitated by entering the Patient ID from a bar-coded wristband into the MWL query (as an institution's cath lab standard operating procedure).

- *Select Patient*: In the event of a single SPS in the MWL response, a modality may optimize the Select Patient function to select that SPS without further explicit user action.

See Appendix B for further description.
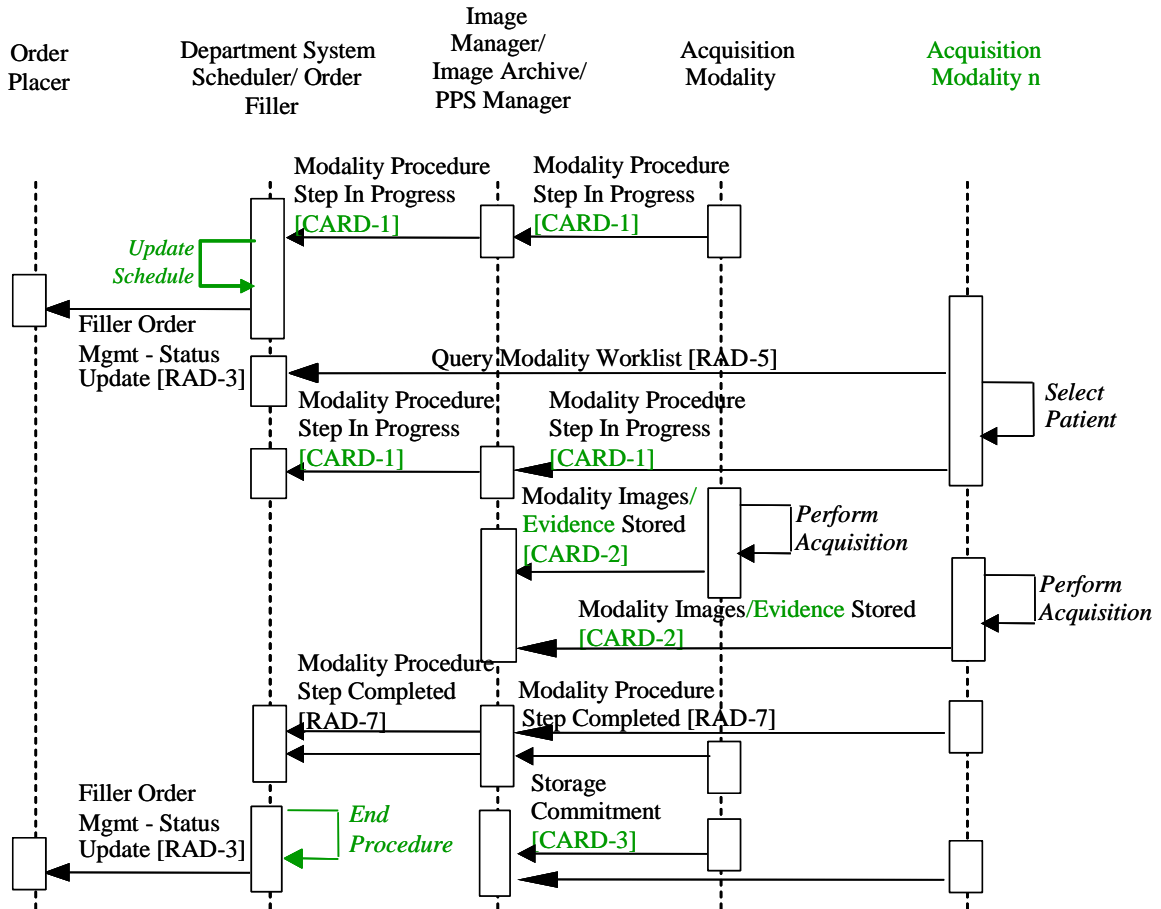
Figure 3.3-2. Scheduled Workflow: Procedure Performance Process Flow

The following should be noted in relation to the Procedure Performance process flow:

- *Modality Procedure Step In Progress* and *Update Schedule*: Initial Procedure scheduling may be vague (i.e., not exactly specify a time or cath lab), or the procedure may be performed in a lab room different from the one in which it was scheduled. If the DSS/OF has not started the procedure, upon receipt of first MPPS In Progress for the Cath Lab, which includes the patient ID/name and the modality Station AE Title (which allows it to be linked to a specific cath lab), the DSS/OF updates the Scheduled Procedure Steps for all the

modalities in that same cath lab to reflect the current active case (i.e., that first MPPS serves as "current patient / lab selection").

- *Query Modality Worklist*: MWL queries from modalities in that cath lab subsequent to the Update Schedule process may be able to use a broad query with sufficient request keys that would return in the MWL response only a single SPS for the current patient, allowing optimization of modality start-up.

- *Perform Acquisition*: Each Modality may produce a variety of images and other evidence (waveforms, analysis reports, etc.) that are stored to the Image Manager/Archive. The Image Manager/Archive must support all the object types (beyond just images) as specified by the Cardiac Cath Option (see CARD-TF-2: 4.2.1).

- *Modality Procedure Step Complete* and *End Procedure*: Modality Procedure Step Complete also includes Modality Procedure Step Discontinued. The simple transmission of a Complete or Discontinued does not indicate that a modality is then available, due to multi-step procedures (diagnostic/interventional) and multi-modality cross-dependencies in a procedure room. It is a function of the DSS/OF (outside the scope of this document) to determine when to end the procedure, and declare the modality resources in the room are available for another procedure.

- *Storage Commitment:* The Image Manager/Archive accepts responsibility for stored images and evidence, allowing the modality to delete the data from its local storage. The Image Manager/Archive shall support mobile devices, such as intravascular ultrasound (IVUS) and intracardiac echocardiography (ICE), that may be intermittently connected to the network and temporarily unable to receive Storage Commitment messages.

- *Filler Order Management - Status Update*: Status Update transactions may be sent to the Order Placer at several points in the workflow, although only the update after the first Modality Procedure Step In Progress and the last Modality Procedure Step Complete are shown.

3.4 Cath Workflow Use Cases

This section describes the specific use cases and process flows defined for the Cath Workflow Profile.

Clinical Context: Currently, the most common scenario for the performance of a cardiac catheterization is that a consulting cardiologist recommends that the patient undergo a catheterization, and makes the arrangements by phone for the procedure. This is a simple logistical arrangement with the cath lab that rarely involves a formal electronic scheduling activity (this function is served instead by the ubiquitous "whiteboard"). At this point, one of three paths may be used: the procedure is ordered at the Order Placer system, the procedure is ordered at the departmental system, or the procedure begins without an order in the cath lab.

Note that in operations typical of current practice in the cath lab, there is little (if any) interaction between the department information systems and a hospital Order Placer system. One of the goals of IHE is to facilitate better integration between those two worlds, and enable the Order

Placer system to provide a uniform system of order management for the departments. The clinical context of the Cath Workflow Profile encourages the evolution from current practice to a more highly integrated enterprise workflow.

IHE Context: Many of the use cases include the set of transactions necessary for post-hoc updating of patient information. In the Radiology Technical Framework, this is specified in a separate Patient Information Reconciliation Profile, but because the cath workflow needs to deal with this in a large percentage of cases, patient updating has been included in the basic Cath Workflow Profile. However, the specific data flows for such reconciliation are indicated in the Process Flow Diagrams in blue.

The use cases parallel those defined in the Radiology Patient Information Reconciliation Profile (RAD-TF 1:4.4). To facilitate comparison for those readers familiar with RAD-TF, the differences between the radiology Process Flow Diagrams and those in cardiology are shown in green in the figures of the following subsections.

There are six specific Use Cases defined for Cath Workflow, C1 through C6, whose variations occur based on whether or not and where a patient is registered, as well as whether or not and where an order is placed. These variations are listed in Table 3.4-1. Cath use cases C1 through C6 correspond closely to RAD-TF Patient Information Reconciliation use cases 1 through 6.

Additional use cases, C7: Change Rooms During Procedure, C8: Cancel Procedure, and C9: Post-Procedure Evidence Creation, are not shown in the Table.

Table 3.4-1. Cath Workflow Cases

Order Placement / Patient Registration	Order Placed at Order Placer	Order Placed at Order Filler	Order Not Placed
Patient Registered at ADT	**Case C1**	**Case C2**	**Case C3**
Patient Registered in the Department (see note)	Not Applicable - the Order Placer requires the patient registration from the ADT system	**Case C4**	**Case C5**
Patient Updated	**Case C6**	**Case C6**	**Case C6**

Note: Patient is registered in the department either in the DSS/OF system, or manually (temporary ID assigned on paper and manually entered into the modality).

> Note: The transactions for Modality Image/Evidence Stored and Storage Commitment are not shown in the following subsections, and select Order Status Update transactions are not shown, as they do not impact the process control workflow. Also only selected transactions for "Modality N" (i.e., representing multiple additional modalities in the lab) are shown to indicate the multi-modality nature of the Process Flow.
>
> Also note that the Performed Procedure Step Manager as shown on the Process Flow diagrams is presumed to be grouped with the Image Manager for the purpose of presentation. In actual implementations it may be grouped with the Department System Scheduler/Order Filler with corresponding changes in the flow of PPS related transactions between the Image Manager and Department System Scheduler/Order Filler.

3.4.1 Case C1: Patient Registered at ADT and Procedure Ordered at the Order Placer

Clinical Context: This corresponds to the more traditional Radiology Structured Workflow, where an order is placed in the hospital ordering system for the Cardiac Catheterization. It also accounts for the special situation where an emergency identifier has been created for the patient (so that the patient is registered in the ADT and has been assigned a unique identifier). Since the order is placed before the procedure begins, common identifiers can be used to enable the coordinated presentation and electronic distribution of all of the information related to the cardiac cath.

IHE Context: This case includes the full scheduled workflow when all three levels of control (order, requested procedure, and scheduled/performed procedure steps) in the IHE data model are fully utilized to request a procedure (see section 3.3).

The patient may be registered at the ADT system as a known patient with complete demographics, or with incomplete demographics, including the case of a totally unidentified patient for whom only a Patient ID and a temporary name are assigned. To the subsequent systems in the Cath Workflow, it is irrelevant to procedure performance whether or not the complete demographics are known. This case thus includes both identified and unidentified patients, registered at the ADT system, for whom Orders are created at the Order Placer, and whose procedures are scheduled at the Department System Scheduler/Order Filler (DSS/OF).

For unidentified patients the ADT system is a single point of patient reconciliation in the enterprise. When the real patient identity is known, the ADT is responsible for reconciliation of its own records, as well as informing the Order Placer and DSS/OF about corresponding changes. The ADT sends a Patient Update message to both the Order Placer and DSS/OF. The DSS/OF sends the Patient Update message to the Image Manager.
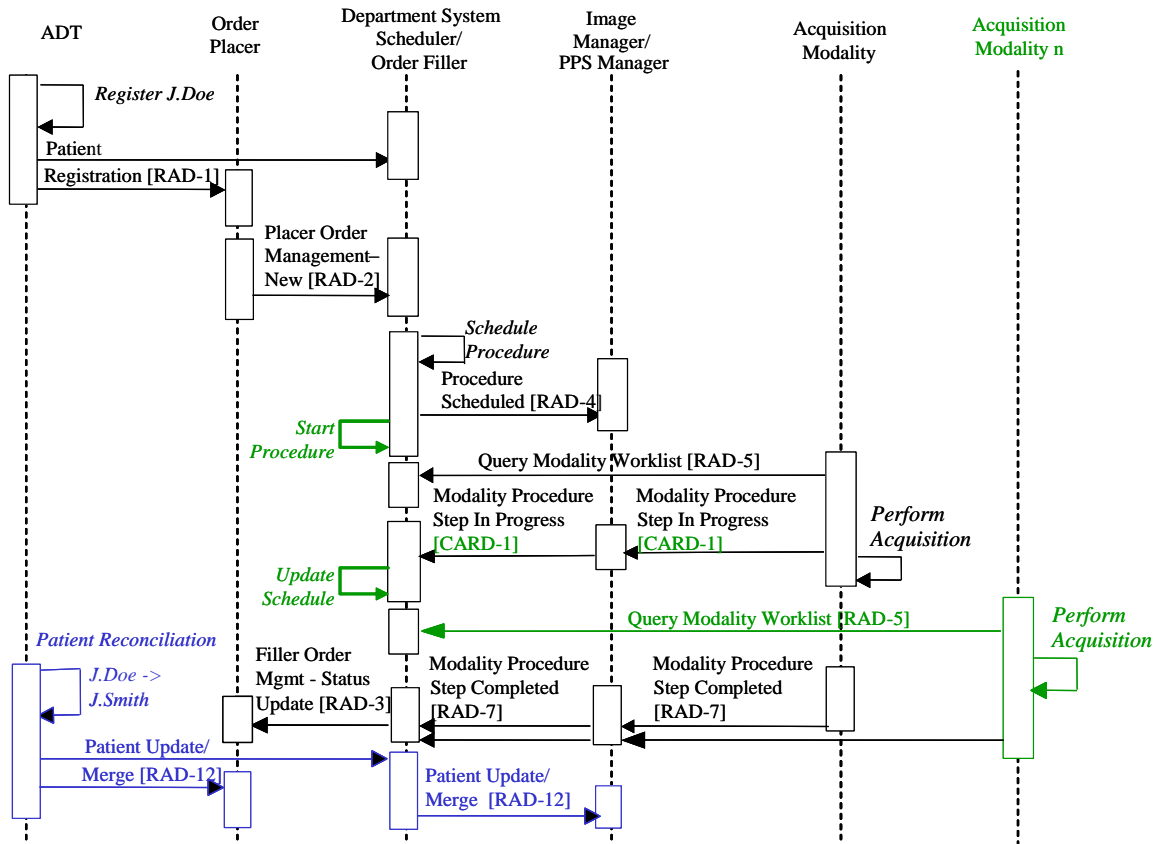
Figure 3.4-1. Patient Registered at ADT and Ordered at the Order Placer – Case C1

Significant Transactions (see also Section 3.3):

- To reconcile the patient information, the ADT may register a new patient and merge the temporary patient with the correct patient, and send both Patient Registration [RAD-1] and Patient Update [RAD-12] (Merge) transactions to the Order Placer and DSS/OF.

- If a permanent Patient ID was assigned, then the ADT may only send a Patient Update [RAD-12] transaction with proper information.

Note that if the Order has been placed, but not scheduled, there will be no response to the Modality Worklist query. In that case, the system will treat this as Case C3 (Patient Registered at ADT and Procedure Not Ordered), and the original Order will need to be canceled by a manual process.

3.4.2 Case C2: Patient Registered at ADT and Procedure Ordered at DSS/OF

Clinical Context: This scenario is closely akin to Case C1, however, an order is not placed in the traditional hospital ordering system, but rather, the procedure information is entered at the

Departmental System, which then submits the information to the hospital ordering system. This workflow is typical of many institutions, and alleviates the need to have an Order Placer system (HIS) terminal in the department or cath lab.

IHE Context: This case is based on case C1. However, in this situation the order for a procedure for a registered patient is generated by the Department System Scheduler/Order Filler and submitted to the Order Placer. Procedures are scheduled normally and acquisition systems use Modality Worklist.

If the patient information requires subsequent reconciliation, the ADT sends the Patient Update messages to both the Order Placer and Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler sends the Patient Update message to the Image Manager as in case C1.

Figure 3.4-2. Patient Registered at ADT and Ordered at DSS/OF – Case C2

Significant Transactions:

- A Filler Order Management (New Order) transaction [RAD-3] is sent from Department System Scheduler/Order Filler to the Order Placer.

3.4.3 Case C3: Patient Registered at ADT and Procedure Not Ordered

Clinical Context: This scenario is similar to case C2, but the procedure information is not entered at the departmental system (e.g., due to time constraints). One of the participating modalities will therefore need to initiate the process of creating the common procedure identifiers. The identifiers are created at the departmental system based on an action taken by the first modality to start the procedure (typically the hemodynamics system); they are then available for subsequent modalities to share. The amount of detail in the procedure information will be limited to what is provided by the first modality, e.g., if it does not provide a coded procedure type, it will necessarily appear as a "generic cath procedure". It is desirable whenever possible to use case C1 or case C2 process flows.

IHE Context: As in cases C1 and C2, this uses a permanent Patient ID generated by the ADT for a registered patient (identified, or unidentified). However, no order entry or scheduling takes place before an Acquisition Modality begins performing the procedure. The permanent Patient ID is entered at the Acquisition Modality (typically, from a patient wristband; a barcode reader may minimize the occurrence of data entry errors).

This case differs from the corresponding Radiology use case. Because the cath procedure is inherently multi-modality, it is essential for all devices to use a common set of identifiers for the patient and study. Therefore, upon receiving the first Modality Procedure Step In Progress, the DSS/OF will automatically create a Requested Procedure for the cath exam, and its associated Scheduled Procedure Steps for all modalities in the same cath lab (room), utilizing the Study UID provided by the first Modality Procedure Step In Progress. The other modalities in that lab can then obtain coordinated identifiers using the Query Modality Worklist transaction.

See Appendix B for further details.

When the Requested Procedure is automatically created, the DSS/OF generates and submits an order to the Order Placer, as in case C2, using a generic cardiac cath procedure code, and then sends a Procedure Scheduled to the Image Manager.

> Notes: 1. The difference from the Radiology TF is that the DSS/OF creation of a Requested Procedure occurs upon the MPPS In Progress (N-CREATE) message, not the MPPS Completed message; this allows multi-modality synchronization to the same Requested Procedure.
> 2. Also, the DSS/OF does not wait for the Order Placer to return a response with an Order Placer Number before creating the Requested Procedure, as this may delay expeditious creation of SPSs to enable time-critical multi-modality start-up in the cath lab.

If the patient information requires subsequent reconciliation, the ADT sends the Patient Update messages to both the Order Placer and Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler sends the Patient Update message to the Image Manager as in case C1.
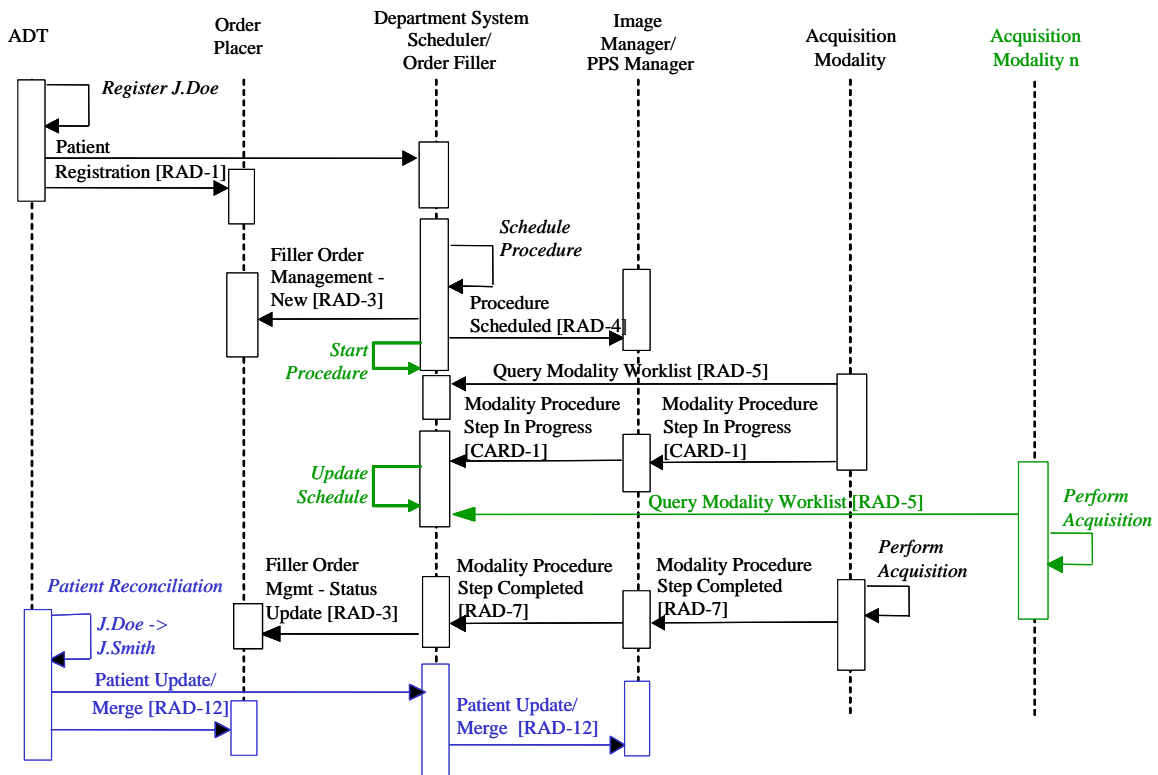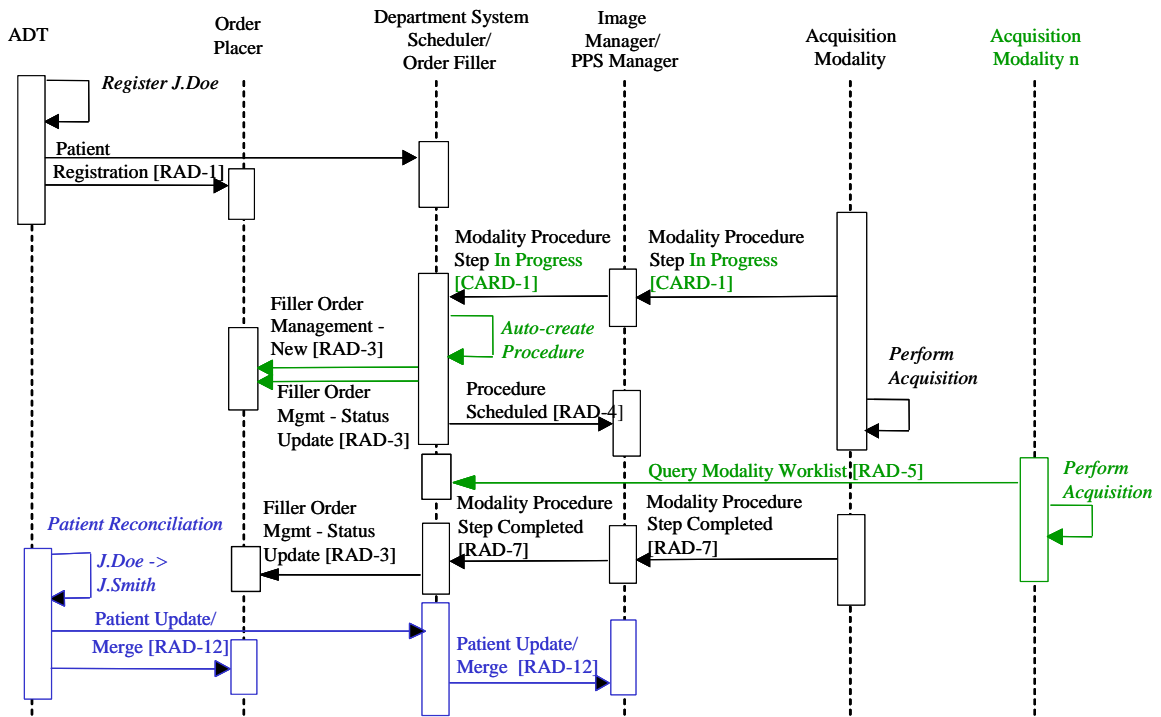
Figure 3.4-3. Patient Registered at ADT and Procedure Not Ordered – Case C3

Significant Transactions:

- From the first acquisition modality's perspective, the difference between this and cases C1 and C2 is that the MWL query (not shown) will not return a response for the current patient. An unscheduled Performed Procedure Step will need to be created.

