Integrating the Healthcare Enterprise

IHE Eye Care (EYECARE)
Technical Framework

Volume 1
IHE EYECARE TF-1
Profiles

Revision 4.0 - Final Text

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1 Introduction

This document, Volume 1 of the IHE Eye Care (EYECARE) Technical Framework, describes the clinical use cases, actors, content module, and transaction requirements for the Eye Care profiles.

1.1 Introduction to IHE

Integrating the Healthcare Enterprise (IHE) is an international initiative to promote the use of standards to achieve interoperability among health information technology (HIT) systems and effective use of electronic health records (EHRs). IHE provides a forum for care providers, HIT experts and other stakeholders in several clinical and operational domains to reach consensus on standards-based solutions to critical interoperability issues.

The primary output of IHE is system implementation guides, called IHE profiles. IHE publishes each profile through a well-defined process of public review and Trial Implementation and gathers profiles that have reached Final Text status into an IHE Technical Framework, of which this volume is a part.

1.2 Introduction to IHE Eye Care (EYECARE)

The IHE Eye Care domain was formed in 2005 and is sponsored by the American Academy of Ophthalmology (AAO). The mission of the IHE Eye Care domain is to bring together information technology stakeholders and healthcare professionals to implement standards for communicating patient information efficiently throughout healthcare facilities, large and small.

1.3 Intended Audience

The intended audience of IHE Technical Frameworks Volume 1 (Profiles) is:

Those interested in integrating healthcare information systems and workflows

IT departments of healthcare institutions

Technical staff of vendors participating in the IHE initiative

1.4 Pre-requisites and Reference Material

For more general information regarding IHE, refer to www.ihe.net. It is strongly recommended that, prior to reading this volume, the reader familiarizes themselves with the concepts defined in the *IHE Technical Frameworks General Introduction*.

Additional reference material available includes:

1. Radiology Technical Framework Volume 1, Integration Profiles
2. Radiology Technical Framework Volume 2, Transactions
3. Cardiology Technical Framework Volume 2, Transactions
4. IT Infrastructure Technical Framework Volume 1
5. IT Infrastructure Technical Framework Volume 2

6. [IT Infrastructure Technical Framework Volume 3](#)

7. [IHE Patient Care Coordination Technical Framework Volume 1](#)

8. [IHE Patient Care Coordination Technical Framework Volume 2](#)

9. HL7®[1] Implementation Guide for CDA®[2] Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012

10. HL7 and DICOM®[3] standards documents referenced in Volume 1 and Volume 2

1.4.1 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.

A list of actors defined for all domains and their brief descriptions can be found as an appendix to the *IHE Technical Frameworks General Introduction*.

1.4.2 Transaction Descriptions

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

A list of transactions defined for all domains, their transactions numbers, and a brief description can be found as an appendix to the *IHE Technical Frameworks General Introduction*.

1.4.3 Content Modules

Content modules are data and data definitions shared between actors.

A list of content modules defined for all domains, their reference numbers, and a brief description can be found as an appendix to the *IHE Technical Frameworks General Introduction*.

1.4.4 IHE Integration Statements

IHE Integration Statements provide a consistent way to document high level IHE implementation status in products between vendors and users.

The instructions and template for IHE Integration Statements can be found as an appendix to the *IHE Technical Frameworks General Introduction*.

IHE also provides the IHE Product Registry (http://www.ihe.net/IHE_Product_Registry) as a resource for vendors and purchasers of HIT systems to communicate about the IHE compliance of such systems. Vendors can use the Product Registry to generate and register Integration Statements.

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[1] HL7 is the registered trademark of Health Level Seven International.

[2] CDA is the registered trademark of Health Level Seven International.

[3] DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

1.5 Overview of Technical Framework Volume 1

Volume 1 is comprised of several distinct sections:

- Section 1 provides background and reference material.
- Section 2 presents the conventions used in this volume to define the profiles.
- Sections 3 and beyond define Eye Care profiles, actors, and requirements in detail.

The appendices in Volume 1 provide clarification of uses cases or other details. A glossary of terms and acronyms used in the IHE Technical Framework is provided in the *IHE Technical Frameworks General Introduction*.

1.6 Comment Process

IHE International welcomes comments on this document and the IHE initiative. They can be submitted by sending an email to the co-chairs and secretary of the Eye Care domain committees at eyecare@ihe.net.

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265 http://www.ihe.net/Patent_Disclosure_Process. Please address questions about the patent disclosure process to the secretary of the IHE International Board: secretary@ihe.net.

1.10 History of Document Changes

This section provides a brief summary of changes and additions to this document.

Date	Document Revision	Change Summary
2006	2.0	First Release of IHE Eye Care Technical Framework, generated Eye Care Workflow, Charge Posting and Eye Care Evidence Documents
2007-2008	3.2	Update CPs and Generated Eye Care Displayable Reports
2009-2010	3.7	Update CPs
June 2016	4.0	Update CPs, add Unified Eye Care Workflow, retire A, B and C Workflow

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2 Eye Care Integration Profiles

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

IHE integration profiles are defined in terms of IHE actors (defined in Volume 1), transactions (defined in Volume 2), and content modules (defined in Volume 3). Actors are information systems or components of information systems that produce, manage, or act on information associated with clinical and operational activities in healthcare. Transactions are interactions between actors that communicate the required information through standards-based messages. Content modules define how the content used in a transaction is structured. A content module is specified so as to be independent of the transaction in which it appears.

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

IHE profiles which have reached the status of *Final Text* are published as part of the domain's Technical Framework Volumes 1-4. Prior to Final Text status, IHE profiles are published independently as *Profile Supplements* with the status of *Public Comment* or *Trial Implementation*.

For a list and short description of Eye Care profiles, see http://wiki.ihe.net/index.php/Profiles#IHE_Eyecare_Profiles. The list includes all of the profiles in this document (Final Text) and may include profiles in the Trial Implementation stage.

2.1 Required Actor Groupings and Bindings

The IHE Technical Framework relies on the concepts of *required actor groupings* and *bindings*.

Required actor groupings may be defined between two or more IHE actors. Actors are grouped to combine the features of existing actors. This allows reuse of features of an existing actor and does not recreate those same features in another actor. Internal communication between grouped actors is not specified by IHE. An example of grouped actors in the IHE Radiology Scheduled Workflow Profile is the grouping between the Image Manager and Image Archive.

Additionally, required actor groupings may cross profile boundaries. For example, an XDS Document Registry Actor is required to be grouped with an ATNA Secure Node Actor. Required actor groupings are defined in each profile definition in Volume 1. To comply with an actor in an IHE profile, a system must perform all transactions required for that actor in that profile. Actors supporting multiple integration profiles must support all of the transactions of each profile. (Note: In previous versions of IHE Technical Framework documents, the concept of profile dependencies existed. For simplification, profile dependencies have been combined with required actor groupings and are enumerated/repeated within each profile in Volume 1.)

310   Bindings refer to content modules. Bindings map data from a content module to the metadata of a specific transport profile. Bindings for content modules, and the associated concepts, are defined in Volume 3.

2.2 Security Implications

315   IHE transactions often contain information that must be protected in conformance with privacy laws, regulations and best practices. This protection is documented in the Security Considerations section of each profile, which communicates security/privacy concerns that the implementers need to be aware of, assumptions made about security/privacy pre-conditions and, where appropriate, key elements of a risk mitigation strategy to be applied.

2.3 Integration Profiles Overview

320   An overview of the profiles is listed at http://www.ihe.net/Profiles.

2.4 Product Implementations

As described in detail in the *IHE Technical Frameworks General Introduction*, an implementer chooses specific profiles, actors, and options to implement for their product. To comply with an actor in an IHE profile, a system must perform all the required transactions required for that
325   actor in that profile.

To communicate the conformance of a product offering with IHE profiles, implementers provide an IHE Integration Statement describing which IHE integration profiles, IHE actors and options are incorporated.

To make consumers aware of the product integration statement, enter it in the IHE Product
330   Registry (http://product-registry.ihe.net/).

2.5 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
335   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
340   across multiple domains. Therefore the actor names will remain as defined below.

Acquisition Modality – A system that acquires and creates medical images while a patient is present. A modality may also create other evidence objects such as Grayscale Softcopy Presentation States for the consistent viewing of images or Evidence
345   Documents containing measurements, etc. In eye care, modalities acquire diagnostic information such as images and/or evidence documents. Some examples of these may

include photography, topography, refractive exams, corneal and retinal topography, visual fields, etc.

Acquisition Modality Importer – A system that interfaces to a non-DICOM ready modality in order to integrate that modality into eye care workflows.

ADT/Patient Registration – 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. Some possible eye care examples include a Practice Management System (PMS) or a Hospital Information System (HIS).

Appointment Consumer - An information system responsible for consuming patient appointment information. It updates its system with the appointment information and statuses.

Appointment Scheduler - An information system responsible for scheduling patient appointments. It performs scheduling features such as, new appointment, confirmed appointment, patient checked in, cancelled, deleted, etc.

Charge Processor – Receives the posted charges and serves as a component of the financial system (for instance a PMS or billing system).

Department System Scheduler/Order Filler – A department-based system that provides functions related to the management of orders received from external systems or through the department system's user interface. An eye care example of a department based system could be an eye care Electronic Health Record (EHR).

Evidence Creator – A system that creates additional evidence objects such as derived images or measurements (Evidence Documents), and transmits them to an Image Archive (for instance, acquisition modalities, image displays, post processing systems, EHR, etc.).

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.

Image Storage/Display - A system responsible for receiving DICOM SOP Instances, storing those SOP Instances, and the ability to present them for viewing to the user.

Order Placer – A hospital or enterprise-wide system that generates orders for various departments and distributes those orders to the correct department (i.e., PMS, HIS, etc.).

385   **Patient Registration Source -** A system responsible for the generation of patient demographic and visit information. It registers new patients and provides updates.

Patient Registration Consumer - A system responsible for consuming patient demographic and visit information.

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

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

Report Reader – A system that can query/retrieve and view reports encoded as DICOM objects.

395   **Report Repository –** A departmental system that receives reports and stores them for long-term access.

Note: The above Eye Care examples are typical products that may perform these roles, but IHE does not dictate this and any product may choose to implement any role.

400   The following table shows which actors are used in which integration profiles.

Table 2.5-1: Integration Profile Actors

Integration Profile / Actor	Unified Eye Care Workflow	Advanced Eye Care Workflow (Retired)	Eye Care Charge Posting	Eye Care Evidence Document	Eye Care Displayable Report
Acquisition Modality	X	X	X	X	
Acquisition Modality Importer	X	X	X		
ADT Patient Registration		X	X		
Appointment Scheduler Consumer	X				
Appointment Scheduler	X				
Charge Processor	X		X		
Department System Scheduler/Order Filler	X	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			
Patient Registration Consumer	X				
Patient Registration Source	X				
Performed Procedure Step Manager	X	X	X		
Report Creator					X
Report Reader					X
Report Repository					X

2.6 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 Patient Registration Source Actor registers and/or updates
patient information and forwards this data to other information systems [EYECARE-15]

Appointment Scheduling Management – The Appointment Scheduler Actor generates new
patient appointments and manages the appointment updates, status changes, etc. This
information is forwarded to other information systems [EYECARE-16]

Eye Care Charge Posted - The Department System Scheduler/Order Filler provides
procedure and other billing charges data that is used by the Charge Processor. The
Charge Processor may or may not expect the actual transaction fees associated with
the procedures included in the transaction. [EYECARE-17]

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 Department System
Scheduler/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 Department System Scheduler/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 - An HL7 OMG V2.5.1 message from the DSS/Order Filler to notify
the Image Manager/Image Archive that a procedure has been scheduled. [EYECARE-21]

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 [EYECARE-1], derived from [RAD-5].

Modality Procedure Step In Progress – An Acquisition Modality or Acquisition Modality
Importer 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. [RAD-6]

Modality Procedure Step Completed – An Acquisition Modality or Acquisition Modality
Importer 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. [EYECARE-6], derived from [RAD-7]

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

450 **Modality Images/Evidence Key Objects Stored -** Requires acquisitions systems to select and send key image/measurement objects to a storage/display system (i.e., not an image archive). Also enables Image Manager/Image Archive Actors to send selected key images/measurements. [EYECARE-18]

Instructions for Performing a Procedure (Placer Order Management)- When an order is created, an Order Placer provides a mechanism for the health care provider to enter
455 free text instructions to the technician who will be performing the procedure. [EYECARE-10]

Instructions for Performing a Procedure (Filler Order Management)- When an order is created, a DSS/Order Filler provides a mechanism for the health care provider to enter free text instructions to the technician who will be performing the procedure.
460 [EYECARE-11]

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

Patient Demographics Update - Enables systems to update patient demographic information within an ambulatory (i.e., outpatient, such as an eye care clinic) or an in-patient setting. [EYECARE-19]

Merge Patient IDs - Enables systems to merge Patient IDs for a patient that was incorrectly
470 filed under two different identifiers. [EYECARE-20]

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]

475 **Procedure Status Update -** An HL7 OMG V2.5.1 message from the Image Manager/Image Archive to convey an order status update (such as completed and images available). It updates the order created from the Procedure Scheduled [EYECARE-21] transaction. [EYECARE-22]

Procedure Update – The Department System Scheduler/Order Filler sends the Image
480 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. [EYECARE-5], derived from [RAD-14]

Retrieve Images – An Image Display requests and retrieves a particular image or set of
485 images from the Image Archive. [EYECARE-3], derived from [RAD-16]

Charge Posted – The Department System Scheduler/Order Filler sends descriptions of potential procedure and material charges. [RAD-35]

Account Management - The ADT Patient Registration Actor informs the Charge Processor about creation, modification and ending of the patient's account. [RAD-36]

490   **Query Evidence Documents** – A user of Evidence Documents (i.e., Image Display, Evidence Creators, etc.) queries the Image Archive for a list of entries representing Evidence Documents. [EYECARE-4], derived from [RAD-44]

      Retrieve Evidence Documents – A user of Evidence Documents (Image Display, Evidence Creators, etc.) requests and retrieves an Evidence Document from the Image Archive.

495   [RAD-45]

      Displayable Report Storage – A Report Creator sends a draft or final diagnostic Encapsulated Document report to the Report Repository. [EYECARE-7]

      Query Displayable Reports – A Report Reader provides a set of criteria to select the list of entries representing diagnostic reports by patient, study, series, or instance known by

500   the Report Repository. [EYECARE-8]

      Retrieve Displayable Reports – A Report Reader requests and retrieves a diagnostic report from the Report Repository. [EYECARE-9]

The following table shows which transactions are used in which integration profiles.

505   **Table 2.6-1: Integration Profile Transactions**

Integration Profile Transaction	Unified Eye Care Workflow	Advanced Eye Care Workflow *(Retired)*	Eye Care Charge Posting	Evidence Documents	Eye Care Displayable Report
Patient Registration [EYECARE-15]	X				
Appointment Scheduling Management [EYECARE-16]	X				
Eye Care Charge Posted [EYECARE-17]	X				
Patient Registration [RAD-1]		X	X		
Placer Order Management [RAD-2]		X			
Filler Order Management [RAD-3]		X			
Procedure Scheduled [EYECARE-21]	X				
Procedure Scheduled [RAD-4]		X			
Query Modality Worklist [EYECARE-1]	X	X			
Modality Procedure Step In Progress [RAD-6]	X	X	X		
Modality Procedure Step Completed [EYECARE-6]	X	X	X		
Modality Images/Evidence Stored [EYECARE-2]	X	X		X	
Modality Images/Evidence Key Objects Stored [EYECARE-18]	X				
Instructions for Performing a Procedure (Placer Order Management) [EYECARE-10]		X			
Instructions for Performing a Procedure (Filler Order Management) [EYECARE-11]		X			
Storage Commitment [CARD-3]	X	X		X	
Patient Demographics Update [EYECARE-19]	X				
Merge Patient IDs [EYECARE-20]	X				
Patient Update [RAD-12]		X			
Procedure Status Update [EYECARE-22]	X				

Transaction / Integration Profile	Unified Eye Care Workflow	Advanced Eye Care Workflow *(Retired)*	Eye Care Charge Posting	Evidence Documents	Eye Care Displayable Report
Procedure Update [RAD-13]		X			
Query Images [EYECARE-5]	X	X			
Retrieve Images [EYECARE-3]	X	X			
Charge Posted [RAD-35]			X		
Account Management [RAD-36]			X		
Query Evidence Documents [EYECARE-4]				X	
Retrieve Evidence Documents [RAD-45]				X	
Displayable Report Storage [EYECARE-7]					X
Query Displayable Report [EYECARE-8]					X
Retrieve Displayable Report [EYECARE-9]					X

2.7 Product Implementations

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

510
- For a system, select which actors it will incorporate. (Multiple actors per system are acceptable.)

- For each actor, select which integration profiles it will participate in.

- For each actor-profile, select which optional transactions will be implemented. All required transactions must be implemented for the profile to be supported. (Refer to the Integration
515 Profile Tables in Sections 3-9.)

- Finally, for each transaction, select which optional features will be supported. (Refer to the transaction descriptions in EYECARE TF-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
520 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 certain profiles such as U-EYECARE the implementation of one actor requires the implementation of one or more additional actors, for example:

- The Image Archive shall be grouped with the Image Manager, and the Image Manager shall
525 be grouped with the Image Archive.

- The Patient Registration Source shall be grouped with the Appointment Scheduler.

- The Patient Registration Consumer shall be grouped with the Appointment Consumer and Department System Scheduler/Order Filler.

530   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
535   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
540   are outside the scope of the IHE Technical Framework.

3 Advanced Eye Care Workflow (A-EYECARE)

Retired (Replaced by Unified Eye Care (U-EYECARE))

See IHE Eye Care Technical Framework – Revision 3.7, February 15, 2010 for specification at http://ihe.net/Technical_Framework_Archives/#eyecare.

545

4 Eye Care Charge Posting (EC-CHG)

The Eye Care Charge Posting Integration Profile describes mechanisms to transfer charge information to the clinic or enterprise Charge Processing System. This section corresponds to Transaction [RAD-35] of the IHE Technical Framework. Transaction [RAD-35] is used by the Department System Scheduler/Order Filler and Charge Processor Actors. This section also refers to [RAD-36] of the IHE Radiology Technical Framework that is used by the ADT Patient Registration and Charge Processor Actors. This section will correlate the activities that occur in the eye care clinic with these IHE defined transactions. The standards used are HL7 v2.3.1: Chapter 6 - Financial Management and DICOM PS 3.4 Modality Performed Procedure Step SOP Class.

4.1 Actor/Transactions

The actor names are defined below.

> Note: Eye Care Charge Posting as used by the eye care domain currently covers the area of billing for procedure acquisition information. The defined radiology profile supports these plus additional charges for professional reports, etc. Future versions of the IHE Eye Care TF will also address professional reports, etc., very likely just as defined by Radiology. However, since it is not in this version, this is not formally defined.

Acquisition Modality – A system that acquires and creates medical images while a patient is present. A modality may also create other evidence objects such as Grayscale Softcopy Presentation States for the consistent viewing of images or Evidence Documents containing measurements, etc. In eye care, modalities acquire diagnostic information such as images and/or evidence documents. Some examples of these may include photography, topography, refractive exams, corneal and retinal topography, visual fields, etc.

Acquisition Modality Importer – A system that interfaces to a non-DICOM ready modality in order to integrate that modality into eye care workflows.

ADT Patient Registration – A system responsible for adding and/or updating patient demographic and encounter information. In particular, it registers a new patient with the Department System Scheduler/Order Filler and the Charge Processor. In eye care, an ADT system is commonly called a Practice Management System.

Department System Scheduler/Order Filler – A department-based system that provides functions related to the management of orders received from external systems or through the department system's user interface. An eye care example of a department based system could be an eye care Electronic Health Record (EHR). The Department System Scheduler/Order Filler system sends charges to the Charge Processor.

Charge Processor – It processes and combines charges in order to issue an insurance claim or patient's billing statement. An eye care example could be a Practice Management System.

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

Figure 4.1-1 diagrams the actors involved with the Eye Care Charge Posting Profile and the
transactions between actors. The transactions denote changes from the Radiology workflow.
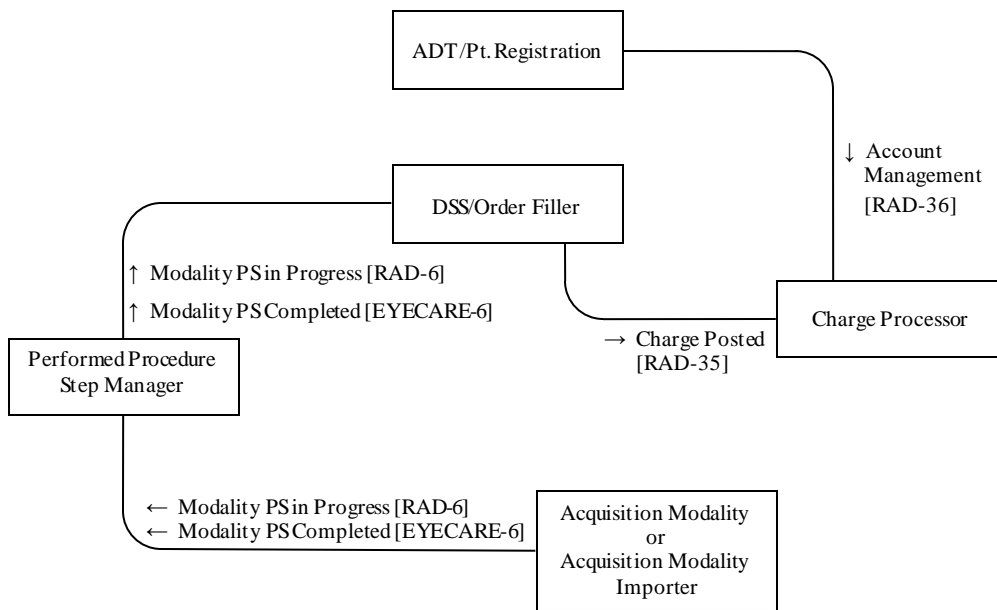
590

Figure 4.1-1: Eye Care Charge Posting Transaction Diagram

Table 4.1-1 lists the transactions for each actor directly involved in the Eye Care Charge Posting
Profile as used by the Eye Care Domain. In order to claim support of this integration profile, an
implementation must perform the required transactions (labeled "R"). Transactions labeled "O"
595   are optional.

Table 4.1-1: Charge Posting – Actors and Transactions

Actors	Transactions	Optionality	Section
ADT Patient Registration	Account Management [RAD-36]	R	RAD TF-3: 4.36
Department System Scheduler/Order Filler/Performed Procedure Step Manager	Charge Posted [RAD-35]	R	RAD TF-3: 4.35
	Modality Procedure Step In Progress [RAD-6]	R	RAD TF-2: 4.6
	Modality Procedure Step Completed [EYECARE-6]	R	EYECARE TF-2: 4.6
Acquisition Modality	Modality Procedure Step In Progress [RAD-6]	R	RAD TF-2: 4.6
	Modality Procedure Step Completed [EYECARE-6]	R	EYECARE TF-2: 4.6

Actors	Transactions	Optionality	Section
Acquisition Modality Importer	Modality Procedure Step In Progress [RAD-6]	R	RAD TF-2: 4.6
	Modality Procedure Step Completed [EYECARE-6]	R	EYECARE TF-2: 4.6
Charge Processor	Charge Posted [RAD-35]	R	RAD TF-3: 4.35
	Account Management [RAD-36]	R	RAD TF-3: 4.36

4.2 Eye Care Charge Posting Integration Profile Options

600   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. Dependencies between options when applicable are specified in notes.