- On receiving a Modality Procedure Step In-progress [CARD-1], the Department System Scheduler/Order Filler recognizes it as an unscheduled case, but can match the Patient ID to ADT information previously received.

- Using the information from the MPPS transaction, which includes the patient ID and the modality station AE Title, the DSS/OF creates a new Requested Procedure, and also creates Scheduled Procedure Steps for all the modalities in that same cath lab to reflect the current active case. Note that since the patient is registered, the DSS/OF will have received the demographics associated with the patient ID.

- The Department System Scheduler/Order Filler sends a Filler Order Management (New Order) transaction [RAD-3] to the Order Placer, then a Filler Order Management (Status Update) indicating the in-progress state, and sends a Procedure Scheduled transaction [RAD-4] to the Image Manager.

- Subsequent Modality Worklist queries [RAD-5] from equipment in this cath lab will receive the appropriate scheduled procedure steps including the necessary patient/study identifiers.

3.4.4 Case C4: Patient Registered at DSS/OF and Procedure Ordered

Clinical Context: This is a variation of Case C2 where the order is being placed in the department. This accommodates the emergency case when there is not enough time to register the patient in the hospital system, or the event that the ADT system is unavailable (e.g., after hours). In this scenario, however, the patient identifier is not available from the hospital ADT. A temporary patient identifier is created at the department level, and the procedure information can be entered. The Order Placer system cannot be notified yet (while the patient ID is still temporary). At some later time, the registration will occur at the ADT system, at which time the reconciliation with the temporary patient ID can happen (manually at the department system). The Order Placer system can then also be notified.

IHE Context: In this case, no valid Patient ID is available to the Department System Scheduler/Order Filler from the ADT system. The DSS/OF assigns a temporary Patient ID and a temporary name and schedules the required procedure. The scheduled procedure with the temporary Patient ID is conveyed to the Image Manager.

> Note: The Department System Scheduler/Order Filler must ensure that the assigned temporary Patient ID is unique within its scope.

However, unlike case C2, the DSS/OF does not send the Filler Order Management (New Order) transaction to the Order Placer when the Requested Procedure is created, since the temporary Patient ID is out of the ADT domain scope of the Order Placer. Similarly, a Filler Order Management - Status Update transaction is not sent based on the first MPPS In Progress.

Procedure performance at the modalities proceeds as normal based on Modality Worklist.

When patient information becomes known, the ADT system sends new patient information to both the Order Placer and the Department System Scheduler/Order Filler. The Department System Scheduler/Order Filler (typically using a manual process) reconciles received patient information with that associated with the temporary Patient ID and merges the permanent patient record with its own temporary one and sends a Patient Update transaction to the Image Manager. At the same time, the Department System Scheduler/Order Filler generates and submits an order to the Order Placer using the permanent Patient ID, notifies the Order Placer that the order is completed, and updates the Image Manager with the Order Placer Number for the order.

Figure 3.4-4. Patient Registered at DSS/OF and Procedure Ordered – Case C4

Significant Transactions:

- Patient information is reconciled internally by the Department System Scheduler/Order Filler using the Patient Registration from ADT.

- The Department System Scheduler/Order Filler sends the Patient Update [RAD-12], and Procedure Update [RAD-13] transactions to the Image Manager.

- The Department System Scheduler/Order Filler sends the Filler Order Management (New Order and Status Update) transactions [RAD-3] to the Order Placer.

3.4.5 Case C5: Patient Not Registered

Clinical Context: This is a combination of Cases C3 and C4 (above). In this case, the patient has not been registered in the ADT system *and* there is no order placed ahead of time in either the Order Placer system or the departmental system. This can occur in an emergency situation where there is either no patient information available or there is not enough time available to create it. It might also occur in the less emergent setting where the ADT or other key component

of the HIS is unavailable. All of the activities of Cases C3 and C4 need to take place. A temporary patient ID assigned by the department is entered at the first modality to start the procedure; that modality forwards the patient and procedure information to the departmental system for sharing with the other modalities. This procedure information cannot be sent yet to the Order Placer system. When a valid identifier is available from the ADT, the departmental system can complete the process of reconciling the patient IDs and notifying the Order Placer system.

IHE Context: In this case, no valid Patient ID is available to the Department System Scheduler/Order Filler from the ADT system, and no ordering or scheduling is done before the procedure is performed. A temporary ID and name are entered at the Modality (not from a patient wristband, since that would be a valid ADT system Patient ID, and is covered in case C3). The Patient ID and name are selected according to the locally defined rules; for example, selected from the predefined pool of "Patient ID–patient name" pairs. The rules for selecting temporary Patient ID shall guarantee its uniqueness within the scope of Department System Scheduler/Order Filler.

As in case C3, it is essential for all devices to use a common set of identifiers for the patient and study. Therefore, upon receiving the first Modality Procedure Step In Progress, the DSS/OF will automatically create a Requested Procedure for the cath exam, and its associated Scheduled Procedure Steps for all modalities in the same cath lab (room), utilizing the Study UID provided by the first Modality Procedure Step In Progress. The other modalities in that lab can then obtain coordinated identifiers using the Query Modality Worklist transaction.

> Note: See note on time delay between the Modality Procedure Step In Progress transaction from the first modality, and the availability of SPSs in the Modality Worklist in Appendix B.

The DSS/OF sends a Procedure Scheduled message to the Image Manager. However, as in case C4, the DSS/OF does not send the Filler Order Management (New Order) transaction to the Order Placer when the Requested Procedure is created, since the temporary Patient ID is out of the ADT domain scope of the Order Placer.

> Note: The difference from the Radiology TF is that the DSS/OF creation of a Requested Procedure occurs automatically upon receipt of the MPPS In Progress (N-CREATE) message, not after manual reconciliation following the MPPS Completed message; this allows multi-modality synchronization to the same Requested Procedure. Since the Requested Procedure and (temporary) Patient identifiers are known, the Image Manager can be notified of a Procedure Scheduled.

When patient information becomes known, the ADT system sends new patient information to both the Order Placer and the Department System Scheduler/Order Filler. As in case C4, the Department System Scheduler/Order Filler (typically using a manual process) reconciles received patient information with that associated with the temporary Patient ID and merges the permanent patient record with its own temporary one and sends a Patient Update transaction to the Image Manager. At the same time, the Department System Scheduler/Order Filler generates and submits an order to the Order Placer using the permanent Patient ID, notifies the Order

Placer that the order is completed, and updates the Image Manager with the Order Placer Number for the order.
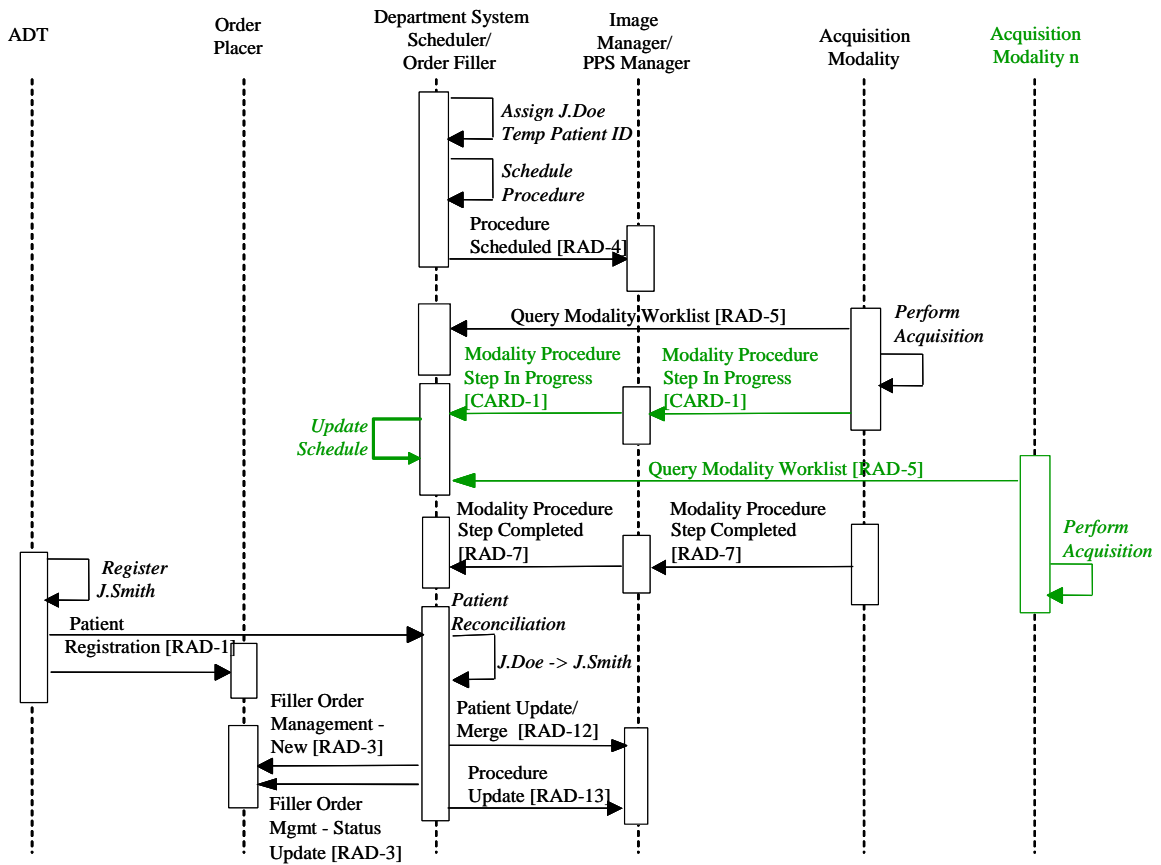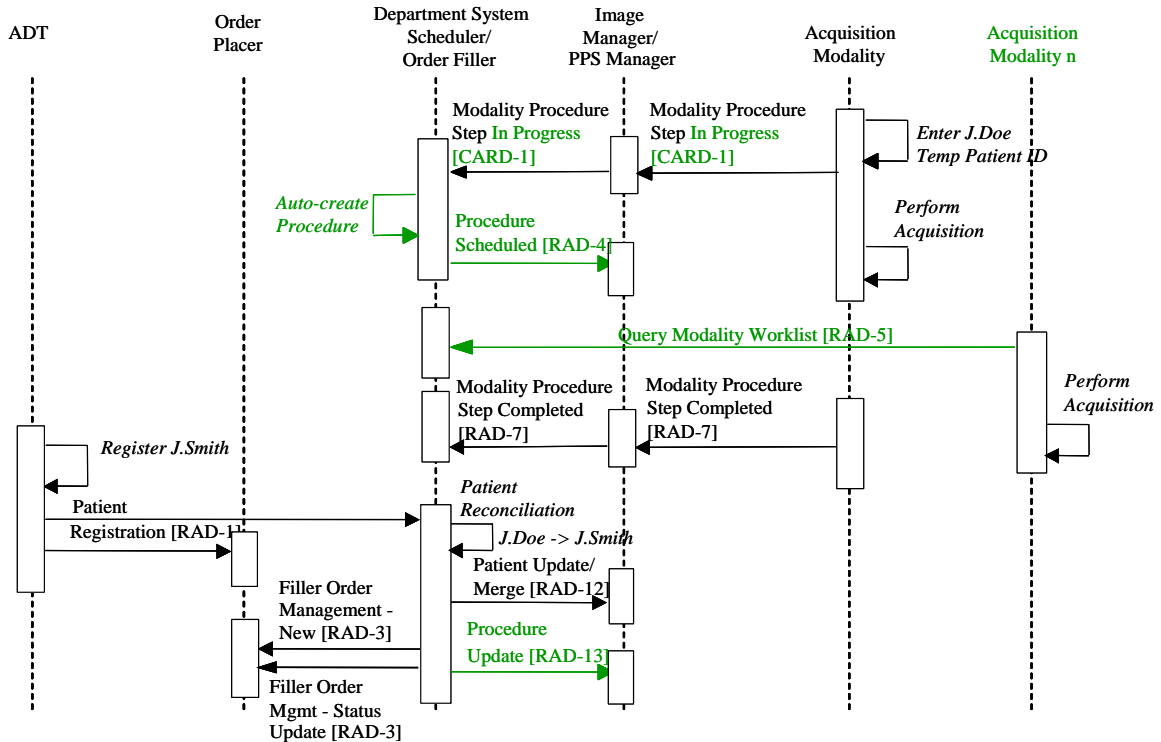

Figure 3.4-5. Patient Not Registered – Case C5

Significant Transactions:

- From the first acquisition modality's perspective, the difference between this and case C3 is that the MWL query (not shown) will not return a response for the current patient, and there is no ADT system-issued Patient ID. An unscheduled Performed Procedure Step will need to be created with a locally created Patient ID.

- On receiving a Modality Procedure Step In-Progress [CARD-1] transaction, the Department System Scheduler/Order Filler recognizes it as an unscheduled case, and in contrast to case C3, cannot match the Patient ID to ADT information previously received.

- Using the information from the MPPS transaction, which includes the temporary patient ID and the modality station name, the DSS/Order Filler creates a new Requested Procedure, and also creates Scheduled Procedure Steps for all the modalities in that same cath lab to reflect the current active case. It sends a Procedure Scheduled [RAD-4] to the Image Manager.

- Patient information is reconciled internally by the Department System Scheduler/Order Filler using the Patient Registration from the ADT.

- The Department System Scheduler/Order Filler sends a Patient Update/Merge transaction [RAD-12] to the Image Manager.
- The Department System Scheduler/Order Filler sends Filler Order Management (New Order and Status Update) transactions [RAD-3] to the Order Placer.
- Using the information from the placed order, the Department System Scheduler/Order Filler sends a Procedure Update [RAD-13] transaction to the Image Manager containing the new official Order Placer number.

3.4.6 Case C6: Patient Updated During Procedure

Clinical Context: An unidentified patient may be registered at the ADT system and brought into the cath lab with temporary patient demographics. While the procedure is in progress, the ADT system is able to obtain the correct patient demographics, and sends an update message. In this situation, some of the information may be obtained with the original (temporary) patient demographics, and some with the revised demographics. This case identifies how reconciliation occurs.

IHE Context: Updates may need to occur after the initial Patient Registration and Order Placement has occurred. The Modality may have requested information from the Department System Scheduler before the update has occurred and continue to send the images with the original Patient Registration and Order information. The Image Manager will need to update the patient information in items stored in the Image Archive, as well as items that it may continue to receive from the modalities.
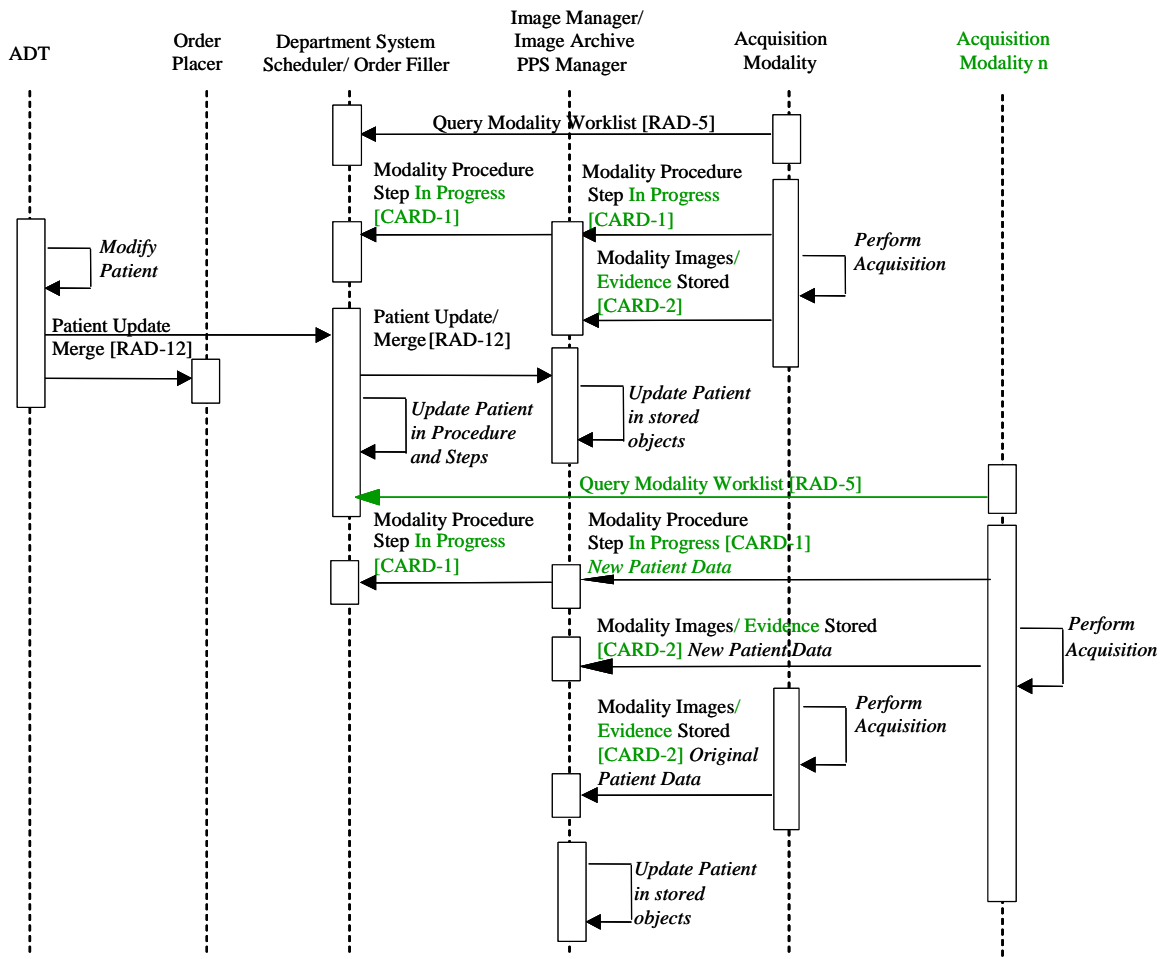
Figure 3.4-6. Patient Updated during procedure – Case C6

Significant Transactions:

- The Modality may continue to send information using the original patient information even after the patient update has occurred.

- The Image Manager must continue to reconcile Patient Information even after the Patient Update transaction has been completed.

Only partial transactions are shown. Other transactions are performed according to the other profile use case requirements.

3.4.7 Case C7: Change Rooms During Procedure

Clinical Context: It is not uncommon in the cath environment that it becomes necessary to change the room in which the procedure is taking place. This may happen when a diagnostic case turns into an interventional case, and the patient is moved to a room that is better suited to

performing interventions. It may also be required when there is an equipment failure in the middle of a procedure, and the patient must be moved to a working room to complete the study.

> Note: There is a part of the clinical workflow where a patient is moved from the procedure room to a "holding area", but information (typically vital signs and cardiac rhythms) is still being monitored and recorded. This is outside the scope of the current IHE Cardiology Technical Framework.

IHE Context: This case describes the process flow for halting a procedure in one room, with one set of modality equipment, and resuming it in another room with different equipment. For continuity of clinical data, it is critical that this be treated as a single Requested Procedure, i.e., it uses the same Study Instance UID.