Table 4.2-1: Eye Care Charge Posting – Actors and Options

Actor	Options
ADT Patient Registration	*No options defined*
Department System Scheduler/ Order Filler	*No options defined*
Acquisition Modality	*No options defined*
Acquisition Modality Importer	*No options defined*
Performed Procedure Step Manager	*No options defined*
Charge Processor	*No options defined*

605 ## 4.3 Eye Care Charge Posting Process Flow
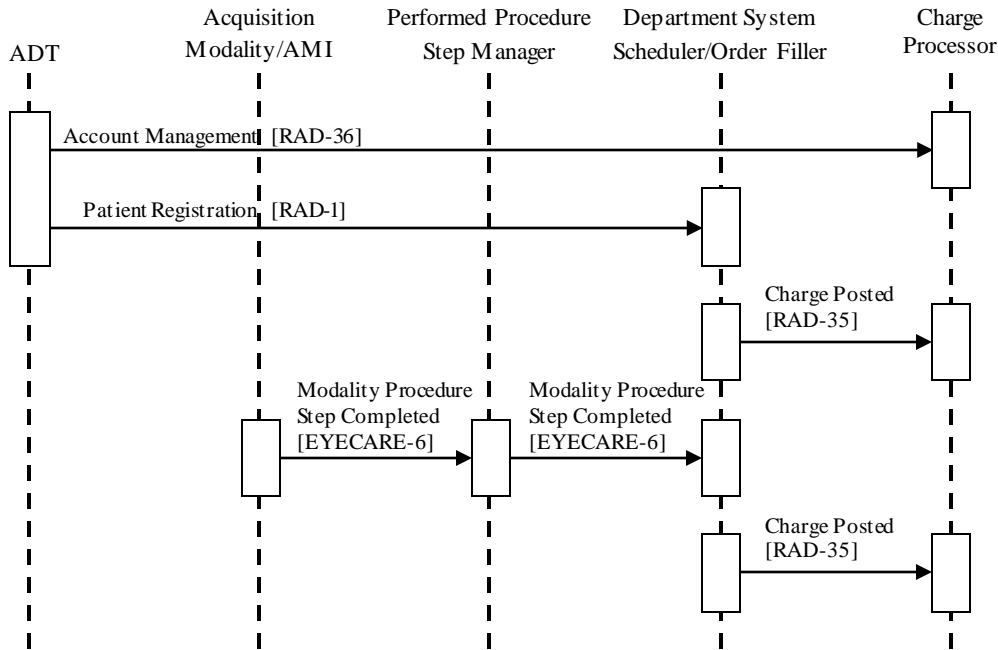
Figure 4.3-1: Eye Care Charge Posting Process Flow

Events that may trigger a charge posted transaction are Procedure Ordered, Procedure Scheduled,
610 and Procedure Completed.

4.3.1 Use Cases

This section describes the potential use cases relating to the charge posting functionality. It is the
responsibility of the Department System Scheduler/Order Filler to ensure that the billing
information is sent to the Charge Processor. The Department System Scheduler/Order Filler
615 forwards the data that is required by the Charge Processor to generate the claim.

The Charge Processor shall accept the Charge Posted Transaction information. Interpretation and
subsequent billing processes by the Charge Processor are beyond the scope of this profile.

Below are two use cases for eye care.

4.3.2 Eye Care Uses Cases for Technical Billing (Procedure Billing)

620 #### 4.3.2.1 New Patient Appointment

A new patient calls and makes an appointment for a visit. The patient arrives at the clinic on the
date scheduled. The front desk clerk asks the new patient to fill out the rest of their demographics
and insurance information on a standard paper form. The clerk accepts completed documents and
enters the information into the ADT Patient Registration. The registration system validates the
625 information and distributes the necessary demographics information to the Department System
Scheduler/Order Filler system. The patient is then led through a series of rooms where standard

tests are usually performed on new patients. These tests could include non-mydriatic fundus photos, refraction, topography, pachymetry, and vision exams. A technician normally performs these tests. The patient is then taken to a room to be seen by the healthcare provider. The healthcare provider will normally perform an external eye, a slit-lamp biomicroscopic and a fundus exam. The healthcare provider may then perform additional examinations and/or procedures that may include gonioscopy, extended sensorimotor exam, removal of foreign bodies, insertion of plugs, application of eye patches, protective contact lenses, etc.

After the above procedures are completed, the Acquisition Modality or Acquisition Modality Importer transmits the Modality Performed Procedure Step Completed [EYECARE-6] as shown in Figure 4.3-1. This transaction includes the Performed Protocol Code Sequence which provides the DSS/OF the needed information to map the protocols to the procedures and CPT codes to automatically send charges to the Charge Processor.

If additional tests that require the use of diagnostic and/or imaging devices (modalities) are required, then an order will be created and the patient will be scheduled for those tests in Department System Scheduler/Order Filler. The patient will arrive at the department responsible for filling the orders issued by the healthcare provider. The technician will perform the diagnostic procedures on the patient using the specified modality. When the diagnostic procedures have been completed, the DSS/Order Filler will automatically send the new charges to the Charge Processor.

4.3.2.2 Existing Patient

The patient is scheduled for an exam that involves a specific test like a visual field. This test has been ordered by the healthcare provider at a previous point in time, which in many cases is not even the same day. The healthcare provider may not see the patient the day that the test is completed. A technician will complete the test. The Department System Scheduler/Order Filler will receive a procedure completed message from the modality that includes the actual protocol performed. The Department System Scheduler/Order Filler will send the charges for the technical portion of the billing to the Charge Processor. The healthcare provider will review the procedure results and the Department System Scheduler/Order Filler will send the professional fee charges to the Charge Processor.

> Note: Professional billing will be addressed in the future.

4.4 Data Model for Eye Care Charge Posting

The data model adopted by the IHE Technical Framework for the HL7 messages used in the Eye Care Charge Posting Profile is based on a subset of HL7 v2.3.1 as described in Section 4.3.1.

4.4.1 Model of the Real World

Figure 4.4-1 depicts the model of the real world within scope of the Eye Care Charge Posting Profile. This model corresponds to the approach suggested in the HL7 standard, in particular:

- Financial data related to the patient are accumulated as properties of accounts. A patient may have more than one active (open) account at a time.

665
- One account may contain financial data pertaining to more than one Visit. A visit, however, cannot span multiple accounts.

- There may be multiple Billable Procedures performed and multiple charges posted as a result of one visit. There may be one charge posted for multiple procedures and one procedure to be charged in multiple charge postings.

670
- Requested Procedures may be Billable Procedures. One Requested Procedure may correspond to more than one Billable Procedure.
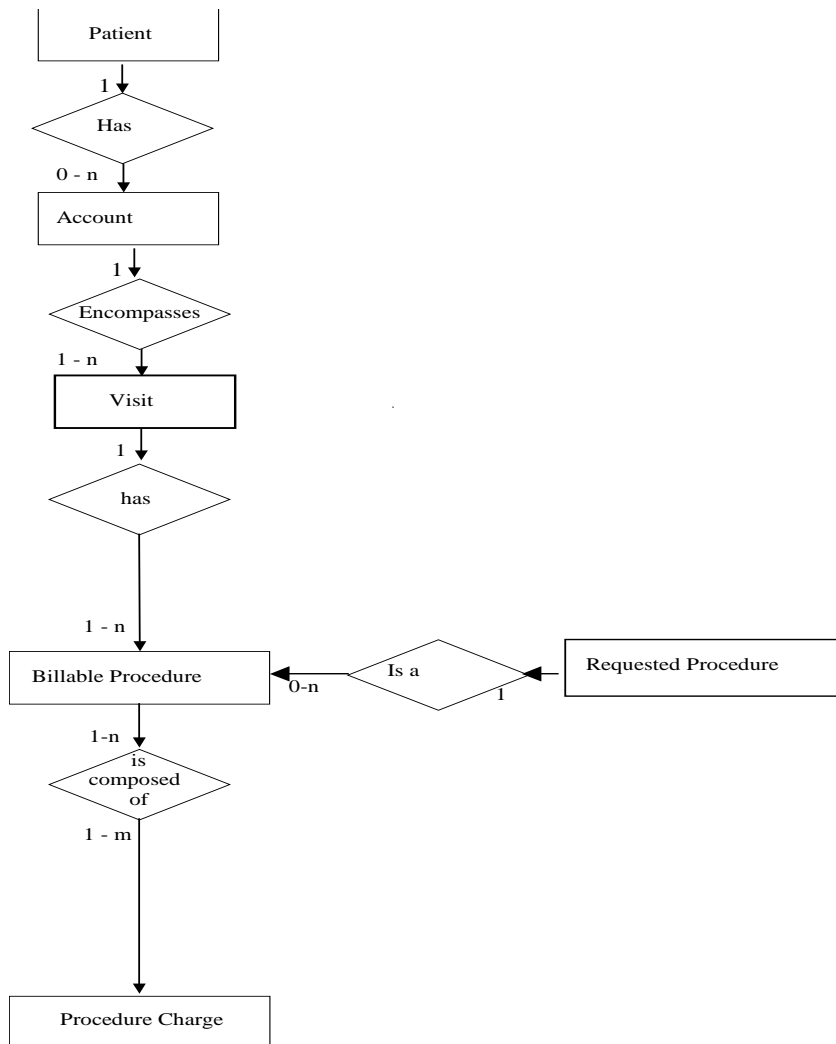
5 Eye Care Evidence Documents (ECED)

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The Eye Care Evidence Documents Profile defines information 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.

680 This allows detailed non-image information, such as measurements, post processing, etc., to be made available as input to the process of generating a clinical Report, either as additional evidence for the reporting healthcare provider, 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

685 adds the eye care specific options for that definition. The main extension for eye care is the use of DICOM Encapsulated PDF.

Note 1: As of this version, DICOM WG 9 is in the process of defining DICOM IODs to convey such information. For procedures that are not defined in DICOM, the IHE framework allows the use of DICOM Encapsulated PDF for measurements and reports, and the use of DICOM Secondary Capture for images. Once DICOM supports DICOM IODs

690 for such evidence documents, Actors are recommended to additionally support eye care specific DICOM IODs.

Note 2: The DICOM standard does not define use of a specific version of PDF when encapsulated PDF is used. This may result in incorrect display of reports when using a different PDF version of software from that which was used to create the files. Other issues arise when using only PDF with pixel data as the files are large and have difficulties with display. IHE EYECARE TF defines specific versions required for support see EYECARE TF-2: 4.2.

5.1 Actors/Transactions

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Figure 5.1-1 shows the actors directly involved in the Evidence Documents Profile and the relevant transactions between them.
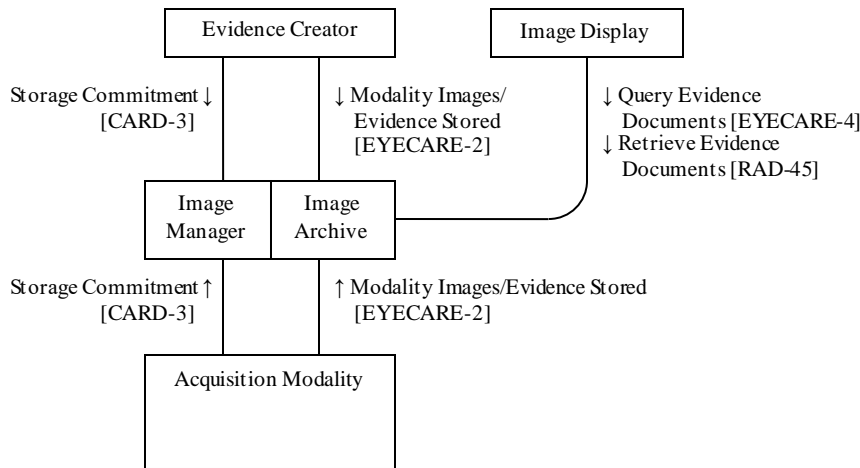
Figure 5.1-1: Evidence Documents Actor Diagram

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Table 5.1-1 lists the transactions for each actor directly involved in the Eye Care Evidence Documents 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 and that implementations may choose to support is listed in Section 5.2.

Table 5.1-1: Evidence Document Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section
Evidence Creator	Storage Commitment [CARD-3]	R	CARD TF- 2: 4.3
	Modality Images/Evidence Stored [EYECARE-2]	R	EYECARE TF- 2: 4.2
Acquisition Modality	Storage Commitment [CARD-3]	R	CARD TF- 2: 4.3
	Modality Images/Evidence Stored [EYECARE-2]	R	EYECARE TF- 2: 4.2
Image Manager/ Image Archive	Storage Commitment [CARD-3]	R	CARD TF- 2: 4.3
	Modality Images/Evidence Stored [EYECARE-2]	R	EYECARE TF- 2: 4.2
	Query Evidence Documents [EYECARE-4]	R	EYECARE TF- 2: 4.4
	Retrieve Evidence Documents [RAD-45]	R	RAD TF- 3: 4.45
Image Display	Query Evidence Documents [EYECARE-4]	R	EYECARE TF- 2: 4.4
	Retrieve Evidence Documents [RAD-45]	R	RAD TF- 3: 4.45

5.2 Evidence Documents Profile – Eye Care Options

The Options defined for the Eye Care domain that may be selected for this integration profile are listed in the Table 5.2-1 along with the actors to which they apply.

Table 5.2-1: Evidence Documents - Actors and Options

Actor	Options
Evidence Creator	*No options defined*
Acquisition Modality	*No options defined*
Image Manager/ Image Archive	*No options defined*
Image Display	*No options defined*

The Evidence Creator, Acquisition Modality and Image Manager/ Image Archive will likely support a variety of DICOM SOP Classes. Each DICOM SOP Class that is supported by the actor shall be listed in the product's DICOM Conformance Statement.

Note: The minimum set of DICOM SOP Classes that must be supported by eye care actors are defined in IHE Eye Care Volume 2 (see EYECARE TF-2: 4.2).

5.3 Eye Care Evidence Document Process Flow

720   Evidence Documents belong to the family of Evidence Objects such as measurements, post processing, images, presentation states, DICOM Structured Reports, etc. These are objects generated as a result of creating eye care diagnostic information after the patient has left the acquisition stage of the procedure.

As with other Evidence Objects, Evidence Documents are used in the process of creating a
725   Diagnostic Report, either by reviewing or interpreting the Evidence Document contents, or by copying selected parts into the Report. Evidence Documents represent the uninterrupted information that is primarily managed and used inside an eye care department, although distribution outside the department is not precluded.
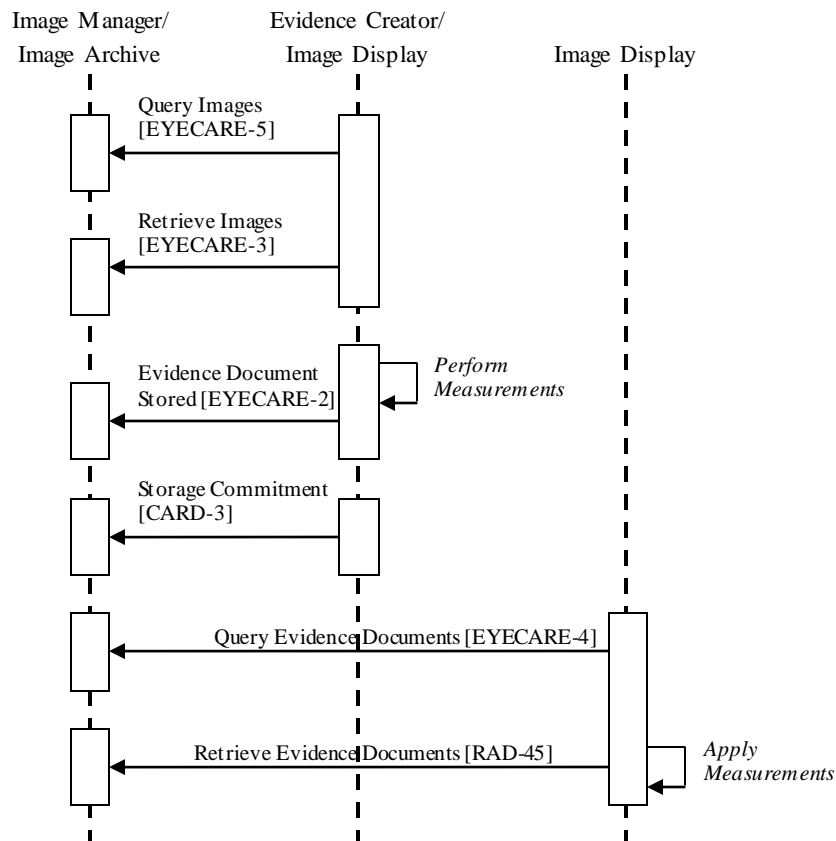
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Figure 5.3-1: Eye Care Evidence Document Workflow Example

5.4 Eye Care Evidence Documents Use Cases

This section describes the specific use cases defined for the Eye Care Evidence Documents Profile.

735   5.4.1   Eye Care Evidence Documents Being Created by Acquisition Modality

A typical use case for evidence documents include them being generated at the Acquisition Modality. A technician performs the acquisition, and the instrument performs implicit post-processing immediately following the acquisition. This may be entirely automatic, or require limited user inputs. An example is glaucoma progression analysis performed on visual field
740   analyzers, or the RNFL analysis performed on an OPT device. The instrument provides the evidence document at the end of the acquisition cycle.

5.4.2   Eye Care Evidence Documents Being Created by Workstations

This use case describes unscheduled post-processing done after the acquisition has completed. A few examples include a workstation using review software, an EHR system, etc. The post-
745   processing software performs as an Image Display and Evidence Creator. The user is often a healthcare provider. Examples are measurements on fundus images, corneal ablation planning based on corneal topography maps, or measurements on anterior chamber OCT images for phakic IOL implantation planning. The Evidence Creator (i.e., post-processing software) may perform queries and retrieves in order to obtain images and other evidence documents. For
750   example, if previous measurements were done, these may be retrieved and used as an input for making more refined measurements. Once the post-processing is completed, the images and/or evidence documents are sent to the Image Archive for storage and the ownership of the objects are handed off to the Image Archive using Storage commitment.

755   Note: A workstation and/or acquisition modality supporting the Eye Care Evidence Document Profile may perform a single query to obtain information about both images and evidence documents (i.e., two queries are not required). Similarly, when retrieving the information, one retrieve could be used to obtain both images and evidence documents.

6 Eye Care Displayable Report (ECDR)

The Displayable Reports Profile specifies transactions supporting the creation, query/retrieve, and reading of display-ready eye care reports. The ECDR Profile allows use of the DICOM Encapsulated Document IOD, which has emerged as a ubiquitous means of encoding documents ready for presentation, including graphical content. Furthermore, the ECDR Profile allows the reporting healthcare provider to control the "look" of the report, which is important for both clinical and business reasons.

Note: The types of Encapsulation documents supported are defined in EYECARE TF-2: 4.7, such as DICOM Encapsulated PDF SOP Class.

Note: The DICOM standard does not define use of a specific version of PDF when encapsulated PDF is used. This may result in incorrect display of reports when using a different PDF version of software from that which was used to create the files. Other issues arise when using only PDF with pixel data as the files are large and have difficulties with display. IHE EYECARE TF defines specific versions required for support see EYECARE TF-2: 4.7.

6.1 Actors/Transactions

Figure 6.1-1 diagrams the actors involved with this profile and the transactions between actors.

```
            ┌─────────────────────┐
            │   Report Creator    │
            └─────────────────────┘
                      │
          ↓ [EYECARE-7]: Displayable Report Storage
          ↓ [CARD-3]: Storage Commitment
                      │
            ┌─────────────────────┐
            │  Report Repository  │
            └─────────────────────┘
                      │
          ↑ {EYECARE-8}: Query Displayable Report
          ↑ [EYECARE-9]: Retrieve Displayable
          Report
                      │
            ┌─────────────────────┐
            │   Report Reader     │
            └─────────────────────┘
```
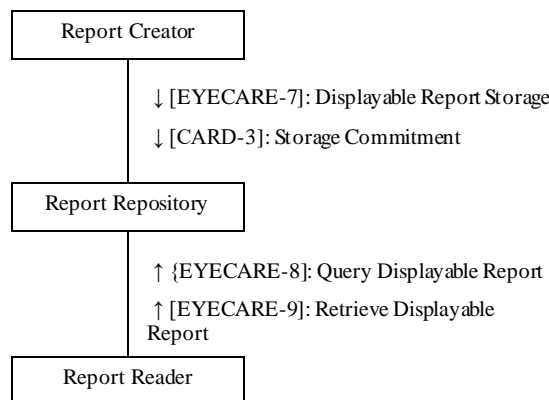
Figure 6.1-1: Eye Care Displayable Report Diagram

Table 6.1-1 lists the transactions for each actor directly involved in the Eye Care Displayable Report 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 and that implementations may choose to support is listed in Section 6.2.

Table 6.1-1: Eye Care Displayable Report - Actors and Transactions

Actors	Transactions	Optionality	Vol 2 / 3 Section
Report Creator	Displayable Report Storage [EYECARE-7]	R	EYECARE TF-2: 4.7

Actors	Transactions	Optionality	Vol 2 / 3 Section
	Storage Commitment [CARD-3]	R	CARD TF-2: 4.3
Report Reader	Query Displayable Reports [EYECARE-8]	R	EYECARE TF-2: 4.8
	Retrieve Displayable Reports [EYECARE-9]	R	EYECARE TF-2: 4.9
Report Repository	Displayable Report Storage [EYECARE-7]	R	EYECARE TF-2: 4.7
	Query Displayable Reports [EYECARE-8]	R	EYECARE TF-2: 4.8
	Retrieve Displayable Reports [EYECARE-9]	R	EYECARE TF-2: 4.9
	Storage Commitment [CARD-3]	R	CARD TF-2: 4.3

6.2 Eye Care Displayable Report Integration Profile Options

785 Options that may be selected for this integration profile are listed in the Table 6.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 6.2-1: Eye Care Displayable Report - Actors and Options

Actor	Options
Report Creator	*No options defined*
Report Reader	*No options defined*
Report Repository	*No options defined*

790 The Report Creator and Report Repository 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).

6.3 Eye Care Displayable Report Use Case

This section describes the specific use cases defined for the Eye Care Displayable Reports
795 Profile.

6.3.1 Typical Displayable Report Example

The healthcare provider is monitoring the progress of a patient who was diagnosed with glaucoma two years ago. The patient is in the clinic for a 3-month intraocular pressure check. During the physical exam in the clinic it is determined that the intraocular pressure in the right
800 eye is slightly elevated. The healthcare provider orders a Visual Field Test for both eyes. The patient has not had this test performed in the past twelve months and is scheduled for it. The Visual Field department notifies the healthcare provider when the Visual Field test is completed

and ready to be interpreted. Automated workflow notification processing is out of the scope of this profile. The Visual Field Modality produces an image that contains analytical metrics and a diagram of the patient's peripheral vision blind spots. The healthcare provider performs a query/retrieve to obtain the new images. In order to determine if the damage is consistent with what existed the last time this diagnostic test was done, the healthcare provider query/retrieves the Visual Field image that was created twelve months ago. The healthcare provider compares the images, usually in a side-by-side display. The healthcare provider's findings are explained in an interpretation narrative that is saved in the encapsulated document object. The plan for continued treatment is also described in the encapsulated document. The encapsulated interpretation document is stored in the Report Repository. The healthcare provider verifies the encapsulated interpretation DICOM object.

7 Basic Eye Care Workflow (B-EYECARE)

815 *Retired (Replaced by Unified Eye Care (U-EYECARE))*

See Basic Eye Care Workflow (B-EYECARE) Supplement – published 2012-04-16 at http://ihe.net/Technical_Framework_Archives/#eyecare.

8 Core Eye Care Workflow (C-EYECARE)

Retired (Replaced by Unified Eye Care (U-EYECARE))

820   See Core Eye Care Workflow (C-EYECARE) Supplement – published 2014-10-03 at
       http://ihe.net/Technical_Framework_Archives/#eyecare.

9 Unified Eye Care Workflow (U-EYECARE)

The Unified Eye Care Workflow (U-EYECARE) Integration Profile establishes the continuity and integrity of basic patient and procedure data in the context of an eye clinic workflow scenario. This profile deals specifically with consistent handling of patient identifiers and demographic data. It specifies the scheduling and coordination of procedure data to a wide variety of diagnostic imaging and testing equipment and the ability to post eye care charges.

This Unified Eye Care Workflow Profile takes the best features of previously defined workflows (which are now retired), combines them into one workflow profile, and provides more flexibility for three real world implementation models for systems such as EHRs and PACS.

An overview of the features is:

- **Patient Registration and Appointment Scheduling:**

  - These messages are typically sent between Practice Management Systems (PMS) and EHRs. Patient registration and updates to patient demographic data are based upon HL7 ADT messages (A04 and A08). Management of patient appointment data (i.e., new appointments, confirmed appointments, patient checked in, cancelled, deleted, etc.) is based upon HL7 SIU messages.

  - All HL7 messages in U-EYECARE utilize HL7 v2.5.1.

  - Optional features include merging patient IDs and the ability to post billing charges.

  - The patient registration and appointments workflow is the same for all real world implementation models.

  - See Section 9.1.1 and 9.4.1.

- Real World Model I - EHR Implements DICOM Modality Worklist and Integrates with a PACS:

  - Real World Model I addresses a scenario where organizations have a Practice Management System (PMS), Electronic Health Record System (EHR), centralized Image Archive, Image Display (PACS) and eye care diagnostic imaging and testing equipment (fundus cameras, slit lamps, refractive measurement devices, visual fields etc.).

  - This model specifies the Transactions and Actors required for the scenario where the DSS/Order Filler Actor (i.e., typically an EHR) supports DICOM Modality Worklist and is integrated with the Image Manager/Image Archive (i.e., typically a PACS).