The basic process is that each modality in the first room will issue a Modality Procedure Step Completed or Discontinued. The DSS/OF through its scheduling functionality can reassign the Requested Procedure to a new room, which will create Scheduled Procedure Steps for the modalities in the new room; those modalities can then restart the procedure using the Modality Worklist information. In the event that the DSS/OF does not reschedule the Requested Procedure to the new location, the modalities in the new room need to issue a broad Modality Worklist query (not constrained to its own AE Title) to obtain the Scheduled Procedure Step for the original room; they can then append a Modality Performed Procedure Step to that Scheduled Step.

Note that the absence of Modality Procedure Step Completed or Discontinued does not impact the ability to continue in a new room. The Modality Procedure Step Completed or Discontinued from the modalities in the first room may be sent at any time, but are required from each modality to complete its Modality Procedure Step in Progress.

Note that there is no comparable case covered in the Radiology Technical Framework.
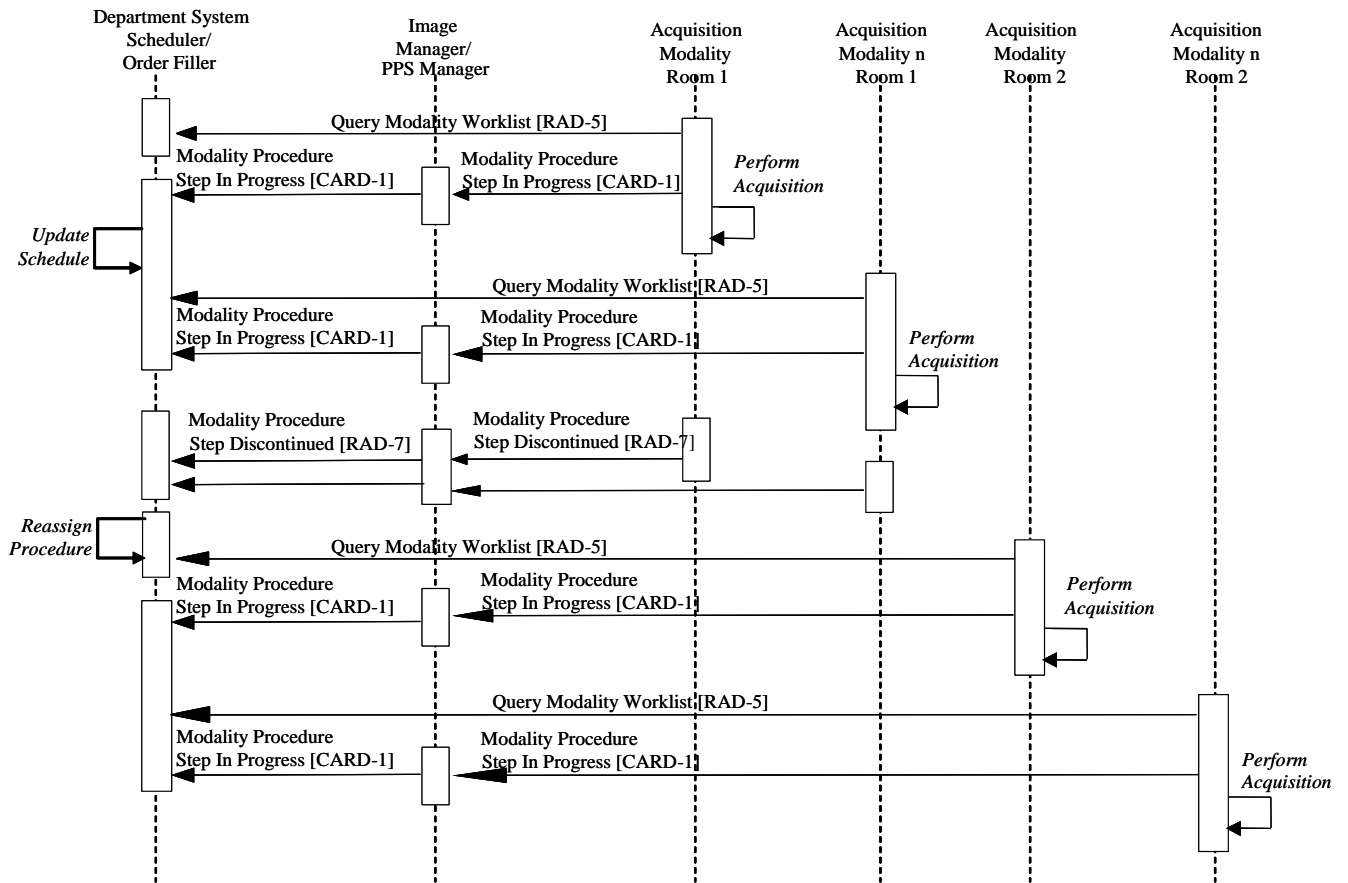
Figure 3.4-7. Change Rooms During Procedure – Case C7

Only partial transactions are shown. Other transactions are performed according to the other profile use case requirements, in particular, Modality Images/Evidence Stored and Storage Commitment.

3.4.8 Case C8: Cancel Procedure

Clinical Context: When a cath procedure is cancelled, it is important for the information systems to keep track of the cancellation to be able to respond to queries that the cath lab personnel will continue to receive regarding that patient.

IHE Context: This case describes the process flow for canceling a cath procedure prior to its start. The procedure is ordered either by the Order Placer system, or by the DSS/OF, as shown in Figure 3.4-8. The DSS/OF assigns the Requested Procedure ID and Study Instance UID, schedules the procedure, and notifies the Image Manger.

If the procedure is cancelled in the department, the DSS/OF notifies the Order Placer system and the Image Manger. All three systems - DSS/OF, Order Placer, and Image Manger – may maintain information about the cancelled Order and Requested Procedure for an implementation- or institutionally-determined length of time.

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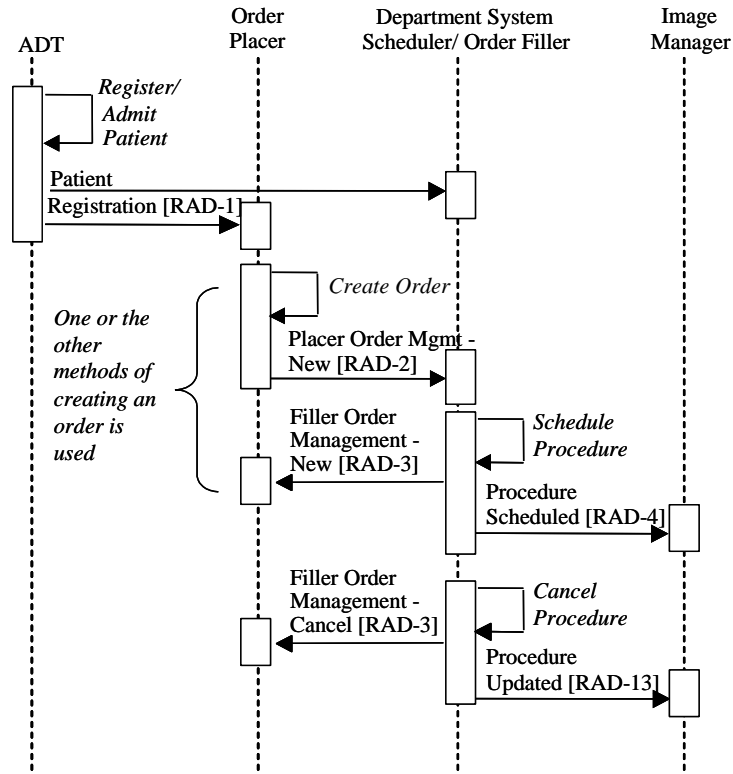
Figure 3.4-8. Cancel Procedure – Case C8

3.4.9 Case C9: Post-procedure evidence creation

Clinical Context: After a cath procedure is performed, the imaging and other procedure data is often analyzed using specialized software. This analysis provides quantitative measurements of the coronary arteries and/or ventricles, coronary tree and intervention documentation, and potentially additional derived images highlighting the findings. This does not include the use of a core lab for clinical trial or outcomes analysis, where the evidence produced is not returned to the clinical environment.

IHE Context: This case describes the process flow for post-procedure analysis of the cath imaging data (angiographic or ultrasound). The analysis is performed at a station that groups the Image Display and Evidence Creator actors, as shown in Figure 3.4-9. The analysis station (Image Display actor) retrieves the images to be analyzed from the Image Manger/Image Archive. The actors participate in both the Cath Profile and the Evidence Documents Profile.

When the analysis is performed, the station (Evidence Creator actor) notifies the Image Manger/Image Archive and the Department System Scheduler/Order Filler of the activity through the Modality Performed Procedure Step In Progress and Complete transactions. The Evidence Creator stores any measurements or derived images to the Image Manager/Image Archive, and commits them using the Storage Commitment transaction.

Another Image Display actor may query the Image Manager for evidence documents. For documents stored as DICOM SR objects, the Query Evidence transaction allows the Image Display to request, and the Image Manager to provide, the document titles, status, and other attributes. The Image Display may retrieve and display the evidence documents.
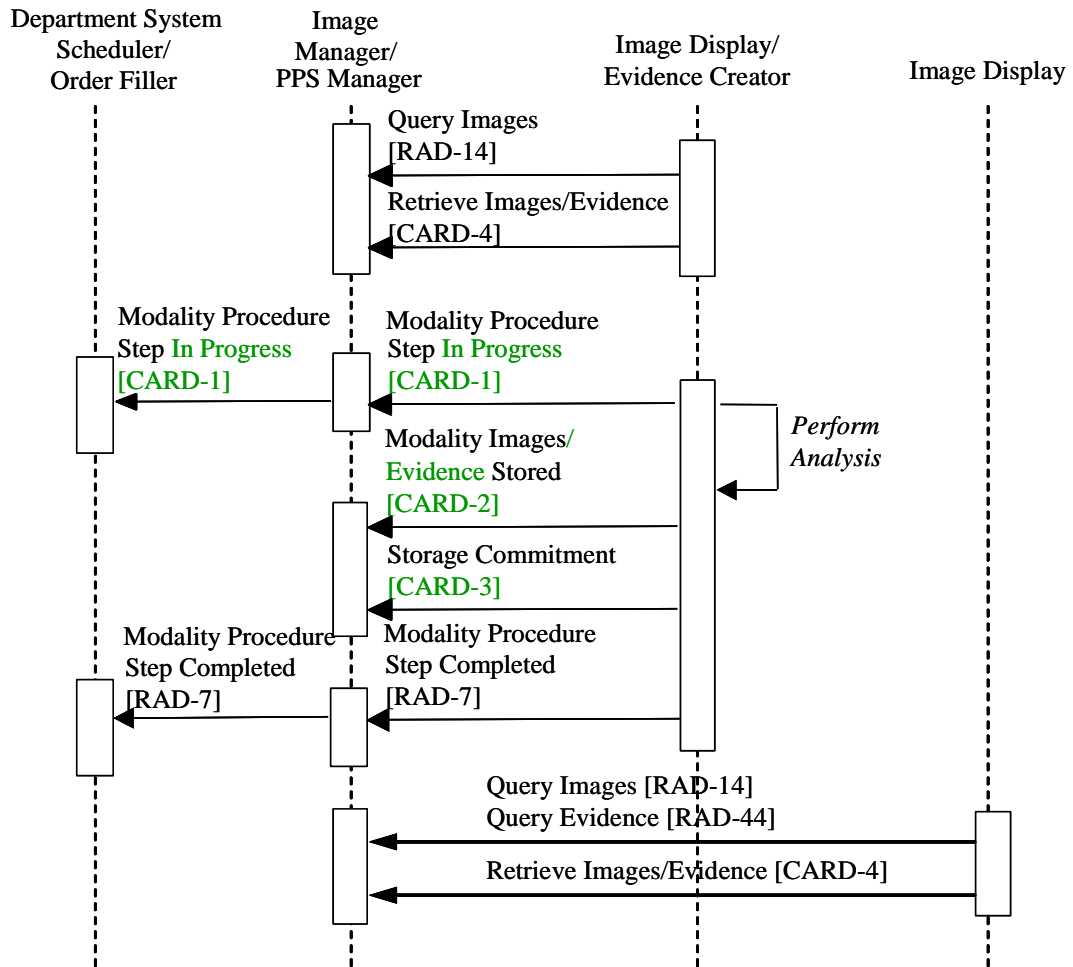
Figure 3.4-9. Post-procedure evidence creation – Case C9

Notes: 1. While the Evidence Creator may not be a modality, it can still use the MPPS transactions indicating an appended procedure step for the modality of the images. The Evidence Creator may use the referenced Scheduled Procedure Step information in the analyzed images as the referenced SPS for the evidence documents created. This keeps the workflow consistent with the case of analysis performed on the original acquisition modality.

2. This profile does not specify the workflow transaction or trigger that causes the analysis station to perform its work. The workflow may be managed using the Post-Processing Workflow (PWF) Profile (see RAD-TF 1:12). The IHE Cardiology Technical Committee

has not evaluated the appropriateness of the PWF Profile for the Cardiology domain, but this may be the subject of a future recommendation.

3. Support for the Query Evidence transaction is part of the Evidence Documents Profile. If either actor does not support it, the Image Display will only be able to present to the user a list of SR Documents differentiated by document instance number and date/time as provided in the Query Images transaction. In this event, the Image Display may achieve the same effect as the Query Evidence transaction by retrieving all the SR documents and extracting from them the relevant attributes for display in the query user interface.

3.4.10 Case C10: EP Ablation / Implantation Lab

Clinical Context: The Cardiac Cath workflow is also applicable to the multi-modality electrophysiology laboratory. Programmers for implantable devices and device-generated data will be addressed in a separate profile.

In electrophysiology laboratory ablation procedures, specialized catheters are placed into the heart to identify and eliminate sources for arrhythmia. The EP lab is also used to implant and adjust cardiac rhythm control devices (pacemakers, cardioverter-defibrillators, and cardiac resynchronization therapy devices).

The EP lab is a multi-modality mix of many types of equipment from many different manufacturers; as many as eight systems from different manufacturers may typically participate in a procedure. In current practice, these systems are unconnected islands, each managing its piece of the patient clinical record. Integration of this data would result in increases in efficiency and a reduction of medical errors.

Increases in efficiency are especially critical due to the rapidly increasing demand for EP procedures and devices, and the limited availability of trained clinical professionals in the field.

For an ablation procedure, the patient is brought to the electrophysiology laboratory and the patient's demographic data is separately entered into the EP recording system, the fluoroscopy system, the intracardiac echocardiographic system, and any specialized mapping systems that will be required for the procedure. Data from the medical record such as allergies and laboratory values are frequently reentered into the procedural record to document that the information has been "reviewed."

A wide array of specialized equipment is used during an ablation procedure; data is acquired from each of these systems independently without any time synchronization, and any documentation of simultaneous acquisition of information from various pieces of equipment must be entered manually in the procedural record. During the procedure, review of data must be evaluated on each individual piece of equipment. For example, if an important event occurred at time X:XX, data from the recording equipment, imaging equipment, and mapping equipment must be queued for display separately to X:XX and reviewed sequentially. Finally, raw data from each system is stored in a variety of formats (optical disc, hard drive, tape) and stored near the electrophysiology laboratory. However, a summary of discrete data from the procedure

(usually paper) is kept in a separate document in the hospital and is often not part of the medical record.

To summarize, for the simplest electrophysiologic/ablation studies, current hospital information systems will typically generate a paper copy of the dictated report, a paper copy of important hemodynamic or electrophysiologic data, an optical disc of electrophysiologic data, a disc of fluoroscopic data, and a disc of echocardiographic imaging data.

IHE Context: For the initial implementation of the EP workflow, the CATH profile includes this special use case to address the workflow in the EP Lab. Given the similarities between the CATH and EP workflows, the process flow diagrams for use cases C1-C9 defined for CATH are also applicable to EP. The emergency use cases C3 and C5 however, are highly unusual in the EP workflow.

The following systems are typical Acquisition Modality Actors for this use case:

- EP recording system
- EP logging system
- Mapping system
- X-ray angiography/fluoroscopy
- Intracardiac echo
- There are other modalities that may be involved during the EP procedure that will be equally applicable to this workflow.

It should be noted that the EP lab acquisition devices are managed by separate Scheduled Procedure Steps within the process flows described in cases C1-C9. These SPSs provide patient demographics and eliminate multiple entry of patient data. All acquired data is consistently time stamped (in accordance with the Consistent Time profile) and stored in the Image Manager/Image Archive for review on multi-modality Image Display actors. A procedure log containing a summary of events and key measurements may be included in the study data set.

4   Echocardiography Workflow (ECHO)

The Echocardiography Workflow Integration Profile describes the workflow associated with digital echocardiography, specifically that of transthoracic echo (TTE), transesophageal echo (TEE), and stress echo. As does the Cath Workflow Integration Profile, this profile deals with patient identifiers, orders, scheduling, status reporting, multi-stage exams (especially stress echo), and data storage. It also specifically addresses the issues of acquisition modality devices that are only intermittently connected to the network, such as portable echo machines, and addresses echo-specific data requirements.

The Echo workflow is focused on the imaging acquisition process, and image-based measurements made either on the modality or on an independent workstation. Items not included would be nursing notes, drug administration documentation, etc. The TEE, TTE, and stress echo workflows are treated identically for the purposes of workflow control.

Intravascular ultrasound (IVUS) and intracardiac echocardiography (ICE) are used in cardiac catheterization procedures, and are supported as modalities in the Cath Workflow, and not in the Echo Workflow.

Note that there is no DICOM standard for 4-D ultrasound, so that is not addressed in this profile.

This profile has much in common with the IHE Radiology Scheduled Workflow, Patient Information Reconciliation, and Evidence Documents Integration Profiles. See **Rad TF-1: 3.4** for the integrated workflow data model adopted by the IHE Technical Framework for HL7 messages and DICOM information objects. This data model offers three major levels of control for workflow:

- **Order**: A request for a Departmental Service
- **Requested Procedure**: Unit of work resulting in one or more reports with associated codified, billable acts.
- **Scheduled and Performed Procedure Step**: the smallest unit of work in the workflow that is scheduled (work to do) or performed (work done).

A clear understanding of the workflow data model is essential to interpreting the Echo Workflow Integration Profile.

4.1 Actors/Transactions

Figure 4.1-1 diagrams the actors involved with this profile and the transactions between actors.
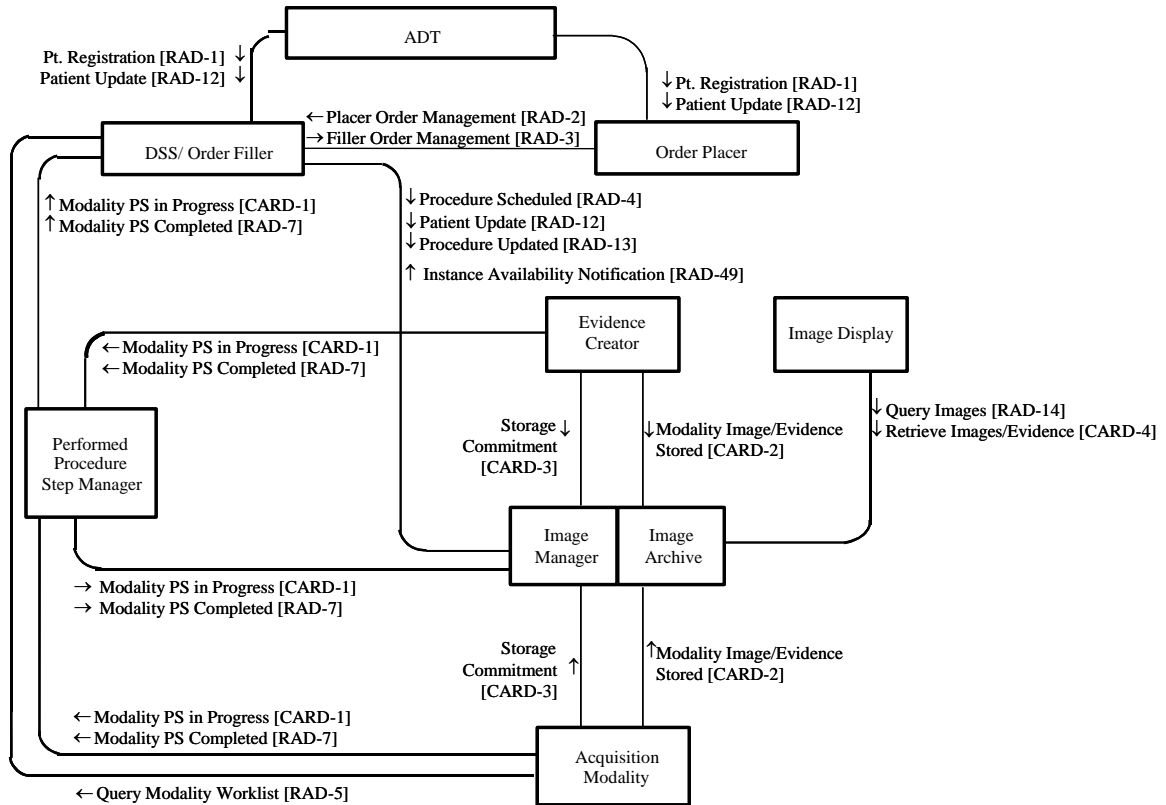
Figure 4.1-1. Echocardiography Workflow Diagram

Table 4.1-1 lists the transactions for each actor directly involved in the Echocardiography Workflow Integration Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options defined by this Integration Profile that implementations may choose to support is listed in Section 4.2.

Table 4.1-1. Echocardiography Workflow - Actors and Transactions

Actors	Transactions	Optionality	Section
ADT Patient Registration	Patient Registration [RAD-1]	R	RAD-TF 2: 4.1
	Patient Update [RAD-12]	R	RAD-TF 2: 4.12
Order Placer	Patient Registration [RAD-1]	R	RAD-TF 2: 4.1
	Patient Update [RAD-12]	R	RAD-TF 2: 4.12

Actors	Transactions	Optionality	Section
	Placer Order Management [RAD-2]	R	RAD-TF 2: 4.2
	Filler Order Management [RAD-3]	R	RAD-TF 2: 4.3
Department System Scheduler/ Order Filler	Patient Registration [RAD-1]	R	RAD-TF 2: 4.1
	Patient Update [RAD-12]	R	RAD-TF 2: 4.12
	Placer Order Management [RAD-2]	R	RAD-TF 2: 4.2
	Filler Order Management [RAD-3]	R	RAD-TF 2: 4.3
	Procedure Scheduled [RAD-4]	R	RAD-TF 2: 4.4
	Query Modality Worklist [RAD-5]	R	RAD-TF 2: 4.5
	Modality Procedure Step In Progress [CARD-1]	R	CARD-TF 2: 4.1
	Modality Procedure Step Completed [RAD-7]	R	RAD-TF 2: 4.7
	Procedure Updated [RAD-13]	R	RAD-TF 2: 4.13
	Instance Availability Notification [RAD-49]	O	RAD-TF 3: 4.49
Acquisition Modality	Query Modality Worklist [RAD-5]	R	RAD-TF 2: 4.5
	Modality Procedure Step In Progress [CARD-1]	R	CARD-TF 2: 4.1
	Modality Procedure Step Completed [RAD-7]	R	RAD-TF 2: 4.7
	Modality Images/Evidence Stored [CARD-2]	R	CARD-TF 2: 4.2
	Storage Commitment [CARD-3]	R	CARD-TF 2: 4.3
Image Manager/ Image Archive	Procedure Scheduled [RAD-4]	R	RAD-TF 2: 4.4
	Modality Procedure Step In Progress [CARD-1]	R	CARD-TF 2: 4.1
	Modality Procedure Step Completed [RAD-7]	R	RAD-TF 2: 4.7
	Modality Images/Evidence Stored [CARD-2]	R	CARD-TF 2: 4.2
	Storage Commitment [CARD-3]	R	CARD-TF 2: 4.3
	Patient Update [RAD-12]	R	RAD-TF 2: 4.12
	Procedure Updated [RAD-13]	R	RAD-TF 2: 4.13
	Query Images [RAD-14]	R	RAD-TF 2: 4.14
	Retrieve Images/Evidence [CARD-4]	R	CARD-TF 2: 4.4
	Instance Availability Notification [RAD-49]	O	RAD-TF 3: 4.49
Performed Procedure Step Manager	Modality Procedure Step In Progress [CARD-1]	R	CARD-TF 2: 4.1
	Modality Procedure Step Completed [RAD-7]	R	RAD-TF 2: 4.7
Image Display	Query Images [RAD-14]	R	RAD-TF 2: 4.14
	Retrieve Images/Evidence [CARD-4]	R	CARD-TF 2: 4.4
Evidence Creator	Modality Procedure Step In Progress [CARD-1]	R	CARD-TF 2: 4.1
	Modality Procedure Step Completed [RAD-7]	R	RAD-TF 2: 4.7
	Modality Images/Evidence Stored [CARD-2]	R	CARD-TF 2: 4.2
	Storage Commitment [CARD-3]	R	CARD-TF 2: 4.3

Refer to Table 2-1 for other profiles that may be pre-requisites for this profile.

4.2 Echocardiography Workflow Integration Profile Options

Many Actors have Options defined in order to accommodate variations in use across domains or implementations. Options that may be selected for this Integration Profile are listed in the table 4.2-1 along with the Actors to which they apply. Certain of these Options are required for implementation by actors in this Profile (although they may be truly optional in other Profiles).

Table 4.2-1: Echocardiography Workflow - Actors and Options

Actor	Option Name	Optionality	Vol & Section
ADT Patient Registration	*No options defined*	-	-
Order Placer	*No options defined*	-	-
Department System Scheduler/Order Filler	PPS Exception Management	O	RAD-TF 2: 4.7
	Availability of PPS-Referenced Instances	O	RAD-TF 3: 4.49
Acquisition Modality	Patient Based Worklist Query	O	RAD-TF 2: 4.5
	Broad Worklist Query	R	RAD-TF 2: 4.5
	Stress Echo	O	CARD-TF 2: 4.2
	PPS Exception Management	O	RAD-TF 2: 4.7
Image Manager/ Image Archive	PPS Exception Management	O	RAD-TF 2: 4.7
	Echocardiography	R	CARD-TF 2: 4.2
	Intermittently Connected Modality	R	CARD-TF 2: 4.3
	Availability of PPS-Referenced Instances	O	RAD-TF 3: 4.49
Image Display	Stress Echo	R	CARD-TF 2: 4.4
Performed Procedure Step Manager	*No options defined*	-	-
Evidence Creator	*No options defined*	-	-

The Acquisition Modality and Image Manager/ Image Archive will likely support a variety of DICOM SOP Classes. It is expected that this level of optionality will be documented by a reference in the IHE Integration Statement (see Appendix C).

4.3 Echocardiography Workflow Process Flow

The process and information flow for echocardiography procedures generally follows the same flow as the Cath Workflow Profile (see sections 3.3 and 3.4). The special use cases for the Echo Workflow Profile are described here.

Clinical Context: Three variations of echocardiography are considered in this version of the IHE Cardiology Technical Framework:

1.   **Transthoracic Echocardiography (TTE):** In the United States, TTE images are usually acquired by sonographers and reviewed off-line by cardiologists (this model varies in other

countries). The studies may be performed on patients who are brought to the Echocardiography Department, or on patients in their hospital beds using a mobile ultrasound machine (cart). Studies are frequently requested (verbally) but not electronically ordered by the time the sonographer gets to the bedside. Procedures on unregistered patients may be required in emergency situations.

2. **Transesophageal Echocardiography (TEE):** Cardiologists perform transesophageal echoes (TEE), as it involves sedating the patient and passing the echo probe down the esophagus. It is less likely that the procedure would be performed on an emergency basis on unregistered patients, but this may occur. Resource management is more extensive than a simple imaging study, and includes staff, room, and equipment. Evidence gathered during a TEE includes information about the procedure, and not just the echocardiographic images.

3. **Stress Echocardiography ("Stress Echo"):** This study is performed to observe the effect of stress (exercise or pharmacologic challenge) on the performance of the heart muscle. The studies are generally scheduled, and unlikely to be performed on an emergency basis. The evidence gathered for stress echocardiograms includes information about the stress used on the patient (exercise or pharmacologic), and information about the patient's response to the stress (blood pressure, heart rate, symptoms, ECG changes, etc.). Like TEE, resource management is more extensive than for simple imaging.

In all of these scenarios, the carts (especially the mobile ones) may be disconnected from the network for significant periods of time.

There are six specific Use Cases defined for Echo Workflow. The variations occur based on whether or not and where a patient is registered, as well as whether or not and where an order is placed.   These variations are listed in Table 4.3-1. The last use case, E6: Stress Echo, is not shown in the Table.

Table 4.3-1. Echo Workflow Cases

Order Placement / Patient Registration	Order Placed and Scheduled (see note)	Order Placed and Scheduled, but schedule not obtained by Modality	Order Not Placed, Not Scheduled
Patient Registered at ADT	**Case E1** **Case E2 (mobile)**	**Case E3 (mobile)**	**Case E4 (mobile)**
Patient Unregistered	Not Applicable - the Order Placer/Order Filler requires patient registration	Not Applicable - the Order Placer/Order Filler requires patient registration	**Case E5 (mobile)**
Patient Updated	**Case E1**	**Case E1**	**Case E1**

Note: Order Placement may be done in the Order Placer System or the DSS/Order Filler (using the Order Filler Management transaction)

4.3.1 Case E1: Patient Registered at ADT and Procedure Ordered

Clinical Context: This corresponds to the more traditional Radiology Scheduled Workflow, where an order is placed in the Order Placer system or in the department system for a given echo procedure. It also accounts for the special situation where an emergency identifier has been created for the patient (so that the patient is registered in the ADT and has been assigned a unique identifier).

IHE Context: This case includes the full scheduled workflow when all three levels of control (order, requested procedure, and scheduled/performed procedure steps) in the IHE data model are fully utilized to request a procedure (see section 3.3).

The patient may be registered at the ADT system as a known patient with complete demographics, or with incomplete demographics, including the case of a totally unidentified patient for whom only a Patient ID and a temporary name are assigned. To the subsequent systems in the Echo Workflow, it is irrelevant to procedure performance whether or not the complete demographics are known. This case thus includes both identified and unidentified patients, registered at the ADT system, for whom Orders are created at the Order Placer or Department System Scheduler/Order Filler, and whose procedures are scheduled at the DSS/OF.

The Scheduled Procedure Steps are obtained by the modality through Query Modality Worklist, the acquisition is performed and statused through Modality Performed Procedure Step.

For unidentified patients the ADT system is a single point of patient reconciliation in the enterprise. When the real patient identity is known, the ADT is responsible for reconciliation of its own records, as well as informing the Order Placer and DSS/OF about corresponding changes. The ADT sends a Patient Update message to both the Order Placer and DSS/OF. The DSS/OF sends the Patient Update message to the Image Manager.
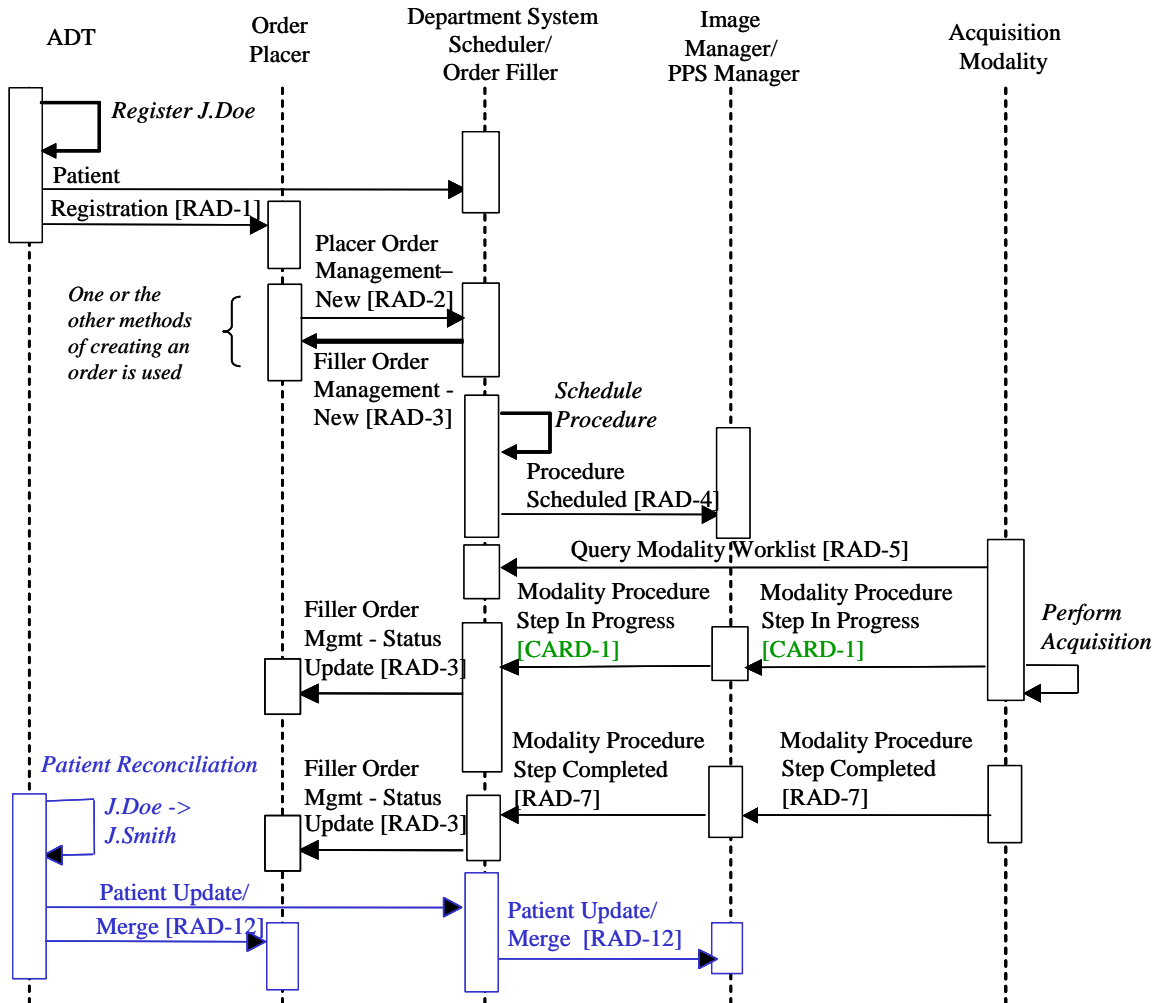
Figure 4.3-1. Patient Registered at ADT and Procedure Ordered – Cases E1/E2

Significant Transactions:

- *Patient Registration*: The Patient Registration data is broadcast to several systems, including the Order Placer and the Department System Scheduler/Order Filler (DSS/OF).

- *Create Order*: The Order Placer is the enterprise repository for all patient orders.

- *Schedule Procedure*: The DSS/OF associates the order with one or more Requested Procedures that have to be performed to satisfy the order. Each Requested Procedure prescribes a number of actions that have to be performed by Acquisition Modalities. Actions are specified in Scheduled Procedure Steps (SPS) based on timing and sequencing, and on modality. Scheduled Procedure Steps are scheduled, i.e., assigned a time slot and performing resource (modality), and are made available for Modality Worklist Query.

- *Query Modality Worklist*: The Modality Worklist (MWL) query may be broad (get a list of scheduled procedures from which one will be selected), or patient-specific (provided with sufficient query keys to get back the scheduled procedure for a single patient).

- *Perform Acquisition*: The Modality may produce a variety of images and other evidence (analysis reports, etc.) that are stored to the Image Manager/Archive. The Image Manager/Archive must support all these object types beyond just images.

- *Modality Procedure Step Complete*: Modality Procedure Step Complete also includes Modality Procedure Step Discontinued.

- *Storage Commitment:* The Image Manager/Archive accepts responsibility for stored images and evidence, allowing the modality to delete the data from its local storage.

- *Filler Order Management - Status Update*: Status Update transactions may be sent to the Order Placer at several points in the workflow, specifically after the first Modality Procedure Step in Progress, and after completion of the procedure (e.g., when the report is signed).

- *Patient Reconciliation:* To reconcile the patient information for an unidentified patient, the ADT may register a new patient and merge the temporary patient with the correct patient, and send both Patient Registration [RAD-1] and Patient Update/Merge [RAD-12] transactions to the Order Placer and DSS/OF. If a permanent Patient ID was initially assigned, then the ADT may only send a Patient Update [RAD-12] transaction with proper information.

4.3.2 Case E2: Intermittently Connected Modality

Clinical Context: This use case covers a mobile workflow, typical of TTE and TEE, in which the acquisition modality is only intermittently connected to the network, and hence to the other actors in the workflow. Connectivity will typically be established at the beginning and end of a shift. For the purpose of this use case, the period of non-connectivity bounded by periods of connectivity constitutes a "shift", regardless of the elapsed time period (several minutes, several hours, or several days). "Intermittently connected" also covers the case of a modality being turned off.

IHE Context: The Process Flow Diagram for this case is identical to Case E1, although the timing of the transactions may be significantly different. At the beginning of a shift, the Query Modality Worklist transaction will retrieve the list of procedure steps scheduled for the shift. Once retrieved, the sonographer will take the modality mobile and perform the procedure steps listed in the worklist.

When disconnected from the network, the Modality Procedure Step In Progress and Modality Procedure Step Completed transactions cannot be sent. At the end of the shift when the machine is connected back to the network, the modality will send the MPPS messages for the activity of the shift. Similarly, the modality will send the Modality Images/Evidence Stored transactions for the acquisitions of the shift, and the Storage Commitment request transactions for those acquisitions. The delay in sending these transactions is consistent with the normal operations of the DSS/Order Filler and Image Manager/Archive under the IHE scheduled workflow profiles.

During the time that the modality is mobile, the Image Manager will not be able to send Storage Commitment response (N-Event Report) messages. An Intermittently Connected Modality option is specified for the Image Manager, under which the Image Manager must queue N-Event Report messages if the modality is not connected. The modality opening an Association (message channel) to the Image Manager shall serve as a trigger for the Image Manager to open a separate Association to the Modality to send the queued N-Event Report messages. This option is required for the Echo Workflow Profile.

See Figure 4.3-1 for the Process Flow Diagram.

Significant Transactions:

- Though the Modality Procedure Step In Progress [CARD-1] will be sent, it is likely to be sent immediately preceding the Modality Procedure Step Complete [RAD-7]

- The Image Manager/Archive must support intermittently connected devices that may be temporarily unable to receive Storage Commitment [CARD-3] messages.

4.3.3 Case E3: Intermittently Connected Modality with Ad Hoc Procedure, Patient Registered, Scheduled Procedure

Clinical Context: This use case describes the situation in which the Modality is mobile (not connected to the network), and during that mobile shift the sonographer has received notice to perform a procedure that was unscheduled at the time the worklist for the shift was downloaded (at the beginning of the shift). However, the procedure has been scheduled, but the modality cannot query for that information since it is not connected to the network.

IHE Context: The Order may be created either at the Order Placer system, or at the DSS/OF, and is scheduled. Even though the procedure has been scheduled by the DSS/OF and is available for the Query Modality Worklist transaction, the modality cannot perform this transaction because it is not currently connected to the network (mobile). Because of this, the perspective of the modality is that the procedure is unscheduled. Therefore, the Patient ID and other demographics must be manually entered at the modality. The modality must also create a Study Instance UID for that study.

Due to the inability to obtain a worklist, when the modality reconnects to the network it sends an MPPS In Progress message [CARD-1] without the Requested Procedure or Scheduled Procedure Step information. This indicates to the DSS/OF that it is an unscheduled procedure. This will cause the DSS/OF to raise an exception for reconciliation (see RAD-TF 2:4.6.4.1.3). The Patient/Order reconciliation includes obtaining the full patient demographics for the Patient ID specified in the MPPS In Progress message. Procedure Reconciliation also includes matching the Performed Procedure with an Order and Requested Procedure that is known to the DSS/OF. It is likely that this will be a manual process.

The DSS/OF then sends a Status Update [RAD-3] indicating in-progress to the Order Placer.

Upon matching the Performed Procedure with the original Requested Procedure, the DSS/OF will cancel the original Procedure using the Procedure Update/Cancelled [RAD-13] with a status of "cancelled" to the Image Manager, and generate a new Procedure Scheduled [RAD-4] containing the Study Instance UID from the MPPS In Progress message, and a Patient Update [RAD-12] with the full patient demographics. The Image Manager/Archive uses the information from the Patient Update transaction to update the demographics in the objects that it has, or will receive, from the acquisition modality.