  - See Section 9.1.2 and 9.4.2.

- Real World Model II - EHR Implements DICOM Modality Worklist, Image Storage and Display (With no PACS):

  - Real World Model II addresses a scenario where organizations have a Practice Management System (PMS), Electronic Health Record System (EHR) and eye care diagnostic imaging and testing equipment (fundus cameras, slit lamps, refractive

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measurement devices, visual fields etc.). The EHR performs the storage (not archive) and display of DICOM images, measurements, etc.

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- This model reduces the PACS implementation requirements of the other eye care workflows by not integrating an Image Archive (i.e., PACS system) and places more responsibility on the EHR and acquisition devices. **Therefore, users of this model must understand that acquisition devices and users are responsible for the safe keeping of the images and/or measurements created upon their system. It is important for users to determine how this is accomplished so that patient data is protected**. How this is accomplished is outside the scope of IHE.

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- This model specifies the Transactions and Actors required for the scenario where the DSS/Order Filler Actor (i.e., typically an EHR) supports DICOM Modality Worklist, Image Storage and Display. Real World Model II does not include an Image Manager/Image Archive Actor (i.e., a PACS system). Acquisition Modality Actors (i.e., eye care instruments) have the requirement to send selective images and/or measurements.

- See Section 9.1.3 and 9.4.3.

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- **Real World Model III - EHR Implements HL7 Only (no DICOM support) and Integrates with a PACS:**

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- Real World Model III addresses a scenario where organizations have a Practice Management System (PMS), Electronic Health Record System (EHR), centralized Image Archive, Image Display (PACS) and eye care diagnostic imaging and testing equipment (fundus cameras, slit lamps, refractive measurement devices, visual fields, etc.).

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- This model specifies the Transactions and Actors required for the scenario where the DSS/Order Filler Actor (i.e., typically an EHR) does <u>not</u> support DICOM and only implements HL7 messages. Therefore, the Image Manager/Image Archive supports DICOM Modality Worklist. All messages utilize HL7 v2.5.1.

- See Section 9.1.4 and 9.4.4.

- **Optional Transactions:**

- Some transactions, such as those based upon DICOM Modality Performed Procedure Step, DICOM Storage Commitment, are optional for actors in U-EYECARE.

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9.1 U-EYECARE Actors and Transactions

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://ihe.net/Technical_Frameworks/.

9.1.1 Patient Registration and Appointment Scheduling

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U-EYECARE enables many different real-world configurations and options. The figures below illustrate some of real-world configurations examples.do

Figure 9.1.1-1 shows the actors directly involved in the U-EYECARE Profile relevant to the patient registration and appointment scheduling workflow and the relevant transactions between them. The Actors and Transactions shown are supported in all Real World Models. Actors which
900 have a mandatory grouping are shown in conjoined boxes.

Note: Merge Patient ID [EYECARE-20] and Eye Care Charge Posted [EYECARE-17] are optional transactions.
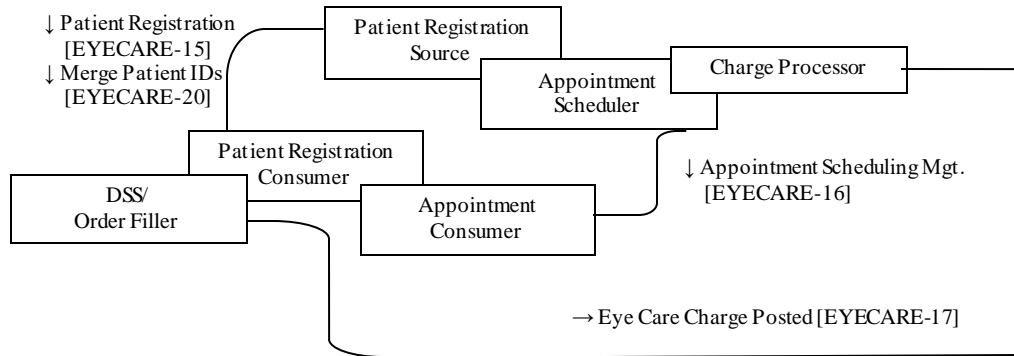
Figure 9.1.1-1: Patient Registration and Appointment Scheduling Workflow Diagram

905 IHE Eye Care does not specify real world systems that implement IHE Actors. However, certain Actors (and/or combination of Actors) often make sense for specific products. For example, a Practice Management System (PMS) real world product may be the type of system that implements the Patient Registration Source, Appointment Scheduler and Charge Processor Actors. An Electronic Heath Record (EHR) real world product may be the type of system that
910 implements the Patient Registration Consumer, Appointment Consumer and Department System Schedule/Order Filler (see Figure 9.1.1-2).

Note: Merge Patient ID [EYECARE-20] and Eye Care Charge Posted [EYECARE-17] are optional transactions.
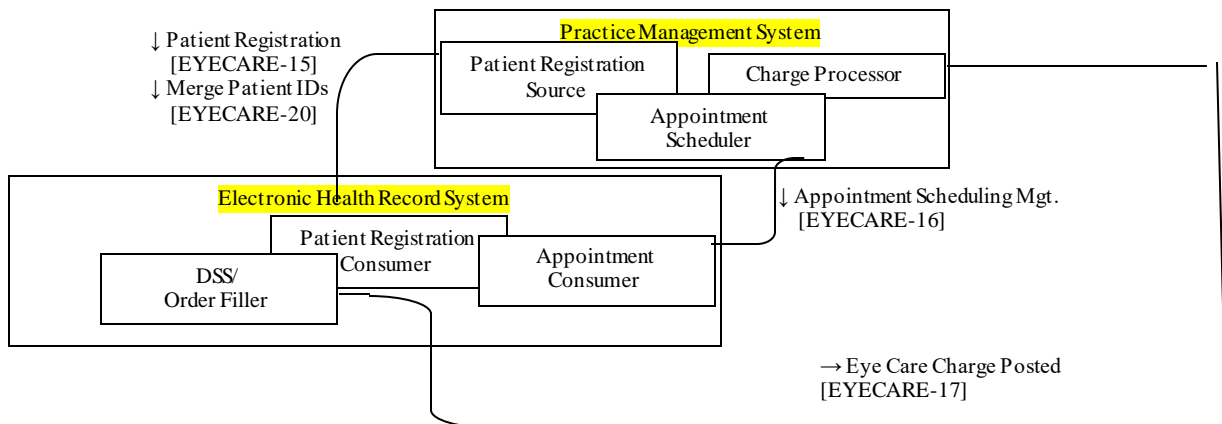
Figure 9.1.1-2: (Informative) Actors Mapping to Real World Systems

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9.1.2 Real World Model I - EHR Supports DICOM Modality Worklist and Integrates with a PACS

Real World Model I addresses a scenario where organizations have a Practice Management System (PMS), Electronic Health Record System (EHR), centralized Image Archive, Image

920 Display (PACS), and eye care diagnostic imaging and testing equipment (fundus cameras, slit lamps, refractive measurement devices, visual fields etc.).

Figure 9.1.2-1 shows the actors directly involved in the U-EYECARE Profile relevant to the scenario were the DSS/Order Filler (i.e., typically an EHR) supports DICOM Modality Worklist and is integrated with an Image Manager/Image Archive (i.e., typically a PACS). Actors which

925 have a mandatory grouping are shown in conjoined boxes. Only required transactions are shown, optional transactions have been omitted from the diagram.

> Note: The ability to display DICOM images, measurements and reports on an EHR is often a desired feature for users. If the EHR does not support DICOM display capabilities, they sometimes use proprietary mechanisms typically called a "context launch" that will run the PACS' display software on the EHR. How or if this is accomplished is
930 outside the scope of IHE.

Figure 9.1.2-1: Real World Model I - Workflow Diagram

935 ### 9.1.3 Real World Model II - EHR Supports DICOM Modality Worklist, Image Storage and Display (With no PACS)

Real World Model II addresses a scenario where organizations have a Practice Management System (PMS), Electronic Health Record System (EHR) and eye care diagnostic imaging and

940 testing equipment (fundus cameras, slit lamps, refractive measurement devices, visual fields etc.). The EHR performs the storage (not archive) and display of DICOM images, measurements, etc.

Figure 9.1.3-1 shows the actors directly involved in the U-EYECARE Profile relevant to the scenario were the DSS/Order Filler (i.e., typically an EHR) supports DICOM Modality Worklist, image storage and display. In this example there is no PACS system integrated. Actors which 945 have a mandatory grouping are shown in conjoined boxes. Only required transactions are shown, optional transactions have been omitted from the diagram.

Figure 9.1.3-1: Real World Model II - Workflow Diagram

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IHE Eye Care does not specify real world systems that implement IHE Actors. However, certain Actors (and/or combination of Actors) often make sense for specific products. For example, a Practice Management System (PMS) real world product may be the type of system that implements the Patient Registration Source and Appointment Scheduler Actors. An Electronic 955 Heath Record (EHR) real world product may be the type of system that implements the Patient Registration Consumer, Appointment Consumer, Department System Schedule/Order Filler and Image Storage/Display Actors (see Figure 9.1.3-2).
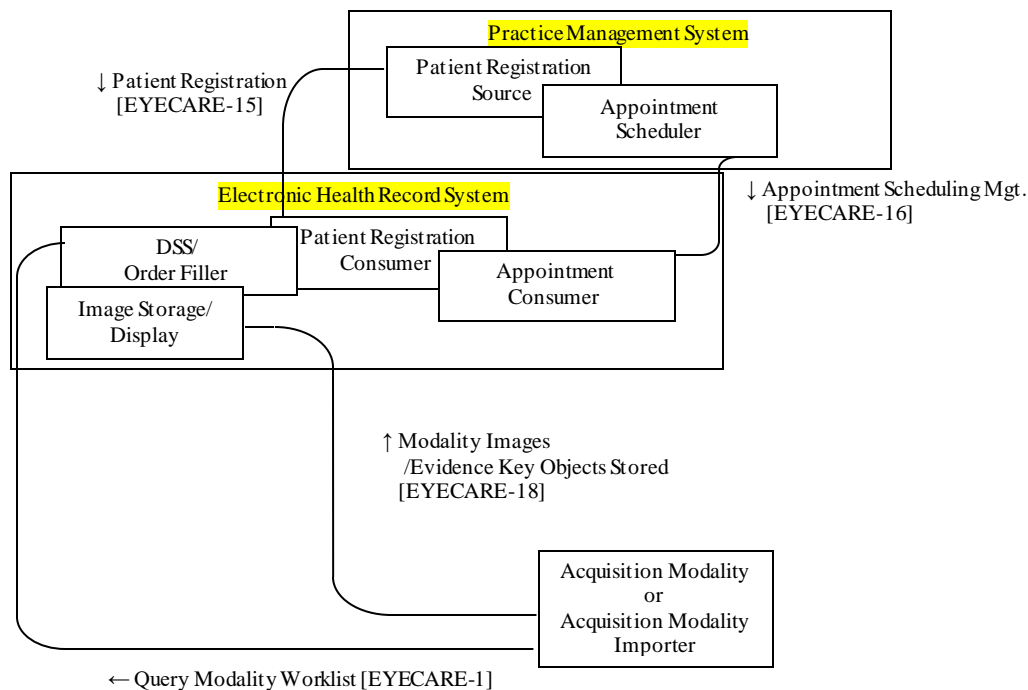
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Figure 9.1.3-2: (Informative) Actors Mapping to Real World Systems

9.1.4 Real World Model III - EHR Implements HL7 Only (no DICOM support) and Integrates with a PACS

965 Real World Model III addresses a scenario where organizations have a Practice Management System (PMS), Electronic Health Record System (EHR), centralized Image Archive, Image Display (PACS), and eye care diagnostic imaging and testing equipment (fundus cameras, slit lamps, refractive measurement devices, visual fields, etc.).

Figure 9.1.4-1 shows the actors directly involved in the U-EYECARE Profile relevant to the
970 scenario were the DSS/Order Filler (i.e., typically an EHR) does not support DICOM transactions (i.e., HL7 messages only), therefore the Image Manager/Image Archive supports DICOM Modality worklist. Actors which have a mandatory grouping are shown in conjoined boxes. Only required transactions are shown, optional transactions have been omitted from the diagram.