Eventually (e.g., after completion of the report), the DSS/OF sends a Status Update [RAD-3] indicating completion to the Order Placer.
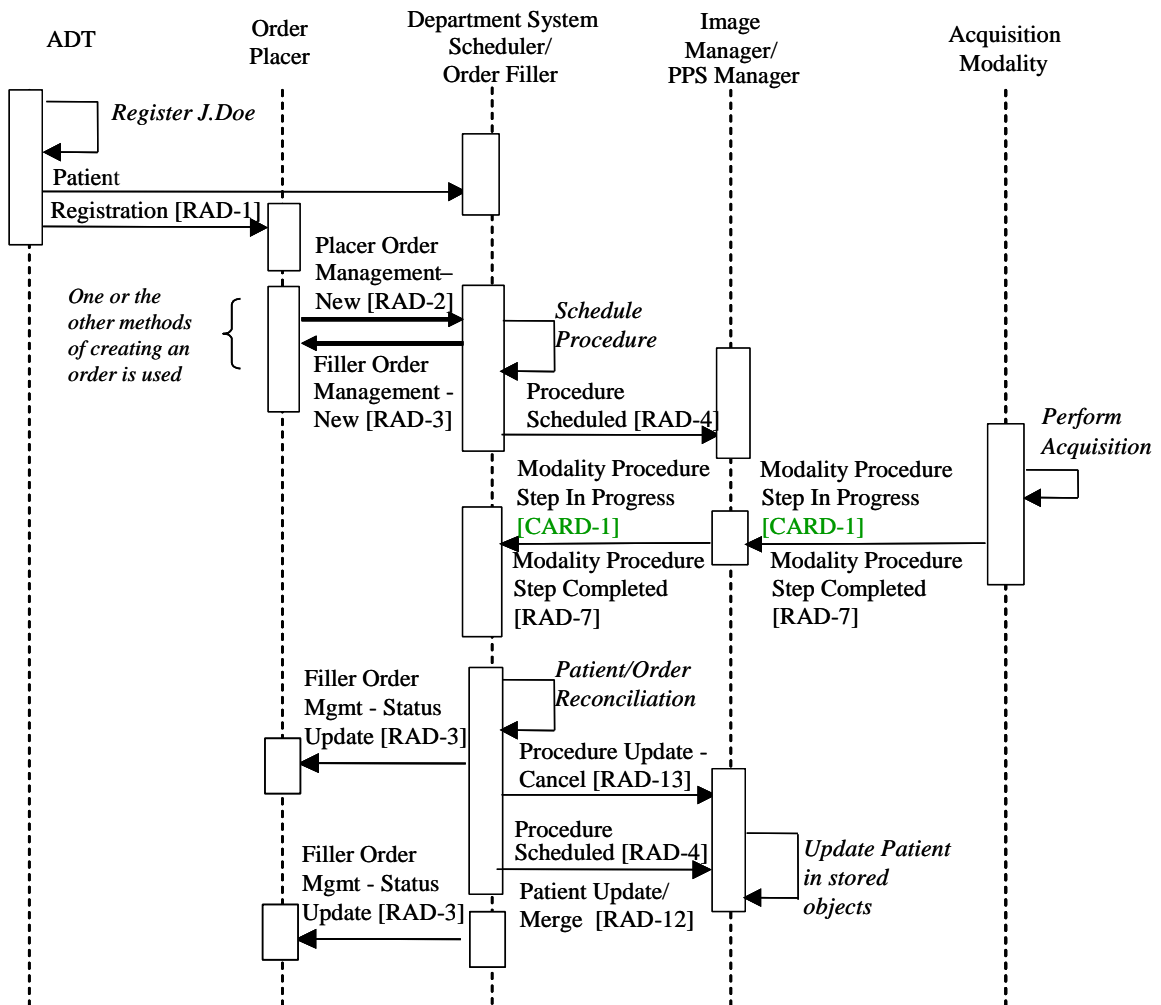

Figure 4.3-2. Intermittently Connected Modality with Ad Hoc Procedure, Patient Registered, Scheduled Procedure – Case E3

Significant Transactions:

- Procedure Update - Cancel [RAD-13] must be used to cancel the Procedure Scheduled sent to the Image Manager, and a new Procedure Scheduled [RAD-4] sent with the Study Instance UID used by the modality (see RAD-TF-2:4.13, table 4.13-2).

Only partial transactions are shown. Other transactions are performed according to the other profile use case requirements.

4.3.4 Case E4: Intermittently Connected Modality with Ad Hoc Procedure, Patient Registered, Unscheduled Procedure

Clinical Context: This use case describes the situation in which the Modality is mobile (not connected to the network), and during that mobile shift the sonographer has received notice to perform an emergent echo procedure for a patient that has been registered. This is not uncommon in the emergency department.

IHE Context: This case is identical to other unscheduled procedure cases, e.g., in the radiology Patient Information Reconciliation Profile.

As in Case E3, the Patient ID and other demographics must be manually entered at the modality. The modality must also create a Study Instance UID for that study. When the modality reconnects to the network, it sends an MPPS In Progress message [CARD-1] without the Requested Procedure or Scheduled Procedure information. This indicates to the DSS/OF that it is an unscheduled procedure. This will cause the DSS/OF to raise an exception for reconciliation.

The Patient reconciliation includes correcting the patient demographics for the Patient ID specified in the MPPS In Progress message. It is likely that this will be a semi-automated process, since the Patient ID matches a registered patient. The DSS/OF then creates a New Order for the performed procedure, and sends it to the Order Placer, as well as a Status Update indicating in-progress [RAD-3].

The DSS/OF will generate a Procedure Scheduled [RAD-4] containing the Study Instance UID from the MPPS In Progress message, and a Patient Update [RAD-12] with the full patient demographics. The Image Manager uses the information from the Patient Update transaction to update the demographics in the objects that it has, or will receive, from the acquisition modality.
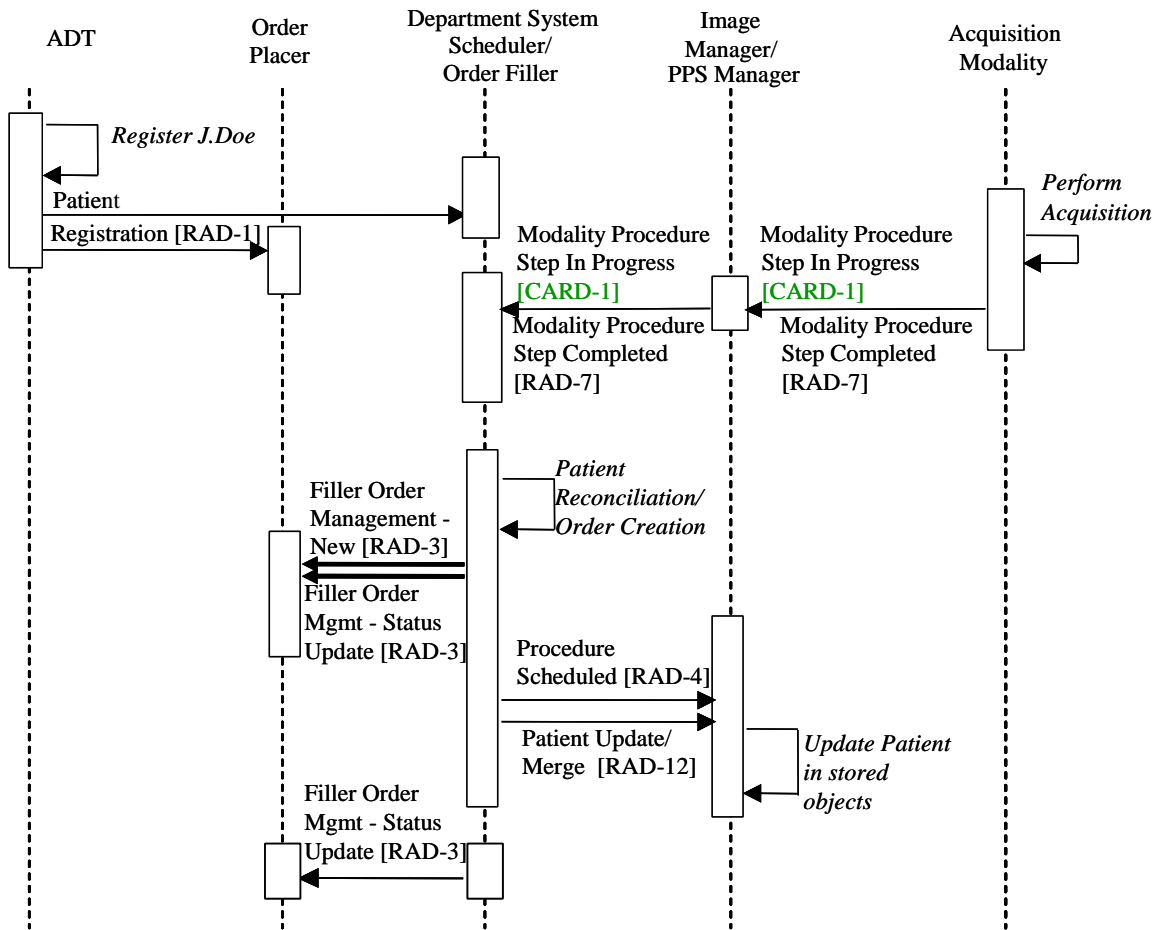
Figure 4.3-3. Intermittently Connected Modality with Ad Hoc Procedure, Patient Registered, Unscheduled Procedure – Case E4

4.3.5 Case E5: Intermittently Connected Modality with Ad Hoc Procedure, Patient Unregistered, Unscheduled Procedure

Clinical Context: This use case describes the situation in which the Modality is mobile (not connected to the network), and the procedure is unscheduled and the patient is unidentified. This scenario, though less common, is similar to case E4 with the exception that the patient is unregistered.

IHE Context: This case is identical to other unscheduled procedure cases, e.g., in the radiology Patient Information Reconciliation Profile.

A temporary ID and name are entered at the Modality (not from a patient wristband, since that would be a valid ADT system Patient ID, and is covered in case E4). The Patient ID and name are selected according to the locally defined rules; for example, selected from the predefined

pool of "Patient ID–patient name" pairs. The rules for selecting temporary Patient ID shall guarantee its uniqueness within the scope of Department System Scheduler/Order Filler.

The modality must also create a Study Instance UID for that study. When the modality reconnects to the network, it sends an MPPS In Progress message [CARD-1] without the Requested Procedure or Scheduled Procedure information. This indicates to the DSS/OF that it is an unscheduled procedure. This will cause the DSS/OF to raise an exception for reconciliation.

When the patient is registered, the DSS/OF reconciles the patient registration with the local identifiers, and sends a Patient Update to the Image Manager. The Image Manager uses the information from the Patient Update transaction to update the demographics in the objects that it has, or will receive, from the acquisition modality.

The DSS/OF then creates a new order for the performed procedure, and sends it to the Order Placer. The DSS/OF will then generate a Procedure Scheduled [RAD-4] containing the Study Instance UID from the MPPS In Progress message. The Image Manager uses the information from the Procedure Scheduled transaction to update the Order and Procedure information in the objects.
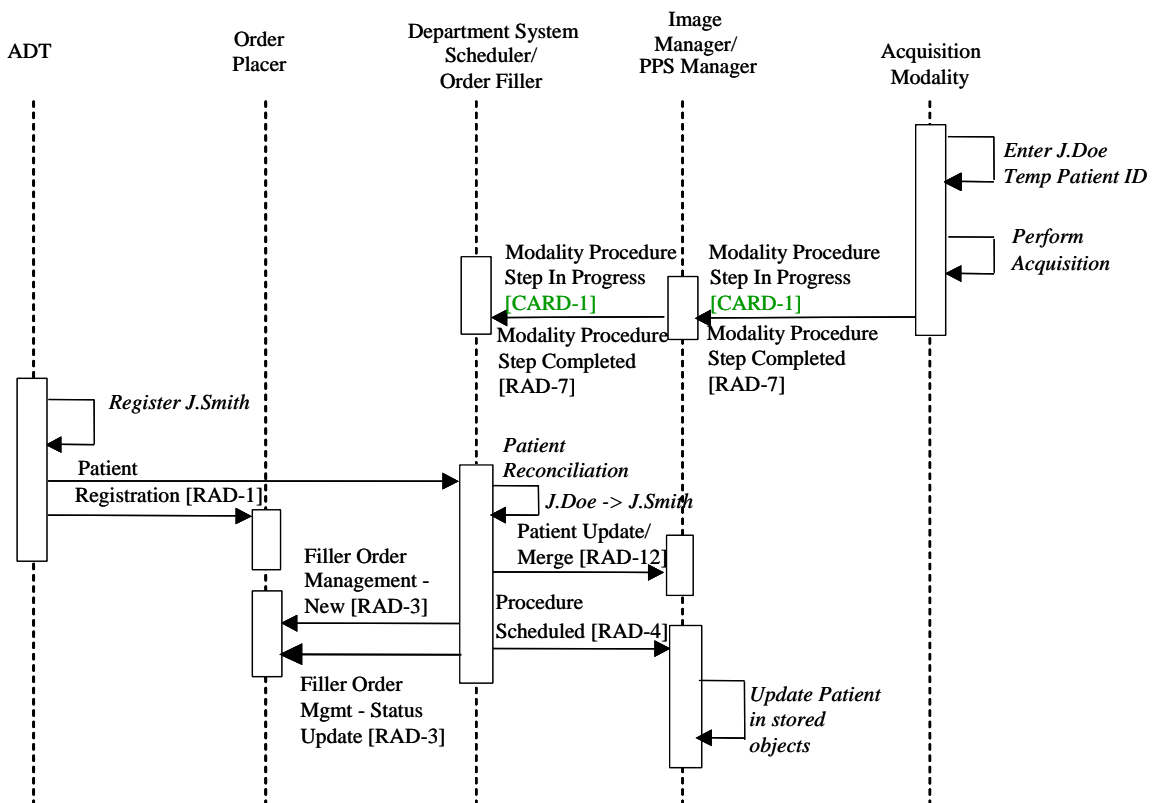

Figure 4.3-4. Intermittently Connected Modality with Ad Hoc Procedure, Patient Unregistered, Unscheduled Procedure – Case E5

4.3.6 Case E6: Stress Echo Staged Protocol

Clinical Context: A "Staged Protocol Exam" acquires images in two or more distinct time intervals called "Stages" with a consistent set of images called "Views" acquired during each Stage of the exam. A View is of a particular cross section of the anatomy acquired with a specific ultrasound transducer position and orientation. During the acquisition of a Staged Protocol Exam, the modality may also acquire non-Protocol images at one or more Protocol Stages.

A common real-world example of an ultrasound Staged Protocol exam is a cardiac stress-echo ultrasound exam. Images are acquired in distinct time intervals (Stages) of different levels of stress and Views. Typically, stress is induced by means of patient exercise or medication.

Typical Stages for such an exam are baseline, mid-stress, peak-stress, and recovery. During the baseline Stage the patient is at rest, prior to inducing stress through medication or exercise. At mid-stress Stage the heart is under a moderate level of stress. During peak-stress Stage the patient's heart experiences maximum stress appropriate for the patient's condition. Finally, during the recovery Stage, the heart recovers because the source of stress is absent.

A typical stress exam goes through progressive stages until a clinical end-point is reached, such as achieving a pre-determined heart rate or emergence of symptoms preventing the patient from continuing (arrhythmia, hypotension, angina, fatigue, etc.). A procedure may be complete, even though fewer than the full number of planned stages have been acquired.

At each Stage an equivalent set of Views is acquired. Examples of typical Views are parasternal long axis and parasternal short axis. Examination of wall motion between the corresponding Views of different Stages may reveal ischemia of one or more regions ("segments") of the myocardium. These views need to be displayed in a clinically relevant manner, grouping selected images by View and Stage.

IHE Context: This workflow is the same as in Cases E1 (for a network connected modality) or E2 (for an intermittently connected modality).

The type of stress protocol is specified to the Acquisition Modality through the Scheduled Protocol Code Sequence or the Scheduled Procedure Step Description of the Modality Worklist. The Scheduled Protocol Code Sequence may use the codes specified in CARD-TF 2: 4.2.3, Table 4.2-3.

Within the "perform acquisition" activity, there are several stages, but these are typically considered part of the same Procedure Step (see figure 4.3-5). The final MPPS shall indicate status Complete for all cases that reach a clinical end-point. A status of Discontinued may be used for a technical failure that prevents reaching a clinical end-point.
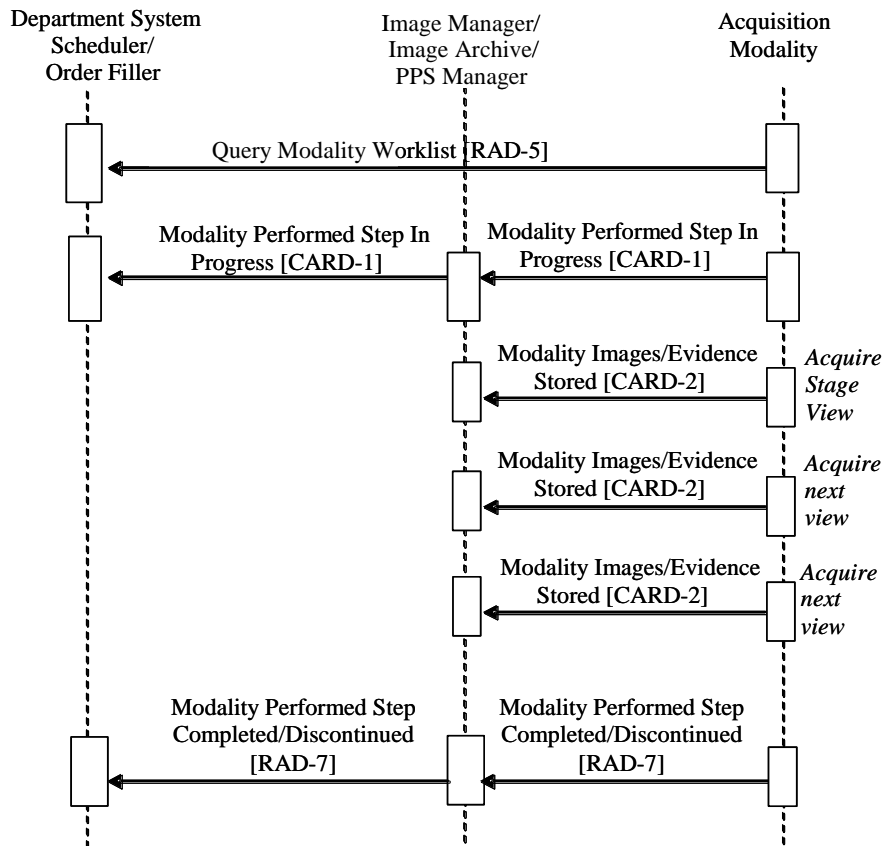
Figure 4.3-5. Stress Echo Staged Protocol – Case E6

4.3.7 Case E7: Echo measurement evidence creation

Clinical Context: During the echo procedure some measurements and analysis may be performed on the acquiring ultrasound system. These measurements (e.g., systolic and diastolic left ventricular diameters) and preliminary analysis (e.g., Regional Wall Motion Score) would be transferred with the images to the Image Manager. After the procedure is completed, the echocardiographer reviews the images along with the measurements and preliminary analysis offline (not on the ultrasound system, but on a separate workstation), and uses this information to create the final report. During this report creation, the echocardiographer may disagree with some measurement or may wish to create additional measurements for the final report. This revised set of measurements is saved with the study data.

IHE Context: This case describes the process flow for echocardiography measurement generation. Figure 4.3-6 shows the process mapped to IHE actors and transactions. This process flow is similar to the CATH Profile Case C9. The actors participate in both the Echo Profile and the Evidence Documents Profile.

The process begins with images and preliminary measurements (evidence documents) being acquired on the ultrasound system during the procedure. These images and measurements are sent to the Image Manager using the transaction Modality Images/Evidence Stored [CARD-2]. The measurements are stored as DICOM Structured Report objects.

After the procedure, the user at the reporting workstation (Image Display actor) queries and retrieves the images and preliminary measurements, which were stored from the acquisition modality, for verification and possible update. For the documents stored as DICOM SR objects, the Query Evidence transaction provides the Image Display actor with the ability to request the document titles, status, and other attributes.

The reporting workstation (as an Evidence Creator actor) notifies the Image Manager/Image Archive and the Department System Scheduler/Order Filler of its activity through the Modality Performed Procedure Step "In Progress" and "Complete" transactions. The Evidence Creator may create measurements, analysis, and derived images that are stored to the Image Manager/Image Archive, and commits them using the Storage Commitment transaction. If the reporting workstation creates revisions of the preliminary measurements, those are stored in a new (different) DICOM SR object; the preliminary measurements object is referenced from the new object.
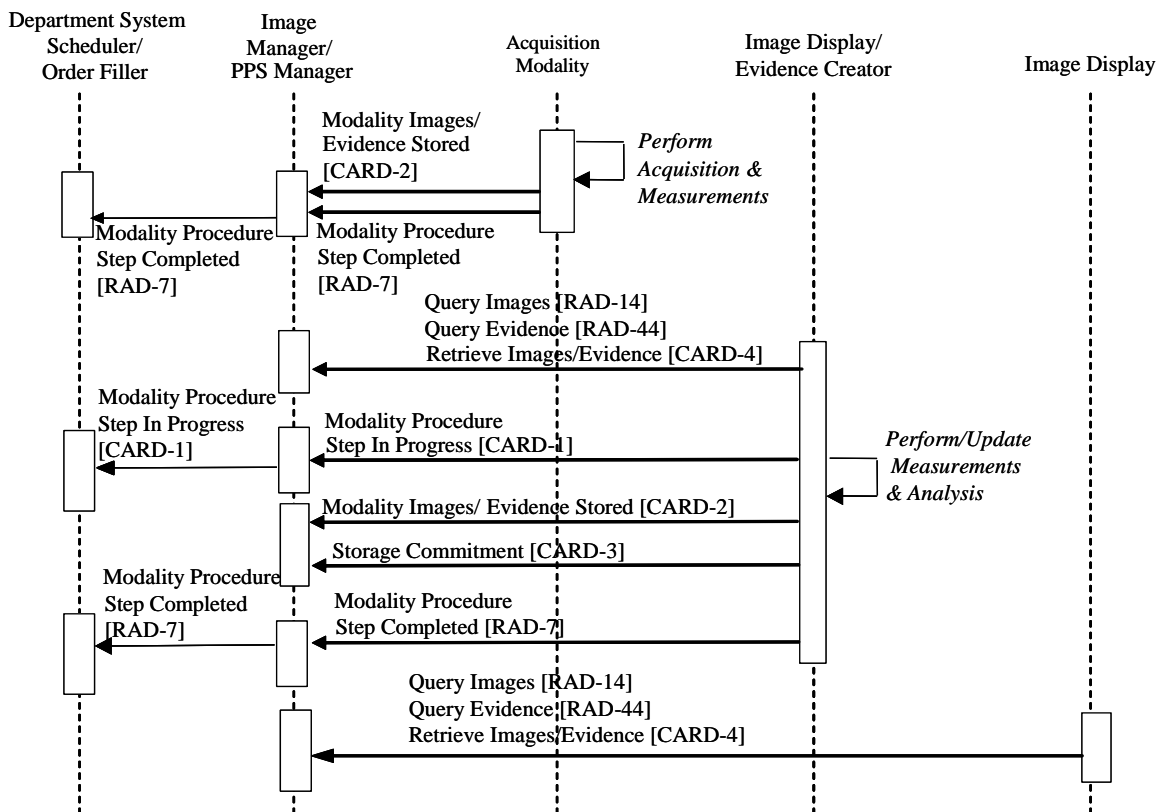
Figure 4.3-6 Echo Measurement Evidence Creation– Case E7

Notes: 1. While the Evidence Creator may not be a modality, it can still use the MPPS transactions indicating an appended procedure step for the modality of the images. The Evidence Creator may use the referenced Scheduled Procedure Step information in the analyzed images as the referenced SPS for the evidence documents created. This keeps the workflow consistent with the case of analysis performed on the original acquisition modality.

2. This profile does not specify the workflow transaction or trigger that causes the reporting station to perform its work.

3. A reporting station that includes the Evidence Creator may also include grouped actors of other Profiles, in particular the Report Creator actor of the SINR or DRPT Profiles.

4. Support for the Query Evidence transaction is part of the Evidence Documents Profile. If either actor does not support it, the Image Display will only be able to present to the user a list of SR Documents differentiated only by document instance number and date/time as provided in the Query Images transaction. In this event, the Image Display may achieve the same effect as the Query Evidence transaction by retrieving all the SR documents and extracting from them the relevant attributes for display in the query user interface.

5   Retrieve ECG for Display (ECG)

ECG documents, including waveforms, measurements, and interpretations, are often created and managed on ECG management systems to which cardiographs are connected. Broad access to the ECG documents throughout the enterprise as well as outside the enterprise is facilitated by this Integration Profile.

The primary use case involves a Cardiologist interpreting a 12 lead ECG on an ECG management system. The resulting report needs to be accessible not only within the Cardiology Department (e.g., in preparing a later Cath) and by clinicians such as those from the ICU, but also by referring physicians or other cardiologists following the patients. The intended use is essentially to review the report as well as the ECG waveforms at resolution comparable to that used for diagnosis. This Integration Profile allows the display of this information without requiring specialized cardiology software or workstations by using general purpose computer applications. Once displayed, the system where this ECG document is displayed may simply discard the information. It is not the role of the displaying system to manage or archive this information. If it is later needed, it can be requested again using the same "reference" and it will be displayed again in the same way as the first time. The primary goal is to offer a faithful representation of the waveforms at "diagnostic quality", including the measurements and interpretation.

This Integration Profile is intended primarily for retrieving resting 12-lead ECGs, but may also retrieve ECG waveforms gathered during stress, Holter, and other diagnostic tests. This Integration Profile only addresses ECGs that are already stored in an information system. It does not address the process of ordering, acquiring, storing, or interpreting the ECGs. It also is not intended for highly dynamic information such as that used for patient monitoring.

Discussion of the combined use of this Profile with the ITI-TF Enterprise User Authentication and Patient Identifier Cross-Reference Profiles can be found in ITI-TF-1: Appendix E.

5.1   Actors/Transactions

Figure 5.1-1 shows the actors directly involved in the ECG Integration Profile and the relevant transactions between them.
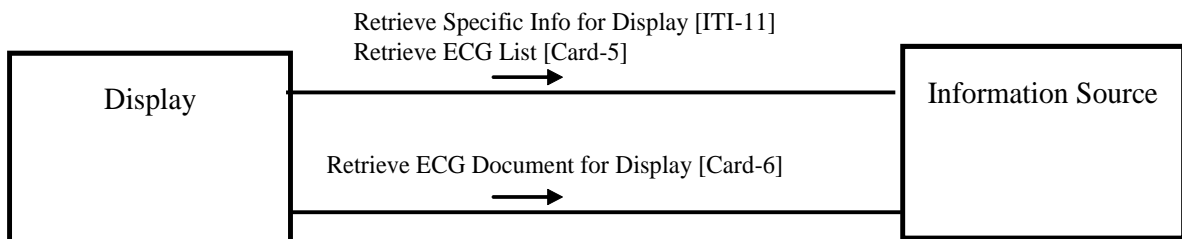

Figure 5.1-1. Retrieve ECG for Display Actor Diagram

Table 5.1-1 lists the transactions for each actor directly involved in the ECG Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" are optional.

Table 5.1-1 Retrieve ECG for Display Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Display	Retrieve Specific Info for Display [ITI-11]	O	ITI-TF 2: 4.11
	Retrieve ECG List [CARD-5]	O	CARD-TF 2: 4.5
	Retrieve ECG Document for Display [CARD-6]	R	CARD-TF 2: 4.6
Information Source	Retrieve Specific Info for Display [ITI-11]	R	ITI-TF 2: 4.11
	Retrieve ECG List [CARD-5]	R	CARD-TF 2: 4.5
	Retrieve ECG Document for Display [CARD-6]	R	CARD-TF 2: 4.6

5.2 ECG Integration Profile Options

Many Actors have Options defined in order to accommodate variations in use across domains or implementations. Options that may be selected for this Integration Profile are listed in the table 5.2-1 along with the Actors to which they apply. Certain of these Options are required for implementation by actors in this Profile (although they may be truly optional in other Profiles).

Table 5.2-1: ECG - Actors and Options

Actor	Option Name	Optionality	Vol & Section
Display	*No options*	-	-
Information Source	Summary of All Reports	R	ITI-TF 2: 3.11
	Summary of Cardiology Reports	R	ITI-TF 2: 3.11
	All other options of Retrieve Specific Info for Display [ITI-11]	O	ITI-TF 2: 3.11

5.3 ECG Integration Profile Process Flow

This section describes the process and information flow for display of ECG documents retrieved from an information source.

5.3.1 Case D1: Simple Display

This case provides for basic display of a list of ECG documents, and/or display of a specific ECG document. It includes two simple processes, which may or may not be linked together.

The first process provides a method for a display actor (and the person associated) to retrieve a list of ECG documents for a specific Patient ID from an Information Source Actor. The patient ID is assumed to be unambiguous as fully qualified with the assigning authority. A number of additional filtering keys may be used (last N documents, date range, etc.). The Information Source Actor responds with a list of ECG documents for display. The Display Actor simply displays the information to the person that triggered the request. The Information Source Actor shall respond with an error message when it does not support the specific type of request or does not hold any records for the requested patient ID. See Figure 5.3-1.
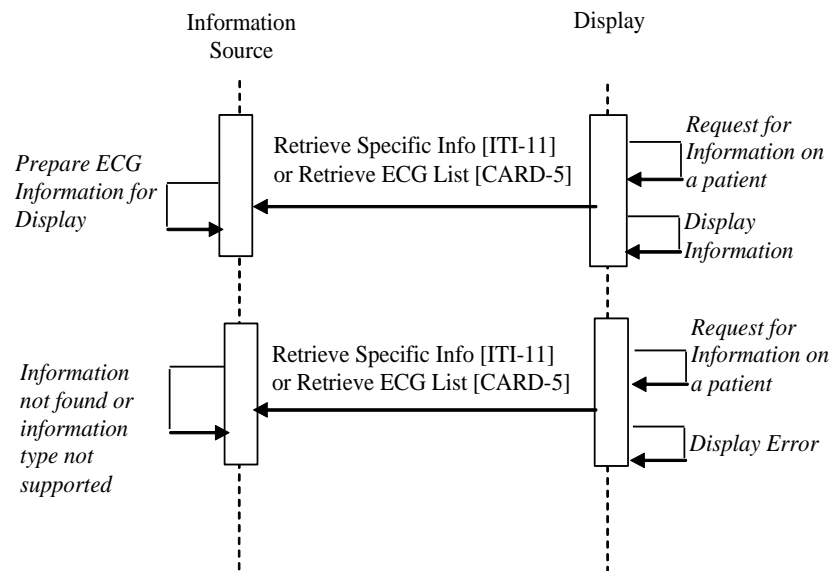
Figure 5.3-1 Retrieve ECG List Process Flow

The Display Actor may request the ECG List using the Retrieve Specific Info [ITI-11] transaction with request type SUMMARY or SUMMARY-CARDIOLOGY, or using the Retrieve ECG List [CARD-5] transaction with request type SUMMARY-CARDIOLOGY-ECG. The ITI-11 transaction returns the response as HTML, and the CARD-5 returns the response as XML with a stylesheet; the Display Actor may thus select its desired response format by specifying the request type.

The second process provides a method for the Display Actor (and the person associated) to request a uniquely identified ECG document. The Information Source Actor responds to the request by using one of the formats proposed by the Display Actor to provide the presentation-ready content of the ECG document it manages. The detailed presentation and the clinical integrity of the content of the document are under the control of the Information Source Actor. The Display Actor simply displays the presentation-ready document content to the person that triggered the request. The Information Source Actor shall respond with an error message when the requested document is unknown or when none of the formats acceptable to the Display Actor is suitable to present the requested document. See Figure 5.3-2.
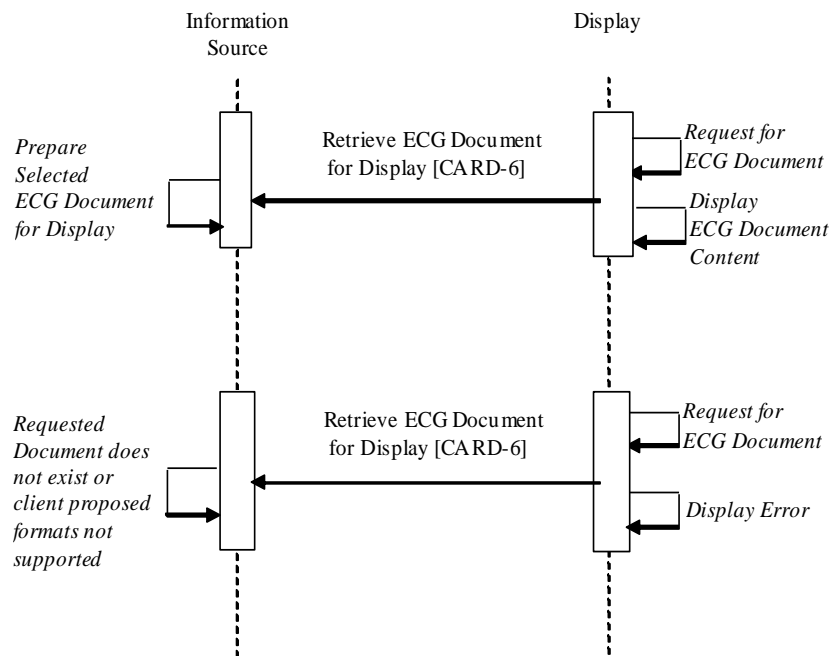
Figure 5.3-2 Retrieve ECG Document Process Flow

The main difference between the Retrieve *ECG List* and the Retrieve *ECG Document* transactions is that the latter applies to a uniquely identifiable persistent object (i.e., retrieving the same document instance at a different point in time will provide the same semantics for its presented content). For the Retrieve ECG List transaction, this information is always related to a well-identified patient (Patient ID), but its content, although of a specific type (ECGs) is generally dynamic (i.e., retrieving the same list at a different point in time is likely to result in different content; for example, a new ECG may have been recorded for the patient between two requests).

The Retrieve ECG Document process is not necessarily linked to the Retrieve ECG List process; a Display Actor may receive a document identifier by some other means (e.g., as a reference in another clinical document).

5.3.2 Case D2: Advanced Display

This case provides for retrieval of a list of ECG documents, coupled with display of one or more specific ECG documents, potentially in a synchronized manner. The list is structured in a manner that may facilitate display applications for serial comparison of ECGs, a common clinical requirement. In this case the Retrieve ECG Document process is closely linked to the Retrieve ECG List process.

This case includes the same processes as case D1. However, in this case the Retrieve ECG List process is limited to the Retrieve ECG List [CARD-5] transaction, with a structured XML

response returned from the Information Source Actor.   The Display Actor is able to parse this structured list, and select specific entries for retrieval using the Retrieve ECG Document [CARD-6] transaction. By having a computer-processable XML list, multiple documents can be retrieved for display in a single synchronized display application.

6 Displayable Reports (DRPT)

This section reserved.

7 Evidence Documents (ED)

The Evidence Documents Profile defines ways for data recorded in the course of carrying out a procedure step, such as observations, measurements, and results (i.e., evidence documents), to be output by devices, such as acquisition systems and other workstations; to be stored and managed by archival systems; and to be retrieved and presented or used by display and reporting systems.

This allows detailed non-image information, such as measurements, CAD results, procedure logs, etc. to be made available as input to the process of generating a clinical Report, either as additional evidence for the reporting physician, or in some cases for selected items in the Evidence Document to be included in the report.

The full specification of the Evidence Documents Profile is found in **RAD-TF 1:14.** This section adds the cardiology-specific options for that definition.

7.1 Actors/Transactions

Figure 7.1-1 shows the actors directly involved in the Evidence Documents Profile and the relevant transactions between them.
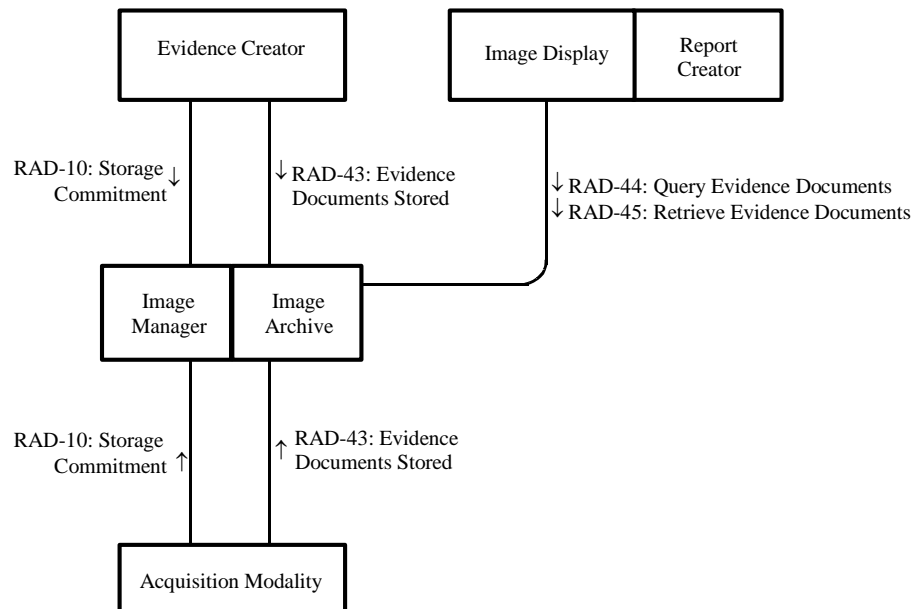
Figure 7.1-1. Evidence Documents Actor Diagram

Note: The Evidence Documents Stored [RAD-43] and Retrieve Evidence Documents [RAD-45] Transactions are equivalent to the Images/Evidence Stored [CARD-2] and Retrieve Images/Evidence [CARD-4] Transactions defined in the Cardiology Technical Framework Volume 2 for the purpose of specifying options. Future editions of the Cardiology Technical

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Framework will harmonize the identification of these Transactions with the Radiology Technical Framework.

7.2 Evidence Documents Profile – Cardiology Options

The Options defined for the Cardiology domain that may be selected for this Integration Profile are listed in the table 7.2-1 along with the Actors to which they apply.

Table 7.2-1 Evidence Documents - Actors and Options

Actor	Options	Vol & Section
Evidence Creator	Cath Evidence	CARD-TF 2: 4.2.4
	Echo Evidence	CARD-TF 2: 4.2.5
Acquisition Modality	Cath Evidence	CARD-TF 2: 4.2.4
	Echo Evidence	CARD-TF 2: 4.2.5
Image Manager/ Image Archive	*No options defined*	-
Image Display	Cath Evidence	CARD-TF 2: 4.4.2
(Report Creator)	Echo Evidence	CARD-TF 2: 4.4.3

7.3 Evidence Documents Process Flow

The use of Evidence Documents in process flows for cardiology is described in Cath Profile Use Case C9, and in Echo Profile Use Case E7.

Appendix A: The Cardiac Catheterization Procedure in Perspective

It is important to understand the scope of the part of the Cardiac Catheterization Procedure ("cath") that is being addressed in the Cardiology Technical Framework, and to put that into perspective with regards to a broader picture. The cath procedure itself occurs inside of a clinical context wherein a patient has a clinical presentation, diagnostic and/or interventional procedures are performed, and events of interest are monitored after the procedure itself has concluded.

Clinicians may use the terms such as "case," "encounter," or "admission" to refer to this broader scope. To help avoid confusion with other standards documents and nomenclature, this Appendix introduces the term "Episode of Care".
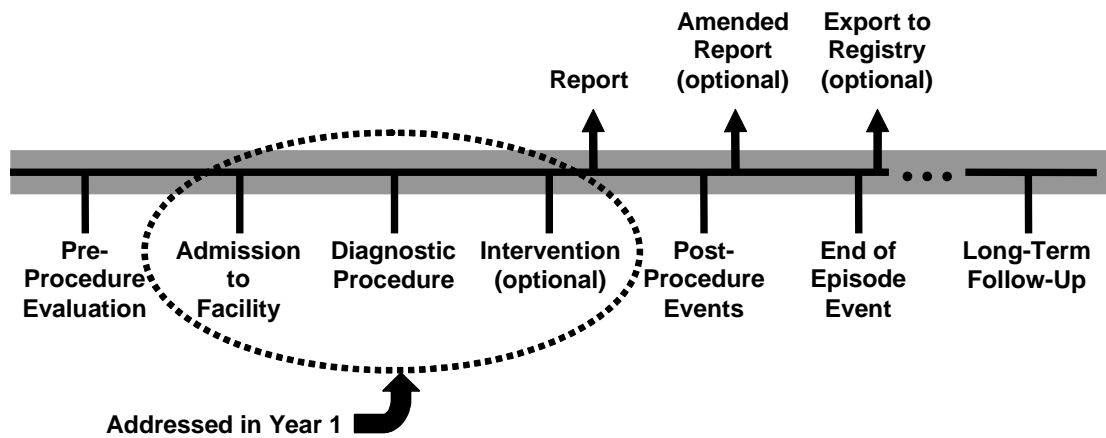

The clinical activities associated with Cardiac Catheterization are shown schematically above. The evidence gathering activities may actually start hours, days or weeks ahead of time as the patient is evaluated before the procedure. The cath procedure itself refers to the events that occur in the cath lab suite itself (this might include a patient prep area, the x-ray room or rooms that are used for the procedures, and a holding area where the patient is monitored before leaving the cath lab suite). Evidence will continue to be gathered after the actual procedure has finished, which would typically include the recording of complications (if any), and subsequent patient outcome.

At some point in time, there is an event (that may be site-specific) that indicates that the cardiac cath Episode of Care has concluded. In its simplest form, this might be represented by the patient's discharge from the facility. Any evidence that is gathered relating to events after that point in time is no longer added directly to the Set of Results associated with the Episode of Care.

In Year 1 of the IHE for Cardiology Technical Framework, we have defined activities that occur between the patient's admission to the cath lab facility and departure from the cath lab suite. In subsequent years, the Technical Framework is expected to be extended to include the entire

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Episode of Care. This will be particularly important as support for national data registries is added, and as models are included for the reporting activities related to the Set of Results.

Appendix B: Challenges of Workflow Management in Cardiac Catheterization

B.1 Clinical Context: Diagnostic and Interventional Procedures

In Radiology, clinicians order very specific studies after evaluation of the patient's history, physical findings, and the results of other studies. However, requests for a Cardiac Catheterization are handled clinically in a very different fashion. The referring clinician typically requests a Cardiology Consultation (or perhaps a more specific Cardiac Catheterization Consultation). The exact procedure(s) to be performed are generally selected in the catheterization laboratory itself, as the initial information is gathered. Clinical activities are selected as deemed appropriate by the performing physician. Moreover, unlike Radiology, the selected activities ("protocols") are more clinically oriented, as opposed to being modality oriented. Thus the x-ray modality typically makes no distinction between imaging for Coronary Angiography and for Left Ventriculography, since the x-ray techniques are identical.

For logistical and administrative purposes, procedures in the cardiac catheterization laboratory are divided somewhat arbitrarily into "Diagnostic" and "Interventional", despite the fact that the demarcation line between the two categories may be indistinct. It is rare, however, that an ordering physician would make the distinction ahead of time and specifically order one or the other, except in the case of an order for interventional follow-up to a diagnostic exam (e.g., due to resource limitations at the time of the diagnostic exam).

B.2 Organizing the Workflow: Requested Procedures and Procedure Steps

In the past (pre-IHE), a common (but not universal) practice in the cath lab has been to create a new DICOM Study for the x-ray angiography (XA) data when the activities move from Diagnostic to Interventional. This is indicative of an administrative desire to identify a distinction between those two phases in a cath procedure. This is a less than ideal method, but in that environment the only available "hammer" for that "nail" was the DICOM XA Study.

However, IHE provides several tools for managing the workflow and organizing the data, principally the Requested Procedures, Scheduled Procedure Steps (SPS), and Performed Procedure Steps (PPS). Moreover, IHE address the full multi-modality context of the cath lab, not just XA. This section describes the required use of these IHE constructs.