975 Note: The ability to display DICOM images, measurements and reports on an EHR is often a desired feature for users. If the EHR does not support DICOM display capabilities, they sometimes use proprietary mechanisms typically called a "context launch" that will run the PACS' display software on the EHR. How or if this is accomplished is outside the scope of IHE.
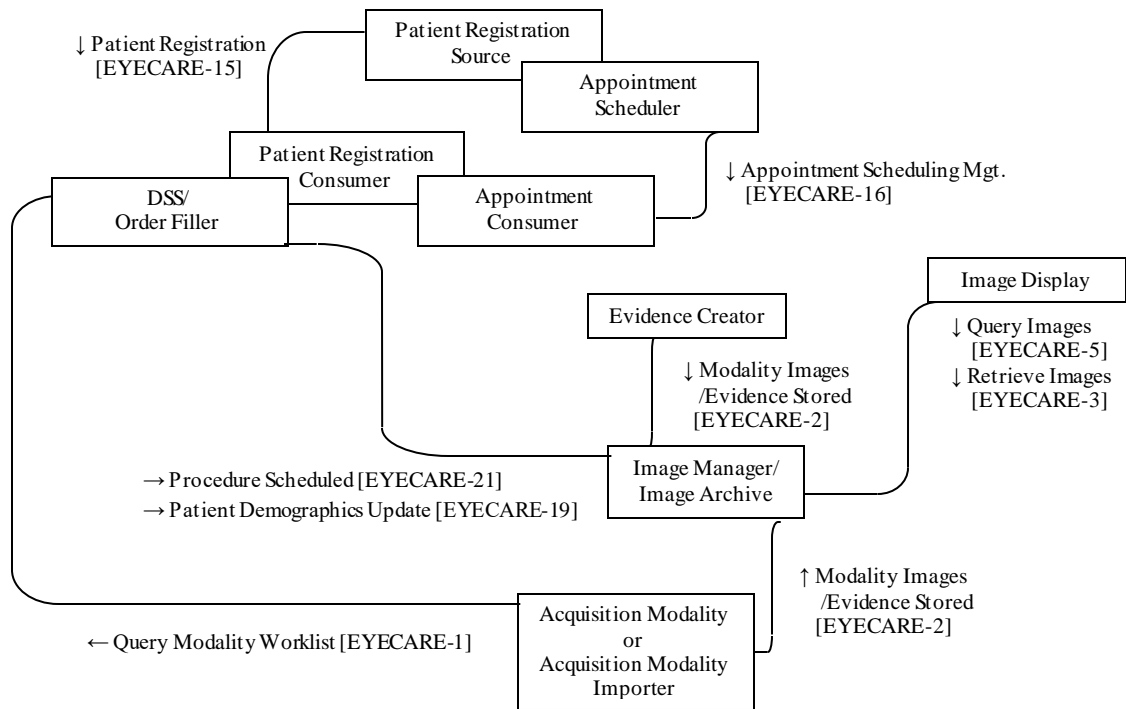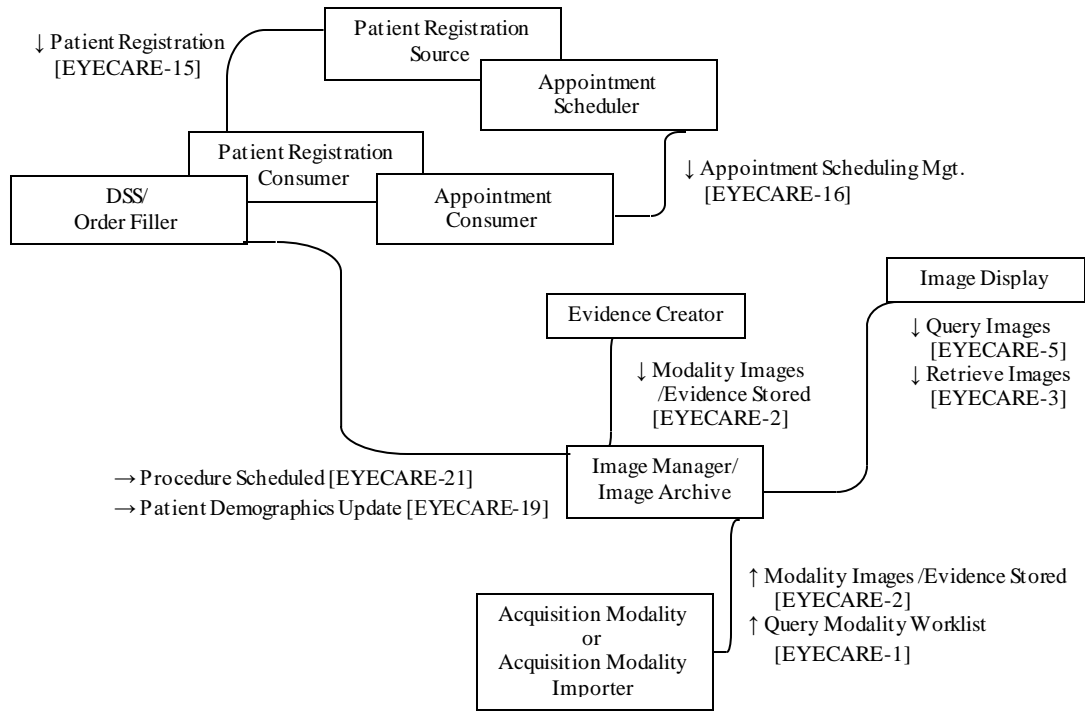
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Figure 9.1.4-1: Real World Model III - Workflow Diagram

9.1.5 U-EYECARE Workflow with DICOM Options

Figure 9.1.5-1 shows the actors directly involved in the U-EYECARE Profile relevant to the
985 required and optional transactions that extend the features of U-EYECARE. They are not
specific to any Real World Model and may be implemented for various workflow scenarios.
These options are defined in Table 9.2-1.
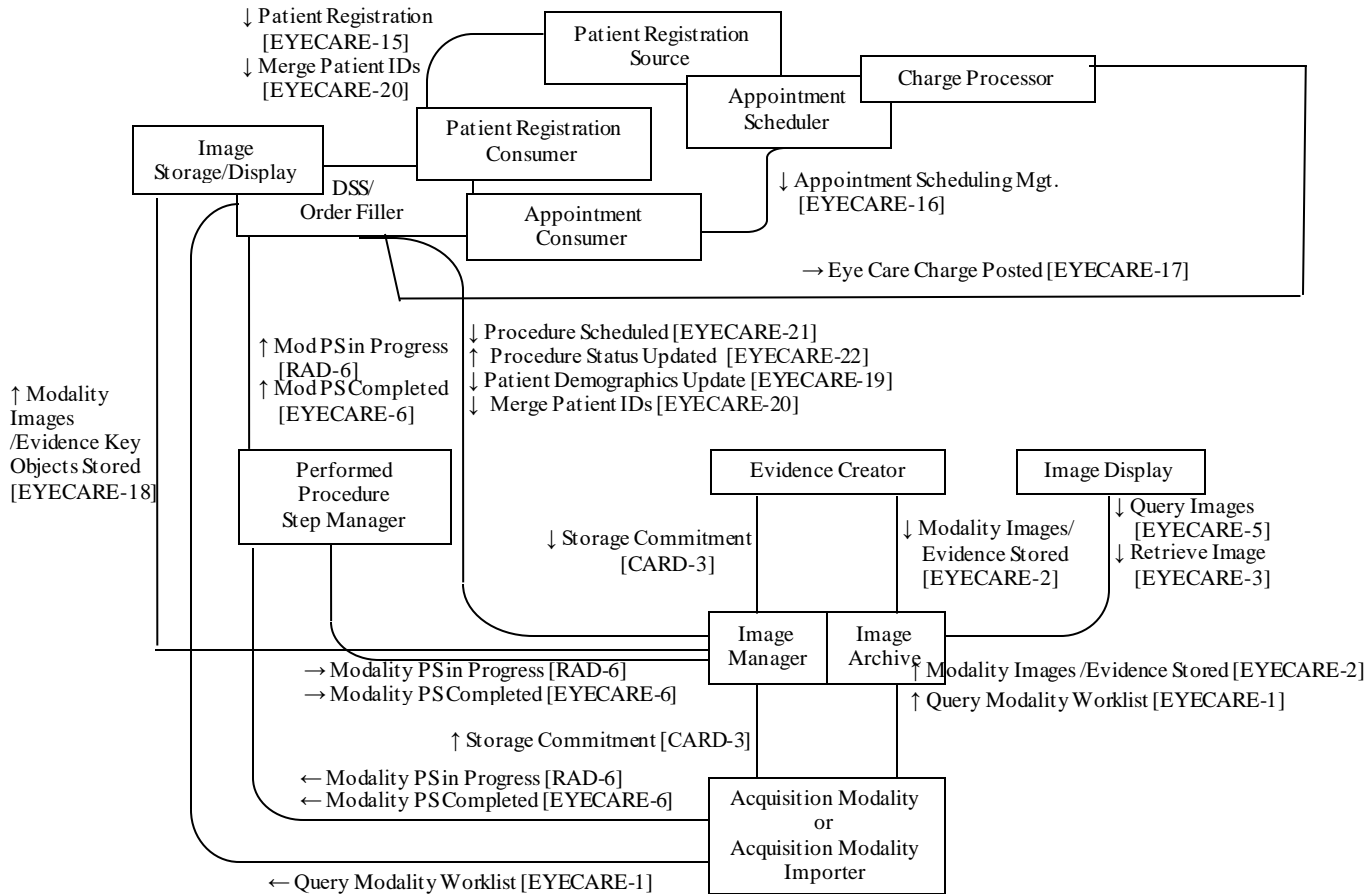
990

Figure 9.1.5-1: U-EYECARE Workflow with Options Diagram

9.1.6 U-EYECARE Actor/Transaction Table

Table 9.1.6-1 lists the transactions for each actor directly involved in the U-EYECARE Profile.
995 To claim compliance with this profile, an actor SHALL support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table 9.1.6-1: Unified Eye Care Workflow – Actors and Transactions

Actors	Transactions	Model I	Model II	Model III	Section
		Transaction Optionality			
Patient Registration Source	Patient Registration [EYECARE-15]	R	R	R	EYECARE TF-2: 4.15
Appointment Scheduler	Appointment Scheduling Management [EYECARE-16]	R	R	R	EYECARE TF-2: 4.16
Patient Registration Consumer	Patient Registration [EYECARE-15]	R	R	R	EYECARE TF-2: 4.15
Appointment Consumer	Appointment Scheduling Management [EYECARE-16]	R	R	R	EYECARE TF-2: 4.16
Department System Scheduler/ Order Filler	Patient Demographics Update [EYECARE-19]	R		R	EYECARE TF-2: 4.19
	Query Modality Worklist [EYECARE-1]	R	R		EYECARE TF-2: 4.1
	Procedure Scheduled [EYECARE-21]	R		R	EYECARE TF-2: 4.21
Image Manager/ Image Archive *(Not an Actor for Model II)*	Procedure Scheduled [EYECARE-21]	R		R	EYECARE TF-2: 4.21
	Patient Demographics Update [EYECARE-19]	R		R	EYECARE TF-2: 4.19
	Query Modality Worklist [EYECARE-1]			R	EYECARE TF-2: 4.1
	Modality Images/Evidence Stored [EYECARE-2]	R		R	EYECARE TF-2: 4.2
	Query Images [EYECARE-5]	R		R	EYECARE TF-2: 4.5
	Retrieve Images [EYECARE-3]	R		R	EYECARE TF-2: 4.3
Image Storage/Display *(Only required in Model II)*	Modality Images/Evidence Key Objects Stored [EYECARE-18]		R		EYECARE TF-2: 4.18
Image Display *(Not an Actor for Model II)*	Query Images [EYECARE-5]	R		R	EYECARE TF-2: 4.5
	Retrieve Images [EYECARE-3]	R		R	EYECARE TF-2: 4.3
Acquisition Modality	Query Modality Worklist [EYECARE-1]	R	R	R	EYECARE TF-2: 4.1
	Modality Images/Evidence Stored [EYECARE-2]	R		R	EYECARE TF-2: 4.2
	Modality Images/Evidence Key Objects Stored [EYECARE-18]		R		EYECARE TF-2: 4.18
Acquisition Modality Importer	Query Modality Worklist [EYECARE-1]	R	R	R	EYECARE TF-2: 4.1
	Modality Images/Evidence Stored [EYECARE-2]	R		R	EYECARE TF-2: 4.2
	Modality Images/Evidence Key Objects Stored [EYECARE-18]		R		EYECARE TF-2: 4.18
Charge Processor	Eye Care Charge Posted [EYECARE-17]	R	R	R	EYECARE TF-2: 4.17
Evidence Creator	Modality Images/Evidence Stored [EYECARE-2]	R		R	EYECARE TF-2: 4.2

Actors	Transactions	Model I	Model II	Model III	Section
		Transaction Optionality			
Performed Procedure Step Manager	Modality Procedure Step In Progress [RAD-6]	R			RAD TF-2: 4.6
	Modality Procedure Step Completed [EYECARE-6]	R			EYECARE TF-2: 4.6

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Note 1: An EHR real world product may be the type of system that implements the Patient Registration Consumer, Appointment Consumer and Department System Schedule/Order Filler Actors and possibly the Image Storage/Display Actor.