The IHE Technical Framework data model offers three major levels of control for workflow:

- **Order**: A request for a Departmental Service
- **Requested Procedure**: Unit of work resulting in one or more reports, with associated codified, billable acts.

- **Scheduled and Performed Procedure Step**: the smallest unit of work in the workflow that is scheduled (work to do) or performed (work done).

B.2.1 Orders

The Order is what the referring clinician requests from the cardiology department. As described above, it generally represents a request for the "Cardiac Catheterization Consultation".

B.2.2 Requested Procedures

The Requested Procedure represents the unit of work that the department uses for clinical and/or administrative purposes. This is the unit for which one or more reports will be written, and whose completion will be reported externally, e.g., for billing purposes. Generally, there will be one Requested Procedure for each Order, but the IHE data model allows a department to create two or more Requested Procedures for an Order.

As discussed below (see B.7 The Approach Adopted by IHE Cardiology), IHE Cardiology strongly advises the use of a single Requested Procedure for a cardiac catheterization procedure, although some institutions may desire to separate diagnostic and interventional phases to two separate Requested Procedures. The Technical Framework does not require a Department System Scheduler/Order Filler to be able to create multiple Requested Procedures from a single Order; that is application capability beyond IHE's scope of interoperability. Institutions that desire such capability must request it in addition to any IHE integration capability.

B.2.3 Scheduled and Performed Procedure Steps

The SPS and PPS are the smallest units of the workflow that are scheduled or performed, whose status is tracked, and that are associated with protocols, i.e., specific actions, techniques, equipment usage, etc. associated with a step of a procedure. Scheduled and Performed Procedure Steps are modality-specific. Thus for a multi-modality Requested Procedure, there would be separate Procedure Steps for each modality, and therefore there is a 1:n cardinality relationship between a Requested Procedure and its Scheduled Procedure Steps.

The Scheduled Procedure Step is always what has been scheduled; what actually gets performed is in the IHE data model a totally separate entity, the Performed Procedure Step. The SPS does not "become" a PPS; the SPS may continue to exist even after the clinical procedure is complete, and may persist until the report for the Requested Procedure has been finalized. The PPS similarly has an independent existence, and in fact is conceptually "permanent", representing the historical actuality of the procedure.

Because what is actually performed may differ from what was scheduled, the SPS and PPS have an n:m (many-to-many) cardinality relationship. The IHE data model even allows a PPS to be related to multiple SPSs in *different* Requested Procedures, although the Cath Profile does not allow that case (see B.6 Grouped Procedures). An entity relationship diagram showing the cardinality relationships of the IHE data model is given in RAD-TF 1: 3.4.3.

B.2.4 Clinical Protocols and Procedure Step Protocols

As described in B.1 above, there are protocols that represent the clinical activities of the cath procedure. Table B.2-1 provides a sample list of Protocols for Diagnostic and Interventional procedure steps.

Table B.2-1. Cath Clinical Protocols

Diagnostic
Left Heart Catheterization
Right Heart Catheterization
Coronary Angiography
Pulmonary Arteriography
Aortography
Renal Arteriography
Femoral Arteriography
Carotid Arteriography
Left Ventriculography
Right Ventriculography
Fluoroscopic evaluation of valve function
Intracardiac echocardiography
Intravascular ultrasound imaging
Interventional
Intracoronary thrombolysis
Balloon angioplasty
Stent deployment
Rotational atherectomy
Brachytherapy
ASD/VSD Closure
Valvuloplasty

Scheduled and Performed Procedure Steps are modality-specific, and their associated protocols would similarly be modality-specific, rather than clinical procedure-related. Nevertheless, it is possible for appropriate modalities to report protocols of Performed Procedure Steps that distinguish between Diagnostic and Interventional procedure phases. The IHE Technical Framework provides flexibility for the configuration of modality protocols to meet the desired workstep status tracking for a user institution.

A real world example of the use of Procedure Step protocols can be demonstrated by a Requested Procedure for a cardiac catheterization. For that Requested Procedure there will be at least one procedure step scheduled for each modality, but there may be multiple procedure steps representing separate Diagnostic and Interventional clinical phases for each modality. This

could result in the set of Scheduled Procedure Steps for the single Requested Procedure shown in Table B.2-2.

Table B.2-2. Scheduled Procedure Step Example

SPS Number	Modality	SPS Protocol
1	HD	Diagnostic Heart Catheterization Hemodynamics
2	XA	Diagnostic Heart Catheterization Angiography
3	HD	Interventional Heart Catheterization Hemodynamics
4	XA	Interventional Heart Catheterization Angiography
5	IVUS	Interventional Heart Catheterization Intravascular Ultrasound

Note that when the procedure is performed there are several possible combinations of Performed Procedure Steps related to the Scheduled Procedure Steps. There may be one PPS for every SPS. There may be no (zero) PPSs for some of the SPSs (e.g., the interventional phase was deemed not necessary, or an IVUS was never performed). There may be one PPS for all the SPSs assigned to a modality (e.g., the hemodynamics system does not support separation of an exam into multiple PPSs). Conversely, an Acquisition Modality could perform several PPSs for a single SPS (e.g., the XA system performs quantitative analysis on the images and reports that as a separate PPS from the image acquisition).

 It should be noted that all of the combinations of SPS:PPS must be handled by a Department System Scheduler/Order Filler.

B.3 Multi-Modality and *Ad Hoc* Scheduling

The cardiac cath lab is inherently multi-modality (hemodynamics, x-ray, IVUS, etc.), and therefore more prone to data entry errors and patient safety issues.   It is critical that the exact same patient is selected on all pieces of equipment. A goal of IHE is to have a single selection of a patient on a single piece of equipment, and then ensuring that patient's information is available at all of the other pieces of equipment within the cath lab, thereby eliminating data entry errors.

This goal is further complicated by the frequent *ad hoc* assignment of rooms to specific patient procedures to accommodate the large proportion of emergent cases. The specific lab to be used is often not determined until the patient is wheeled into one.

The Department System Scheduler/ Order Filler (DSS/OF) is responsible for procedure scheduling. In the multi-modality cath lab, this means creating a Scheduled Procedure Step for each modality that may participate in the procedure. When a particular room and time can be assigned for a procedure, there is no problem with using the simple Modality Worklist information model definition of an SPS that presumes a specific assigned resource; however, this is seldom possible in the real world. And even when such scheduling can be done, it may be overridden by an emergency case.

To accommodate *ad hoc* scheduling, the DSS/OF may therefore typically schedule a procedure with an SPS for a "generic resource" that could be selected by the modality in any particular room.

To facilitate the single selection of a patient within the environment of generic resource scheduling, the Technical Framework has specified a *Multi-Modality Procedure Update* function of the DSS/OF. The DSS/OF shall be able to designate one or more modalities in each lab (typically the hemodynamics system) as a "selector"; that modality is expected to select the patient in the lab by choosing a Modality Worklist SPS, and starting a PPS. When that modality sends its first Modality Procedure Step In Progress for a particular Requested Procedure, the DSS/OF schedules SPSs for that Requested Procedure (and patient) for all modalities in that lab. The other modalities in that lab can then obtain coordinated patient and Requested Procedure identifiers using the Query Modality Worklist transaction.

> Note: There may be a time delay between the Modality Procedure Step In Progress from the first modality and the availability of SPSs for the other modalities in the Modality Worklist. It is expected that this delay would measured in seconds or minutes, not hours. In the cath lab, there is typically a delay between the first modality's MPPS and that of the other modalities, usually sufficient to accommodate the delay in the DSS/OF. However, for clinical reasons, the other modalities may need to start their data acquisition without waiting for the Study Instance UID provided in the Modality Worklist, and will therefore use a different Study Instance UID. It is highly desirable to avoid the proliferation of Study Instance UIDs in a single procedure. This version of the IHE Cardiology Technical Framework does not deal with reconciliation of multiple Study Instance UIDs.

B.3.1 Unscheduled Case

The need for consistent patient and Requested Procedure identifiers is just as important, if not more so, in the Unscheduled Case, where there is no available Requested Procedure to be shared across the multiple modalities (see cath use cases C3 and C5).

The Technical Framework requires that the *Multi-Modality Procedure Update* function of the DSS/OF also includes an automatic creation of a Requested Procedure if the MPPS from the selector modality is unscheduled. Creation of this Requested Procedure is a necessary prerequisite for the creation of the SPSs for all modalities in the lab.

As noted above, the Requested Procedure generally represents the unspecialized "Cardiac Catheterization Consultation". It is possible, therefore, to have a default Procedure type (code and/or description) that may be used to auto-create the Requested Procedure. The DSS/OF may also be able to select an appropriate Procedure type from a set, based on attributes such as protocol in the received MPPS.

This approach differs somewhat from the approach in the Radiology Technical Framework. RAD-TF 2: 4.6.4.1.3 states:

> If the Requested Procedure ID is transmitted empty (Unscheduled Performed Procedure Step case), the Department System Scheduler/Order Filler and the Image Manager shall

> **create an exception** that must be **manually** resolved to link the Performed Procedure Step to the appropriate procedure.

The Radiology Technical Framework intent is to force eventual reconciliation to associate the PPS with an appropriate Requested Procedure.

The fact that the Cardiology Technical Framework uses this condition as a trigger for the DSS/OF to **automatically** create a Requested Procedure (and the multi-modality Scheduled Procedure Steps) contradicts the **letter** of the radiology framework (i.e., manual reconciliation), but **not the intent** (i.e., reconciliation of the unscheduled PPS with a Requested Procedure).

It is the opinion of the Cardiology Technical Committee that the difference in approach between Radiology and Cardiology Technical Frameworks does not represent a significant deviation in required or intended usage of the MPPS In Progress transaction, and that the *Multi-Modality Procedure Update* option sufficiently characterizes the necessary functionality.

B.4   Modality Procedure Step Complete/Discontinue

This Technical Framework requires each modality in the multi-modality cath lab to individually select an SPS from the Modality Worklist to start its PPS/acquisition. Likewise, each modality must complete or discontinue any PPSs it has started.

The same functionality that facilitates single patient selection for all modalities, also facilitates *incorrect* single patient selection. If the patient selection is incorrect on the initial piece of equipment, the patient will be incorrect on all the modalities in the cath lab that have used SPSs based on that initial selection.   It is then crucial to "discontinue" that patient on all cath modalities, thereby reducing misidentification errors.

> Note: This version of the IHE Cardiology Technical Framework does not define a mechanism for completion or discontinuation of all in-progress MPPSs in the multi-modality lab with a single user action; MPPSs must be completed individually at *each* modality.

B.5 Start and End Procedures

The Cardiac Cath Workflow Profile focuses on the workflow within the lab itself. However, given the interventional nature of cath, this Profile cannot ignore the immediate pre- and post-catheterization activities that occur within the cath lab *suite*. The cardiac cath lab environment poses challenges due to its multi-modality nature discussed above, but also to its multi-*location* nature – a single cath procedure may transition across as many as four different rooms, each with its own equipment (a procedure preparation area, a diagnostic lab, an interventional lab, and a recovery holding area).

Pre-cath activities can include gathering critical lab information in advance, verifying the existence of all blood analysis and other results necessary prior to beginning a cath procedure, lab set up, notification of patient arrival, discussions with and signatures from patient, collection of patient vital signs, etc.   Post-procedure activities include monitoring the patient for adverse events, completing the exams on all equipment, cleaning the room, canceling procedure steps

which were not actually completed, etc. The Cath Workflow Profile cannot account for all of these activities, but does recognize that they exist.

For that reason there may be an optional "Start Procedure" function on the DSS/OF for the Cath Workflow. Specifically, the Start Procedure function can provide the advantages of:

- Registering patient arrival to set the status (0040,0020) in the associated SPSs
- Using patient arrival status to reduce the worklist for broad queries provided to the labs (when an individual room/suite assignment has not been made)
- Ensuring that all pre-procedure information which is gathered will be accurately combined with the procedure information from the lab
- Specify the lab/suite where the procedure will take place, which in turn, may simplify the selection the same patient on all equipment within a suite (a potential patient safety feature)

The corresponding optional "End Procedure" function on the DSS/OF can provide the advantages of :

- Verify the exam was manually completed on each piece of equipment.
- Cancel all SPSs for the Requested Procedure which, in turn, may help signify that the room is no longer occupied (and even possibly indicate ready for cleaning or other post-procedure activities)
- Trigger sending an Order Status Update message to the Order Placer

For these reasons, the DSS/OF internal Start Procedure and End Procedure functions are included in the Cath Workflow Use Cases, and it is highly recommended that such functionality be supported in DSS/OF implementations..

B.6 Grouped Procedures

B.6.1 What are Grouped Procedures?

Grouped procedures are described in the IHE Radiology Technical Framework (RAD-TF-1:4.6). The Grouped Procedure case provides a mechanism for facilitating workflow when an operator combines the acquisition steps of two or more separate Requested Procedures, often for the sake of acquisition efficiency and patient comfort. Viewing images and reporting, however, must still be done on the individual Requested Procedures. Through the Grouped Procedure, a single acquired image set (Study) is produced, but the workflow transactions allow separate viewing and interpretation of the image subsets related to each of the Requested Procedures.

Grouped procedures in IHE Radiology are confined to a single modality, e.g., CT head and spine. Each Modality Performed Procedure Step (MPPS) is related to multiple Scheduled Procedure Steps (SPSs) and Requested Procedures.

One of the issues with Grouped Procedures is the identification of the Requested Procedures in relation to the "performed Study". DICOM identifies Requested Procedures by Study Instance

UID, and typically the images produced are stored under that same Study UID. In the Grouped case, this is not possible, since there are multiple Requested Procedures.

In the classic, single-modality Grouped case, study UIDs are relatively straightforward. Each Requested Procedure (RP) identifies its own Order Filler-specified Study Instance UID. The modality selects the multiple Scheduled Procedure Steps (SPSs) associated with the various RPs. As there are *multiple* RP study UIDs referenced, the modality creates its own "I-Study" Study Instance UID to store the images/evidence associated with the Grouped procedures acquisition (MPPS). Now all the images/evidence associated with the acquisition are contained under the single "I-Study" UID, but this contains references to the multiple RP Study UIDs. (See RAD-TF-2, Appendix A for further description of the Data Model used in Grouped cases.)

B.6.2 Why Grouped Case is a Problem with Multimodality Studies

Cardiac catheterization is also a natural candidate for grouped procedures; there are typically multiple procedures which should be billed and reported separately (i.e., the diagnostic and interventional phases of the catheterization), but which share equipment, and for patient safety and efficiency the procedures are performed together.

However, cardiac catheterization is a multi-modality process by nature, and this brings complications to the classic grouped procedure approach outlined previously.

In the classic case, each modality creates its own I-Study UID to store the images/evidence it creates in a Grouped case. But I-Study UIDs are (by definition) unique per modality, thus in a multi-modality procedure the images/evidence relating to the procedure would be scattered across multiple I-Study UIDs, one per modality. This negates the workflow benefits associated with all data related to the procedure sharing a common I-Study UID.

B.7 The Approach Adopted by IHE Cardiology

IHE Cardiology *strongly advises* the use of a ***single Requested Procedure for cardiac catheterization***, even though there may be two reports (diagnostic and interventional) and separate billing resulting from the procedure. A single Procedure Code for "Cardiac Catheterization" is used by the Order Placer (not specifying Diagnostic or Interventional). This allows all data for the procedure to be collected under the single Study Instance UID of the Requested Procedure.

There are several supporting arguments for this choice.

First, even in IHE Radiology (in the most recent version), there is not a strict 1:1 correspondence between Requested Procedure and reporting/billing. The classic counter-example is mammography, where the exam will be read independently by two radiologists, who produce two independent reports, but it is still a single Requested Procedure. The production of multiple reports is an internal process of the Reporting Workflow. The cath case can be treated similarly - it is a single Requested Procedure, but the reporting process will produce two documents. (IHE Cardiology will address reporting and charge posting in subsequent years).

Second, cardiac cath is clinically a single procedure - the patient gets on the table once; the procedure log conveys a continuous record of the patient from before entering the cath lab until after leaving it; and the interventional data cannot be interpreted without the diagnostic data. The clinical use of the cath exam data after the procedure similarly needs to be viewed as a whole to provide context for any single item of data. As a result it makes little sense to separate the exam into two Requested Procedures, which then need to be grouped for effective clinical practice.

Third, a single Requested Procedure simplifies the operations for a diagnostic cath that changes to an interventional - with or without a change of rooms. There is no need to worry about modalities (e.g., IVUS) that join the procedure only in the interventional phase having different study information than those that joined at the start of the diagnostic phase.

Fourth, the ACC NCDR requires as single record for each "cath lab visit" when submitting data. If an implementation is not using a single Requested Procedure for both the Diagnostic and Interventional phases of the exam, combining the data (post procedure) for submission to the NCDR becomes much more difficult.

Even with a single Requested Procedure, it is possible (but optional) for separate MPPSs to be created for data collected by a modality in the diagnostic and interventional phases. These MPPSs can be derived from a single diagnostic/interventional Scheduled Procedure Step for the modality, or from separate diagnostic and interventional SPSs. Conversely, with a single Requested Procedure, if the Order Filler schedules separate diagnostic and interventional SPSs, a modality can fulfill both with a single MPPS (this is not a Grouped Procedure case, since the SPSs are from the same Requested Procedure).

However, an institution can still implement two Requested Procedures, but this would require all the modalities to close out the data acquisition for the diagnostic phase, and start a new interventional study. The Grouped Procedure case thus needs to be forbidden for the multi-modality cath lab use case.

An issue to be resolved in future editions of the Technical Framework is how (and whether) to support institutions that wish to have a separate Interventional Cath Order backfilled to the Order Placer when an intervention is done. This may be related to inadequacies of current charge posting systems, and may be remediated by use of the IHE RAD-TF Charge Posting Profile.

Appendix C: IHE Integration Statements

IHE Integration Statements are documents prepared and published by vendors to describe the intended conformance of their products with the IHE Technical Framework. They identify the specific IHE capabilities a given product is designed to support in terms of the key concepts of IHE: Actors and Integration Profiles (described in Volume 1, section 2 of the Technical Framework).

Users familiar with these concepts can use Integration Statements as an aid 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, DICOM, W3C, etc.).

IHE provides a process for vendors to test their implementation 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, however, 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.

C.1 Structure and Content of an IHE Integration Statement

An IHE Integration Statement for a product shall include:

1. The Vendor Name

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

3. The Product Version to which the IHE Integration Statement applies.

4. A publication date.

5. The following statement:

"This product is intended to implement 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 1. (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 presumes implementation of all required transactions for an actor; options include optional transactions or optional functions for required transactions.

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

1. The specific internet address (or universal resource locator [URL]) where the vendor's Integration Statements are posted

2. The specific 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. The URL of the IHE Initiative's web page for general information on IHE (www.rsna.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.

C.2 Format of an IHE Integration Statement

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

IHE Integration Statement			Date	12 Oct 2002
Vendor		**Product Name**	**Version**	
Any Medical Systems Co.		IntegrateRAD	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**	
Scheduled Workflow	Image Manager/Image Archive		none	
	Image Display		none	
	Image Creator		Performed Procedure Step	
	Order Filler		PPS Exception Management	
Simple Image and Numeric Report	Report Creator		none	
Internet address for vendor's IHE information: www.anymedicalsystemsco.com/ihe				
Links to Standards Conformance Statements for the Implementation				
HL7	www.anymedicalsystemsco.com/hl7			
DICOM	www.anymedicalsystemsco.com/dicom/integrateRAD.pdf			
Links to general information on IHE				
In North America: www.rsna.org/IHE	In Europe: www.ihe-europe.org		In Japan: www.jira-net.or.jp/ihe-j	

Appendix D: GLOSSARY

Terms Specific to this Document

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

Evidence Documents: Evidence Documents represent the uninterpreted information that is primarily managed and used inside the imaging department, although distribution outside the imaging department is not precluded. Evidence documents are non-image information and include things such as measurements, CAD results, procedure logs, etc and are to be encoded as DICOM SR documents.

Evidence Objects: All objects generated as a result of performing procedure steps on systems in an imaging department. These objects are used by the reading physician in the process of creating a diagnostic report and are managed inside the imaging Department. Examples of evidence objects include: Images, Presentation States, Key Image Notes and Evidence Documents.

Expected Actions: Actions which should occur as the result of a trigger event

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

Process Flow Diagram: A graphical illustration of the flow of processes and interactions among the actors involved in a particular example

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

Scope: A brief description of the transaction.

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

Use Case: A graphical depiction of the actors and operation of a system.

DICOM Terms

Basic Text SR Storage SOP Class: See DICOM Supplement 23

DICOM Model of the Real World: See DICOM PS 3.3

Enhanced SR Storage SOP Class: See DICOM Supplement 23

Grayscale Softcopy Presentation State Storage SOP Class: See DICOM PS 3.4

Grayscale Standard Display Function: DICOM PS 3.14

Imaging Service Request: See DICOM PS 3.3

Modality: See DICOM PS 3.3

Modality Worklist SOP Class: See DICOM PS 3.4

Modality Performed Procedure Step: See DICOM PS 3.3

Modality Performed Procedure Step Information Module: See DICOM PS 3.3

Modality Performed Procedure Step Relationship Module: See DICOM PS 3.3

Modality Performed Procedure Step SOP Class: See DICOM PS 3.4

N-Event Report: See DICOM PS 3.7

Patient: See DICOM PS 3.3

Patient Identification Module: See DICOM PS 3.3

Print Presentation LUT SOP Class: See DICOM PS 3.4

Procedure Plan: See DICOM PS 3.3

Procedure Type: See DICOM PS 3.3

Protocol Code: See DICOM PS 3.3

Requested Procedure: See DICOM PS 3.3

Requested Procedure Module: See DICOM PS 3.3

Requested Procedure ID: See DICOM PS 3.3

Results Information Object Definition: See DICOM PS 3.3

Scheduled Procedure Step: See DICOM PS 3.3

Scheduled Procedure Step Module: See DICOM PS 3.3

Storage Commitment SOP Class: See DICOM PS 3.4

Structured Reporting Information Object Definitions: See DICOM PS 3.3

Structured Reporting SOP Classes: See DICOM PS 3.4

Structured Reporting Templates: See DICOM PS 3.16

Unique Identifier (UID): See DICOM PS 3.5

HL7 Terms

ADT: See HL7 version 2.3.1

Filler: See HL7 version 2.3.1

Observation: See HL7 version 2.3.1

Placer: See HL7 version 2.3.1

Universal Service ID: See HL7 version 2.3.1

Acronyms and Abbreviations

ACC: American College of Cardiology

ASE: American Society of Echocardiography

ECG: Electrocardiogram

ESC: European Society of Cardiology

HIMSS: Healthcare Information and Management Systems Society

HIS: Hospital Information System

ICE: Intracardiac Echocardiography

IHE: Integrating the Healthcare Enterprise

IOD: Information Object Definitions

IT: Information Technology

ITI: Information Technology Infrastructure (IHE Domain)

IVUS: Intravascular Ultrasound

MWL: Modality Worklist

MPPS: Modality Performed Procedure Step

NEMA: National Electrical Manufacturers Association

OID: Object Identifier

PACS: Picture Archive and Communication System

PCC: Patient Care Coordination (IHE Domain)

PPS: Performed Procedure Step

RAD: Radiology (IHE Domain)

RID: Retrieve Information for Display

RIS: Radiology Information System

RSNA: Radiological Society of North America

SCU: Service Class User

SCP: Service Class Provider

SPS: Scheduled Procedure Step

SR: Structured Report

TEE: Transesphogeal Echocardiography

TF: Technical Framework

TTE: Transthoracic Echocardiography

UID: Unique Identifier

UUID: Universally Unique Identifier

XA: X-ray Angiography

Appendix E: Security Environment Considerations

IHE compliant systems usually process private healthcare information. This is subject to national privacy regulations, and possibly other state and contractual requirements. The IHE profiles do not fully define the security mechanisms necessary to protect this information. The ITI-TF Audit Trail and Node Authentication (ATNA) Profile provides one component of this solution.

IHE assumes that actors will be installed on nodes with the following characteristics:

- Each node has a security policy and procedure that applies to its operation.
  This is assumed to be part of the healthcare enterprise security policy.

- Any user (human, or application process) external to the node boundaries is submitted to an access control procedure in which the user/application will be authenticated.

- All required audit trail events are captured and recorded.

The profiles in this framework assume the following environment:

- Physical Security Environment

    - The equipment is assumed to be located in a physically protected and actively monitored area. This is normally the case with modality equipment because of other patient safety, privacy, and operational concerns. Similarly, the HIS systems and various archives are normally protected. Equipment like PACS workstations are sometimes placed in unprotected areas, but it is usually located where hospital staff monitors and limit access. It assumes that the threat of equipment modification is protected against by means of the physical security mechanisms.

    - The network equipment that connects the computers is also assumed to be physically protected against unauthorized connections and unauthorized modifications. In the treatment areas of most hospitals the network equipment is in ceilings, cableways, locked cabinets, and other protected areas. There is usually staff present to monitor that no unauthorized activity is taking place.

    - Local procedures and operations will be in place to ensure that the physical security assumptions are valid for other areas of the hospital, such as administrative offices, that may be at greater risk.

    - Remote locations, especially home offices, are not physically protected. Other means will be used to provide equivalent protection. This may include the use of technology such as VPN connections or HTTPS encryption. Use of encryption or VPN is not a complete replacement for physical security but may be part of an overall protection system.

    - The home computer that is used for both personal and professional purposes is difficult to protect. It will be protected from inadvertent modification by malicious software or its use will be prohibited.

- Network Security Environment

- In addition to the physical security of the network, there will be protection against network access by unsupervised systems. This is typically provided by mechanisms such as firewalls and VPNs.

The threat profile is assumed to be:

- Accidental and inadvertent misuse
- Individual abuse for personal gain, malice, revenge, or curiosity. The abusers are assumed to have only limited access to the underlying systems and software. They are not expert at the internal structure of the systems.
- Random untargeted abuse, such as from an Internet hacker.

The threat profile also assumes that the following threats are either not present or otherwise protected.

- Individual abuse by a system administrator, system developer, or other expert.
- Military or hostile government action
- Organized criminal attack

IHE addresses only those security requirements related to IT systems within the scope of IHE healthcare applications. It does not address security requirements for defending against network attacks, virus infection, etc.

IHE does not mandate the use of encryption because the performance impact of current encryption algorithms is excessive. Most hospital networks provide adequate security through physical and procedural mechanisms. The additional performance penalty for encryption is not justified for these networks. The profiles permit the use of encryption so that it can be used as part of an overall security plan.

Appendix F: Displayable Report Distribution Using the DRPT, RID and XDS Profiles

This section is reserved.

Appendix G: Displayable Report Signing

This section is reserved

Appendix H: Cardiology Summary of Relevant Profiles from Other Domains

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

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

H.1 Consistent Time (CT)

The full specification of the Consistent Time Integration Profile is found in **ITI-TF 1:7**.

The Consistent Time Integration Profile provides a means to ensure that the system clocks and time stamps of the many computers in a network are well synchronized. This profile specifies synchronization with a median error less than 1 second. This is sufficient for most procedure and system management purposes. The achievable accuracy is dependent on specific details of network hardware and topology, and on details of computer hardware and software implementation.

Figure H.1-1 shows the actors directly involved in the Consistent Time Profile and the relevant transactions between them.
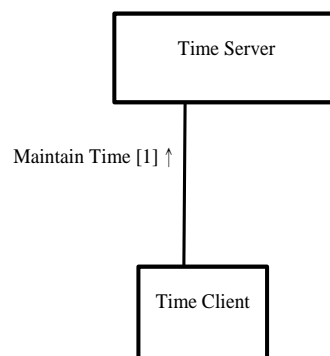

Figure H.1-1. Consistent Time Profile Diagram

H.1.1 CT Actors

Time Client – Establishes time synchronization with one or more Time Servers using the NTP protocol and either the NTP or SNTP algorithms. Maintains the local computer

system clock synchronization with UTC based on synchronization with the Time Servers.

Time Server – Provides NTP time services to Time Clients. It is either directly synchronized to a UTC master clock (e.g., satellite time signal) or is synchronized by being grouped with a Time Client to other Time Server(s).

H.1.2 CT Transactions

Maintain Time - NTP transactions used to maintain time synchronization.

H.1.3 Cardiology Use Cases

Synchronization of a multi-modality procedure requires a common understanding of the current time. Certain Actors participating in the Cath Workflow are required to participate in the Consistent Time Profile (see Sections 2.1 and 2.5).

H.2 Scheduled Workflow (SWF) and Patient Information Reconciliation (PIR)

The full specification of the Scheduled Workflow Profile is found in **RAD-TF 1:3**, and Patient Information Reconciliation in **RAD-TF 1:4**.

The Scheduled Workflow Integration Profile establishes the continuity and integrity of basic departmental imaging data. It specifies a number of transactions that maintain the consistency of patient and ordering information as well as providing the scheduling and imaging acquisition procedure steps. This profile also makes it possible to determine whether images and other evidence objects associated with a particular performed procedure step have been stored (archived) and are available to enable subsequent workflow steps, such as reporting.

The Patient Information Reconciliation Integration Profile extends the Scheduled Workflow Integration Profile by offering the means to match images, diagnostic reports, and other evidence objects acquired for a misidentified or unidentified patient (for example, during a trauma case) with the patient's record. In the example of the trauma case, this integration profile allows subsequent reconciliation of the patient record with images that are acquired (either without a prior registration or under a generic registration) before the patient's identity can be determined. Thus images can be acquired and interpreted immediately and later, when the patient's official registration and order information is entered into the ADT, Order Placer and Order Filler Systems, this information is matched with the acquired image set and reports, greatly simplifying these exception handling situations.

H.2.1 Cardiology Use Case for SWF and PIR

IHE Cardiology has defined specializations of the SWF and PIR Profiles for its Cardiac Catheterization Workflow and Echocardiography Workflow Profiles.

However, IHE Cardiology has not created specialized Workflow Profiles for nuclear cardiology, cardiovascular MR, cardiovascular CT imaging, or standard X-rays commonly used in cardiology (e.g., chest X-rays). It is expected that the SWF and PIR Profiles will be used for those modalities.

H.3 Retrieve Information for Display (RID)

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

The Retrieve Information for Display (RID) Integration Profile provides simple and rapid read-only access to patient-centric clinical information that is located outside the user's current application but is important for better patient care (for example, access to lab reports from cardiology department). It supports access to existing persistent documents in well-known presentation formats such as CDA (Level 1), PDF, JPEG, etc. It also supports access to specific key patient-centric information such as allergies, current medications, summary of reports, etc. for presentation to a clinician.

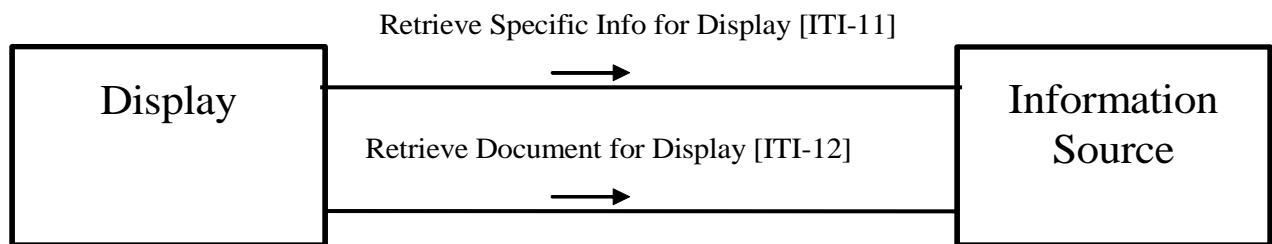Figure H.3-1 shows the actors involved in this Profile and the transactions between actors.

Retrieve Specific Info for Display [ITI-11]

| Display | Information Source |

Retrieve Document for Display [ITI-12]

Figure H.3-1. Retrieve Information for Display Diagram

H.3.1 RID Process Flow

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

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

H.3.2 Cardiology Use Cases

The Retrieve ECG for Display Profile is an extension of the RID Profile, and is based on the RID actors and transactions. (See Section 5 of this document.)

In the Cardiology domain, this Profile may be used to obtain information held outside a Cardiology department. In particular, this Profile may be used to obtain information critical to the performance of a cardiac catheterization procedure, such as patient history and physical exam data, advance medical directives, blood chemistry reports, and current medications. As such, the Display actor of this profile has a significant adjunct role for the Cath Workflow Profile, or for any departmental clinical workstation that needs to present information from both the Cardiology department and from the patient's general electronic health record (EHR).

Additionally, this Profile may be used by systems within the cardiology department to provide information to other departments or users, such as reports. As such, the Information Source actor of this profile has a significant adjunct role for the report repositories of the Displayable Report Profile.

H.4 Cross-Enterprise Document Sharing (XDS)

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

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

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

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

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

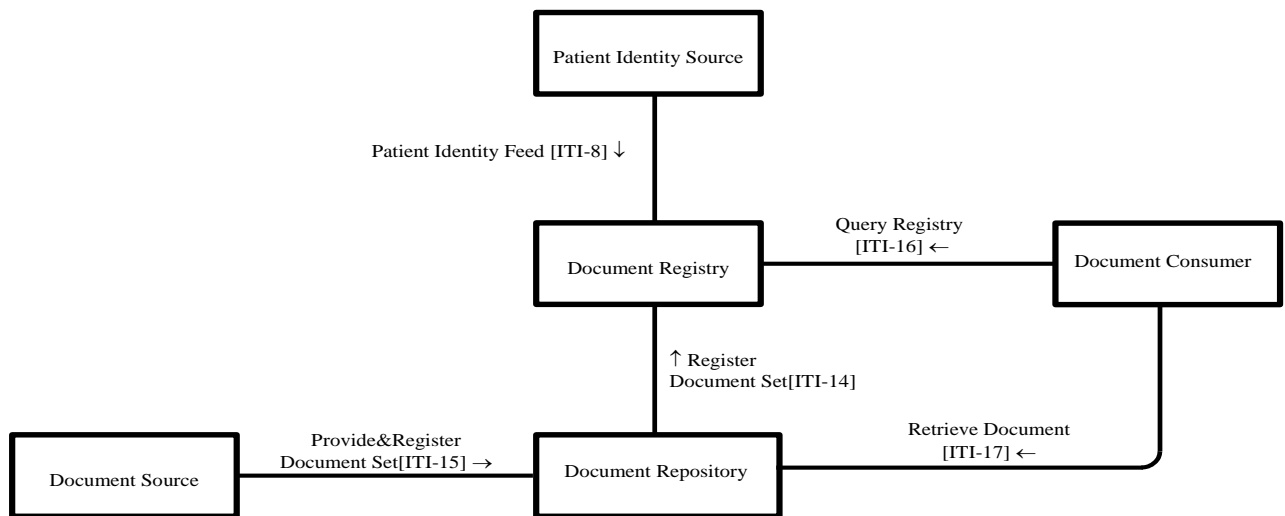Figure H.4-1 diagrams the actors involved with this profile and the transactions between actors.

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

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

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

3. The effective use of this Profile requires profiling the specific document formats to be used in the clinical affinity domain. The IHE Cardiology Technical Committee has not yet established the appropriate document formats for the Cardiology domain, but this may be the subject of a future recommendation. The Committee notes in particular the XDS for Imaging (XDS-I) Profile being developed by the IHE Radiology Technical Committee.

4. For cross-enterprise sharing of cardiology reports, the Document Source and/or Document Repository actors of this profile may be associated with the report repositories of the Displayable Report Profile and the Simple Image and Numeric Report Profile.

H.4.1 XDS Process Flow

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

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

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

A care provider elsewhere in the network wishes to retrieve the patient's shared documents (e.g., in preparation for a diagnostic exam). That provider through a Document Consumer Actor issues a Query Registry transaction to the Document Registry. The Document Registry Actor searches the registry to locate documents that meet the provider's specified query criteria. It will return a list of document entries that contain metadata found to meet the specified criteria including the locations and identifier of each corresponding document in one or more Document Repositories. The provider identifies the documents he is interested in seeing, and the Document Consumer Actor initiates the Retrieve Document transaction. The Document Repository will return the document that was specified by the Document Consumer.

H.4.2 Cardiology Use Cases

In the Cardiology domain, a principal use case would be for the sharing of documents among a cardiologist's office practice and the several secondary and tertiary care facilities to which the cardiologist may refer the patient for specialized tests or procedures.

Although business relationships vary by country, in the many locales it is very common for a cardiologist to practice at both a private clinic office as well as a hospital. The private clinic often is the repository for information such as ECG waveforms and reports, echo images and reports, medication information, some in-house lab measurements and reports, office visit notes, etc. Hospitals are often the repository for information such as cath images and reports, echo images and reports, ECG waveforms and reports, hemodynamic information, lab information, discharge summaries, etc. The private clinic and the hospital are two distinct businesses. However, a cardiologist would have privileges at both facilities and there is a mutual business arrangement between the two facilities.

The first general use case is where patient presents at a hospital (e.g., CCU, cath lab, ED), for whom critical information is located in the clinic. A more specific example of this case is where a patient is admitted to ED after normal business hours with chest pain and the cardiologist on

call comes in to the ED.   This patient was seen at the office the previous week and the medication regimen was changed at that time. The patient is unable to tell the cardiologist the medication and dosages which were prescribed and that information is locked away in the clinic office.

A second general use case is that where the cardiologist is physically located in a clinic office and needs access to information generated and stored in the hospital repository. A more specific example of this use case is that a patient is scheduled for a follow up visit in the cardiologist's office, but the cardiologist does not have immediate access to the cath report and discharge summary created the previous week in the hospital.

Another use case is that of rural healthcare. A patient is seen at a rural hospital for routine cardiac care. Later, that patient has a significant event and is taken by ambulance to a tertiary care hospital with a cardiac center. A business relationship exists between the two facilities to provide acute cardiac care. Once at the tertiary care site, the cardiologist on staff needs access to all of the records currently located at the rural hospital.

H.4.3 XDS Content Profiles

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

H.4.3.1 XDS-MS Medical Summary

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

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

The XDS-MS Profile facilitates transfer of care by defining a minimum set of "record entries" that should be forwarded or made available to subsequent care provider(s) during specific transfer of care scenarios. In addition, this integration profile defines the utilization requirements/options for the receiving entity in order to ensure that the "care context" of the sending entity is appropriately maintained following the information transfer.

Most of the XDS cardiology use cases described in section H.4.2 would utilize the XDS-MS content profile for exchanging a summary of an episode of care – the summary record of an office visit, of an in-patient cath procedure, or of an emergency department encounter.

H.4.3.2 XDS-I Imaging

The full specification of the Cross-Enterprise Document Sharing for Imaging Profile is found in **RAD TF-1:18**.

The XDS for Imaging (XDS-I) Profile extends and specializes XDS to support imaging "documents", specifically including the following:

- Imaging studies that include images acquired on a broad range of different modalities, as well as evidence documents (e.g., post-processing measurements/analysis outcome), and presentation states.

- Diagnostic reports resulting from the interpretation of one or more related imaging studies provided in a ready-for-display form.

- A selection of diagnostically significant images associated with the report content.

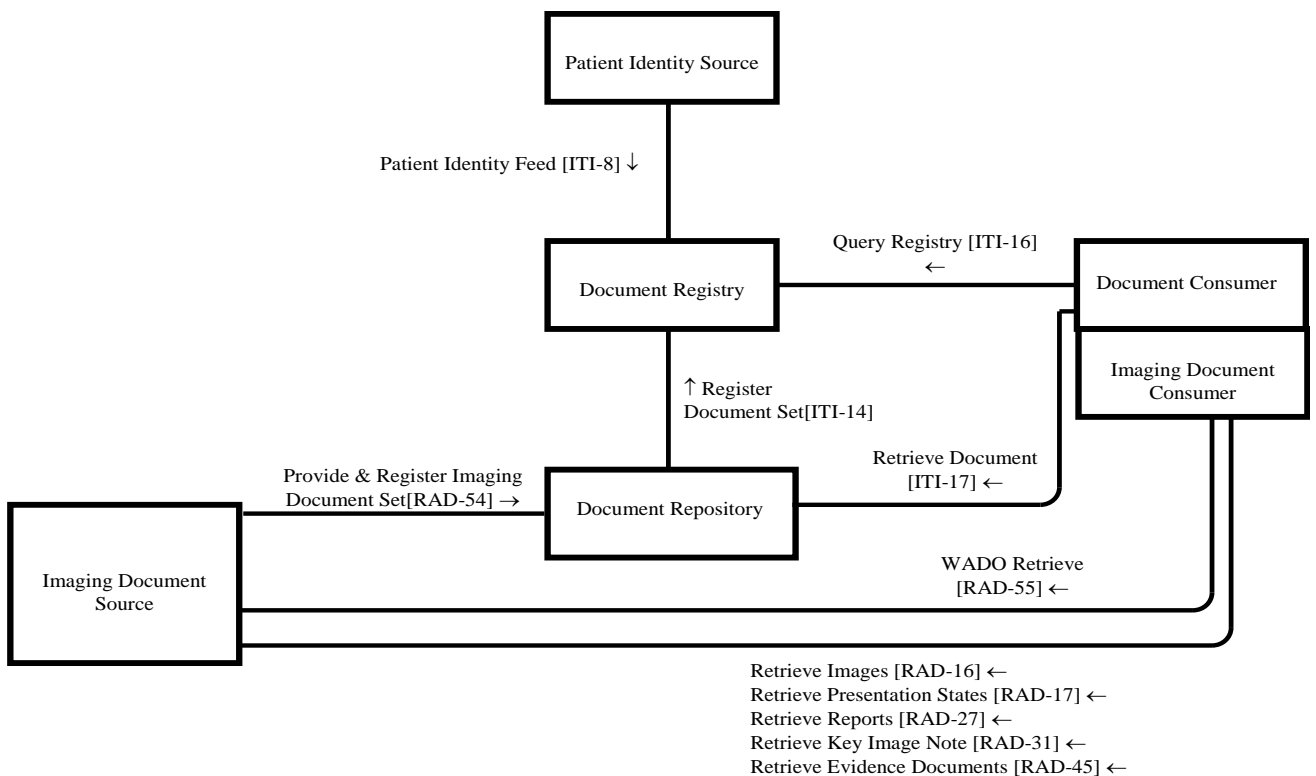Figure H.4-2 shows the extended XDS actors and transactions used for XDS-I.

Figure H.4-2. Cross-Enterprise Document Sharing for Imaging Diagram