Note 2: A PMS real world product may be the type of system that implements the Patient Registration Source, Appointment Scheduler and Charge Processor Actors.

1005 ### 9.1.7 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile's actors and Real World Models.

9.1.7.1 Real World Models

1010 All Actors in U-EYECARE SHALL support their required transactions for one or more Real World Models.

9.2 U-EYECARE Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table 9.2-1. Dependencies between options when applicable are specified in notes. IHE does not place any
1015 restrictions on which options are supported for any of the Real World Models; however, some options do not make sense. For example, in Real World Model III the DSS/Order Filler does not support DICOM; therefore the optional transactions related to DICOM are not relevant.

Table 9.2-1: Unified Eye Care Workflow - Actors and Options

Actor	Option Name	Reference
Patient Registration Source	Patient Record Merging Option	EYECARE TF-1: 9.2.2
Appointment Scheduler	*No options defined*	--
Charge Processor	*No options defined*	--
Patient Registration Consumer	Patient Record Merging Option	EYECARE TF-1: 9.2.2
Appointment Consumer	*No options defined*	--
Department System Scheduler/Order Filler	Patient Record Merging Option	EYECARE TF-1: 9.2.2

Actor	Option Name	Reference
	Imaging Procedure Instructions Option	EYECARE TF-1: 9.2.3
	Imaging Procedure Status Update (DICOM) Option	EYECARE TF-1: 9.2.4
	Imaging Procedure Status Update (HL7) Option	EYECARE TF-1: 9.2.5
	Charge Posting Option	EYECARE TF-1: 9.2.7
	Procedure Status Tracking (DICOM MPPS) Option	EYECARE TF-1: 9.2.9
Image Manager/ Image Archive	Patient Record Merging Option	EYECARE TF-1: 9.2.2
	Eye Care Image Option	EYECARE TF-1: 9.2.1.1
	Encapsulated PDF Option for Evidence Documents	EYECARE TF-1: 9.2.1.2
	Eye Care Measurements Option	EYECARE TF-1: 9.2.1.3
	Imaging Procedure Status Update (DICOM) Option	EYECARE TF-1: 9.2.4
	Imaging Procedure Status Update (HL7) Option	EYECARE TF-1: 9.2.5
	Storage Commitment Option	EYECARE TF-1: 9.2.6
	Procedure Status Tracking (DICOM MPPS) Option	EYECARE TF-1: 9.2.9
	PACS Key Images Sent Option	EYECARE TF-1: 9.2.8
	Stereo Relationship Option	EYECARE TF-1: 9.2.1.5
	Imaging Procedure Instructions Option	EYECARE TF-1: 9.2.3
Image Display	Eye Care Image Option	EYECARE TF-1: 9.2.1.1
	Encapsulated PDF Option for Evidence Documents	EYECARE TF-1: 9.2.1.2
	Relative Image Position Coding Option	EYECARE TF-1: 9.2.1.4 EYECARE TF-2: 4.3.6
	Stereo Relationship Option	EYECARE TF-1: 9.2.1.5 EYECARE TF 2: 4.3.7
Image Storage/Display *(an optional actor in Model I and III)*	Eye Care Image Option	EYECARE TF-1: 9.2.1.1
	Encapsulated PDF Option for Evidence Documents	EYECARE TF-1: 9.2.1.2
	PACS Key Images Sent Option	EYECARE TF-1: 9.2.8
	Relative Image Position Coding Option	EYECARE TF-1: 9.2.1.4
	Eye Care Measurements Option	EYECARE TF-1: 9.2.1.3
Evidence Creator	Storage Commitment Option	EYECARE TF-1: 9.2.6

Actor	Option Name	Reference
Acquisition Modality	Patient Based Worklist Query Option (See Note 1)	EYECARE TF-2: 4.1
	Broad Worklist Query Option (See Note 1)	EYECARE TF-2: 4.1
	Eye Care Image Option (See Note 2)	EYECARE TF-1: 9.2.1.1
	Encapsulated PDF Option for Evidence Documents (See Note 2)	EYECARE TF-1: 9.2.1.2
	Eye Care Measurement Option	EYECARE TF-1: 9.2.1.3
	Imaging Procedure Status Update (DICOM) Option	EYECARE TF-1: 9.2.4
	Storage Commitment Option	EYECARE TF-1: 9.2.6
	Procedure Status Tracking (DICOM MPPS) Option	EYECARE TF-1: 9.2.9
	Relative Image Position Coding Option	EYECARE TF-1: 9.2.1.4
	Stereo Relationship Option	EYECARE TF-1: 9.2.1.5
	Imaging Procedure Instructions Option	EYECARE TF-1: 9.2.3
	Contrast Start Time Reporting in OP Images Option	EYECARE TF-1: 9.2.1.6
Acquisition Modality Importer	Patient Based Worklist Query Option (see Note 1)	EYECARE TF-2: 4.1
	Broad Worklist Query Option (see Note 1)	EYECARE TF-2: 4.1
	Eye Care Measurement Option	EYECARE TF-1: 9.2.1.3
	Eye Care Image Option (See Note 2)	EYECARE TF-1: 9.2.1.1
	Encapsulated PDF Option for Evidence Documents (See Note 2)	EYECARE TF-1: 9.2.1.2
	Imaging Procedure Status Update (DICOM) Option	EYECARE TF-1: 9.2.4
	Storage Commitment Option	EYECARE TF-1: 9.2.6
	Procedure Status Tracking (DICOM MPPS) Option	EYECARE TF-1: 9.2.9
	Relative Image Position Coding Option	EYECARE TF-1: 9.2.1.4
	Stereo Relationship Option	EYECARE TF-1: 9.2.1.5
	Imaging Procedure Instructions Option	EYECARE TF-1: 9.2.3
	Contrast Start Time Reporting in OP Images Option	EYECARE TF-1: 9.2.1.6
Performed Procedure Step Manager	*No options defined*	--

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Note 1: The Radiology TF requires that the Acquisition Modality support at least one of the Worklist Query Options (i.e., Patient-Based or Broad). Eye Care requires Acquisition Modality and Acquisition Modality Importer Actors to support BOTH the Patient-Based and Broad Worklist Query Options.

Note 2: The Acquisition Modality and Acquisition Modality Importer Actors SHALL support either the Eye Care Image Option or the Encapsulated PDF Option for Evidence Documents.

9.2.1 Acquisition Modalities Storage Options

The Acquisition Modality, Acquisition Modality Importer and Image Storage/Display Actors will likely support a variety of DICOM SOP Classes. It is expected that these will be documented by a reference in the IHE Integration Statement (see EYECARE TF-1: Appendix C). The options in this section 'raise the bar' by mandating support for additional features than defined in specific DICOM SOP classes.

9.2.1.1 Eye Care Image Option

The DICOM Standard defines certain Image Storage SOP Classes that are applicable to EYECARE Acquisition Modalities, such as Ophthalmic 8-bit Photography Image Storage, Ophthalmic Tomography Image Storage, etc. See EYECARE TF-2: 4.2.5 for the complete list of SOP Classes.

Acquisition Modality or Acquisition Modality Importer Actors that support the Eye Care Image Option SHALL support one or more SOP Classes listed in EYECARE TF-2: 4.2.5.

Image Manager/Archive and Image Storage/Display Actors that support this option SHALL be able to store all SOP Classes listed in listed in EYECARE TF-2:.4.2.5.

Image Display and Image Storage/Display Actors that support this option SHALL be able to display all SOP classes listed in EYECARE TF-2: Table 4.2.5-1. It is expected that an Image Display or Image Storage/Display that does not support this option will be able to display a subset of the SOP classes listed in the table.

9.2.1.2 Encapsulated PDF Option for Evidence Documents

Image SOP Classes for certain Eye Care Acquisition Modalities are yet to be defined in DICOM. These Acquisition Modalities support the Encapsulated PDF Option for Evidence Documents. An Acquisition Modality may choose to support the Encapsulated PDF Option which may be supported as an addition to the appropriate DICOM SOP Class.

Once the applicable SOP classes are defined by DICOM, it is recommended that the Acquisition Modalities support the Eye Care Image Option with the appropriate DICOM SOP Class.

Note 1: For example, in IHE Eye Care Year 1 there was not a DICOM SOP class defined for Ophthalmic Tomography, therefore, these types of Acquisition Modalities only had the capability to support the Encapsulated PDF Option for Evidence Documents. But in Year 2 DICOM has defined such a SOP Class, therefore, they are recommended to support the approved DICOM SOP Class and additionally they may also support the Encapsulated PDF Option.

Note 2: The DICOM standard does not define use of a specific version of PDF when encapsulated PDF is used. This may result in incorrect display of reports when using a different PDF version of software from that which was used to create the files. Other issues arise when using only PDF with pixel data as the files are large and there may be difficulties with display.

Acquisition Modality, Image Manager/Image Archive and Image Storage/Display Actors that support this option SHALL comply with the storage requirements in EYECARE TF-2: 4.2.6.

Image Display and Image Storage Display Actors that support this option SHALL be able to display the SOP class listed in EYECARE TF-2: Table 4.2.6-1.

9.2.1.3 Eye Care Measurement Option

1065 Acquisition Modalities that support the Eye Care Measurement Option SHALL support one or more of the DICOM Measurement Storage SOP Classes that are applicable to EYECARE Acquisition Modalities, such as Lensometry Measurement Storage, Subjective Refraction Measurement Storage, etc., see EYECARE TF-2: 4.2.7 for the complete list of SOP Classes.

The Image Manager/Image Archive and Image Storage/Display Actors that support this option
1070 SHALL support all SOP Classes in EYECARE TF-2: 4.2.7.

9.2.1.4 Relative Image Position Coding Option

When a healthcare provider is reading fundus photos it is occasionally difficult to determine what location in the retina, or even which eye, he or she is viewing. Laterality (right vs. left eye) is a required attribute in DICOM Ophthalmic Photography Image SOP Classes, enabling image
1075 display vendors to display this information. However, the DICOM attribute Relative Image Position Code Sequence is an optional attribute and often not conveyed in the OP images. The Relative Image Position Coding Option requires this information to be conveyed by Acquisition Modality Actors.

When Acquisition Modality Actors support this option it enables Image Display and Image
1080 Storage/Display Actors to display field position clearly to the user.

Healthcare providers reading fundus images often are most comfortable viewing them in a particular order. The characteristics of this choice are user specific and may vary among healthcare providers. Implementation of the Relative Image Position Coding Option also enables Image Display and Image Storage/Display Actors to provide this functionality.

1085 As an example of implicit display of relative image position, the Image Display or Image Storage/Display Actor may display exactly those images in an OP series that have been tagged with relative image position codes corresponding to a particular protocol such as the Joslin 3-field protocol. Their absolute location of those images in the display layout should then be a function of their relative image position codes. In this example, the application may choose to
1090 display or not to display other images in the series (effectively "rejects" relative to the protocol); however, if such rejects are displayed, their position in the display layout should unambiguously indicate their lack of relative image position codes.

The Image Display and Image Storage/Display Actors may have alternate display modes that do not show the relative image position; for example, they may allow the user to toggle the direct
1095 display of relative image position code meanings on or off, or it may allow toggling between display of all images in a series or a display layout conforming to a particular protocol.

The Relative Image Position Option for an Image Display and Image Storage/Display Actor does not specify a mechanism for hanging protocols for OP images, although hanging protocols supporting relative image position codes may be used to satisfy the requirements. Other
1100 attributes such as laterality, acquisition date and time, etc., should also be considered for hanging protocols.

The eye care domain may utilize many different image position codes (such as Diabetic Retinopathy Study fields, Joslin fields, etc.). DICOM CID 4207 is the location where this list is

1105 managed. Since healthcare providers may wish to utilize image position codes beyond what is defined in DICOM CID 4207 according to other acquisition protocols, this option also requires that Acquisition Modality Actors be able to configure additional codes (beyond what is defined by DICOM CID 4207) based upon IHE extensions and the requirements of the user.

> 1110 Note: IHE has submitted the IHE extended codes to DICOM and they have been added to DICOM CID 4207. Implementations are recommended to use the updated codes specified in DICOM CID 4207 instead of the IHE codes. However, Image Display Actors are recommended to support both DICOM and IHE codes for backwards compatibility.

It should be understood that relative image position codes are not intended to communicate laterality or stereometric relationship information, there being other DICOM attributes and objects for these other purposes.

1115 Acquisition Modality or Acquisition Modality Importer Actors supporting this option SHALL support Relative Image Position Coding Option in EYECARE TF-2: 4.2.8.

Image Display and Image Storage/Display Actors supporting this option SHALL support Relative Image Position Coding Option in EYECARE TF-2: 4.3.6

9.2.1.5 Stereo Relationship Option

1120 Stereo photography such as for the optic disk requires determination of the stereo relationships between two OP images. The DICOM standard provides a mechanism for storing separate stereo relationship objects referencing the left and right images. Typical real world examples of usage include:

Glaucoma - A patient with a family history of glaucoma presents for a routine eye examination
1125 and was found to have elevated intraocular pressure and optic cup enlargement and asymmetry. The ophthalmologist ordered a glaucoma work-up including stereoscopic photographs of the optic nerve head bilaterally. The ophthalmic photographer obtains non-simultaneous stereo pair photographs of the optic nerve head in both eyes. The images are used for serial follow-up of the discs using a handheld stereoscopic viewing device.

1130 **Diabetic macular edema** - A patent with a 15-year history of type II diabetes presents for teleretinal screening of diabetic retinopathy. A standard 7 field ETDRS series is obtained with non-simultaneous stereoscopic pairs obtained for each of the standard fields captured. The patient had difficulty remaining still, and the photographer was fairly certain that some of the peripheral photos had vertical disparity in the stereo pairs. The images are used for evaluation of
1135 the macula using a CRT and polarizing stereoscopic goggles.

Macular hole - A patient with a history of old trauma in the right eye presented for evaluation of chronically decreased vision. Clinical examination was consistent with a full thickness macular hole, and stereoscopic photographs of the macula were ordered. A 30-degree color photograph centered on the fovea was obtained with a camera that used fixed angle "simultaneous" capture
1140 of a stereoscopic pair for photo documentation of the condition.

Acquisition Modality or Acquisition Modality Importer Actors supporting this option SHALL support Stereo Relationship Option in EYECARE TF-2: 4.2.9.

Image Archive and Image Display Actors supporting this option SHALL support Stereo Relationship Option in EYECARE TF-2: 4.3.7.

9.2.1.6 Contrast Start Time Reporting in OP Images Option

The time stamp for initiation of contrast injection is termed Contrast Bolus start time. Timing of contrast injection is very important in some clinical settings, but due to variable clinical workflow in ophthalmic angiography there is potential for this data field to not strictly represent the contrast injection time. The only way to control quality of this data is through proper implementation of the OP acquisition modality. This hinges on proper manufacturers' documentation, end user training, and strict attention to protocol during operation. Clinical settings where this feature may be useful include a variety of cerebral and ocular vascular occlusive diseases such as carotid artery occlusion, and central retinal artery/vein occlusion. As an example, in carotid occlusive disease a significant delay in the arm to retinal circulation time (ARCT) could be used to facilitate risk stratification for further cerebrovascular and cardiovascular work-up.

Acquisition Modality or Acquisition Modality Importer Actors that support this option SHALL support Contrast Start Time Reporting in OP Images in EYECARE TF-2: 4.2.10.

9.2.1.7 Radiological Studies of the Eye

Eye care healthcare providers frequently order radiological studies of the eye and surrounding anatomy. In many instances the interpretation of the study by a radiologist is all that is required. However, in certain instances such as suspected disease or trauma of the orbit (eye socket) or sinuses the ophthalmologist considers both a radiologist report and personal evaluation of the imaging study. One common example would be an orbital CT scan looking for fracture of the orbital floor, which may require surgical repair. Another example is the use of an orbital MRI looking for suspected tumor. Plain x-ray films of the facial bones may be obtained when there is trauma near the eye. In all these instances the ophthalmologist gains specific diagnostic value by his or her own evaluation of the images and may also use this function in the OR to guide surgical intervention.

Image Display and Archive Actors are recommended to support the radiological SOP Classes defined in EYECARE TF- 2:4.2.5.

9.2.2 Patient Record Merging Option

This option allows the Patient Registration Source (i.e., PMS) to control the Patient Registration Consumer (i.e., EHR) to merge patient records when needed. Otherwise, manual steps are required in the DSS/Order Filler to keep the database "clean" and synchronized with the Patient Demographic Source.

It also allows the DSS/Order Filler (i.e., EHR) to control the Image Manager/Image Archive to merge patient records when needed. Otherwise, manual steps are required in the Image Manager/Image Archive to keep the database "clean" and synchronized with DSS/Order Filler.

The Patient Registration Source, Patient Registration Consumer, DSS/Order Filler or Image Manager Archive that supports this option SHALL support the Merge Patient IDs [EYECARE-20] transaction (see EYECARE TF-2: 4.20).

9.2.3 Imaging Procedure Instructions Option

This option allows the healthcare provider to convey electronic instructions to the technician or photographer who will perform the imaging procedure. For example, there might be instructions to tape the eyelids while performing a visual field or to concentrate on a specific region of the eye during the early stage of an angiogram, etc.

In Model I and II:

- a DSS/Order Filler that supports this option SHALL be able to transmit procedure instructions in the DICOM Modality Worklist to an Acquisition Modality or Acquisition Modality Importer as defined in EYECARE TF-2: 4.1.6.

In Model III:

- a DSS/Order Filler that supports this option SHALL be able to transmit procedure instructions to the Image Manager/Image Archive in the NTE segment in Procedure Scheduled [EYECARE-21] as defined in EYECARE TF-2: 4.21.4.1.2.7.

- an Image Manager/Image Archive that supports this option SHALL receive the procedure instructions in the NTE segment in Procedure Scheduled [EYECARE-21] and transmit them in the DICOM Modality Worklist to an Acquisition Modality or Acquisition Modality Importer as defined in EYECARE TF-2: 4.21.4.1.2.7 and EYECARE TF-2: 4.1.6.

In Model I, II and III:

- an Acquisition Modality or Acquisition Modality Importer that supports this option SHALL be able to receive instructions in the DICOM Modality Worklist and SHALL be able to displays the instructions to the technician prior to performing the procedure as defined in EYECARE TF-2: 4.1.6.

9.2.4 Imaging Procedure Status Update (DICOM) Option

This option allows the DSS/Order Filler (i.e., EHR) to display the imaging procedure status and signal the doctor that the interpretation should be performed. The imaging procedure status is conveyed by an Acquisition Modality or Acquisition Modality Importer that send DICOM Modality Performed Procedure Step messages to signal the imaging procedure status.

An Acquisition Modality, Acquisition Modality Importer, DSS/Order Filler, or Image Manager/Image Archive that supports this option SHALL support the Modality Procedure Step in Progress [RAD-6] and Modality Procedure Step Completed [EYECARE-6] transactions. See RAD TF-2: 4.6 and EYECARE TF-2: 4.6.

Note: This option is not applicable to a DSS/Order Filler in Model III since it does not support DICOM Modality Performed Procedure Step.

9.2.5 Imaging Procedure Status Update (HL7) Option

This option allows the DSS/Order Filler (i.e., EHR) to display the imaging procedure status and signal the doctor that the interpretation should be performed. The imaging procedure status is conveyed by an Image Manager/Image Archive that sends HL7 messages to signal the imaging procedure status (e.g., images and/or measurements have been archived and are available for

interpretation. It also provides an optional ability to for an Image Manager/Image Archive to convey a reference pointer (i.e., URL) to one or more images/measurements.

An Image Manager/Image Archive or DSS/Order Filler that support this option SHALL support the Procedure Status Update [EYECARE-22] transaction.

> Note: This option is not applicable to a DSS/Order Filler in Model II since there is no Image Manager/Image Archive in that Model to initiate the EYECARE-22 transaction.

9.2.6 Storage Commitment Option

DICOM Storage Commitment enables formal release of storage responsibility from the Acquisition Modality, Acquisition Modality Importer, or Evidence Creator to the Image Manager/Image Archive, allowing the Modality to reuse its internal resources allocated to the study.

The Acquisition Modality, Acquisition Modality Importer, Evidence Creator or Image Manager/Image Archive that supports this option SHALL support the Storage Commitment [CARD-3] transaction (see CARD TF-2: 4.3).

9.2.7 Charge Posting Option

This option allows the DSS/Order (i.e., EHR) to post charges for both technical and professional charge components to the Charge Processing System (i.e., PMS), using the [EYECARE-17] transaction to convey the charge posting information.

A DSS/Order Filler that supports the Charge Posting Option SHALL support the [EYECARE-17] transaction (see EYECARE TF-2: 4.17).

9.2.8 PACS Key Images Sent Option

This option allows the Image Manager/Image Archive to send key images/measurements to an Image Storage/Display (i.e., EHR). It enables the ability for the EHRs to store and display key images/measurements as part of the patient's medical record by integrating the Image Storage/Display Actor. It is an option that may be used by an Image Manager/Image Archive and an EHR with an Image Storage/Display participating in Real World Model I.

The Image Manager/Image Archive in Real World Model I that supports this option SHALL support the Modality Images/Evidence Key Objects Stored [EYECARE-18] transaction as a C-STORE SCU.

The Image Storage/Display that supports this option SHALL be grouped with the Patient Registration Consumer, Appointment Consumer, and DSS/Order Filler Actors (i.e., the EHR) in Real World Model I and supports the Modality Images/Evidence Key Objects Stored [EYECARE-18] transaction as a C-STORE SCP.

9.2.9 Procedure Status Tracking (DICOM MPPS) Option

Procedure Status Tracking enables users to provide tracking information for procedures being performed on a patient. It is provided at the point of acquisition from the Acquisition Modality and/or Acquisition Modality Importer Actors. This option specifies the use of DICOM Modality Performed Procedure Step (MPPS).

1260 DICOM MPPS provides procedure statuses such as in progress, completed and discontinued. It lists DICOM images, measurements, reports and/or Encapsulated PDF documents generated on the acquisition device. It also captures scheduled procedure information/codes and the procedure code that was actually performed (which may be the same as what was scheduled or different). The performed procedure code facilitates the ability to capture billing charges related to the
1265 performed procedure (a DSS/Order Filler feature).

The DSS/Order Filler and/or Image Manager/Image Archive Actors receive the DICOM MPPS messages which enables tracking the progress of the patient's procedure on the system and to the user.

The Acquisition Modality or Acquisition Modality Importer that supports this option SHALL
1270 implement the transactions Modality Procedure Step in Progress [RAD-6] (defined in IHE RAD TF-2: 4.6) and Modality Procedure Step Completed [EYECARE-6] (defined in IHE EYECARE TF-2: 4.6) as a DICOM SCU.

The DSS/Order Filler or Image Manager/Archive that supports this option SHALL implement the transactions Modality Procedure Step in Progress [RAD-6] (defined in IHE RAD TF-2: 4.6)
1275 and Modality Procedure Step Completed [EYECARE-6] (defined in EYECARE TF-2: 4.6) as a DICOM SCP.

9.3 U-EYECARE Actor Groupings

9.3.1 U-EYECARE Required Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions and/or
1280 content modules in this profile in addition to all of the transactions required for the grouped actor (Column 2).

If this is a content profile, and actors from this profile are grouped with actors from a workflow or transport profile, the Content Bindings reference column references any specifications for mapping data from the content module into data elements from the workflow or transport
1285 transactions.

In some cases, required groupings are defined as at least one of an enumerated set of possible actors; this is designated by merging column one into a single cell spanning multiple potential grouped actors. Notes are used to highlight this situation.

These groupings apply to all Real World Models.

1290 Note: Requirements for grouping of actors are enumerated in the table below. Implementations must support all of the grouped actors if they support the U-EYECARE Actor listed in column 1. For example, implementations supporting a Patient Registration Consumer (row 4), must support the grouped actors Appointment Consumer, and Department System Scheduler/Order Filler.

1295 **Table 9.3-1: U-EYECARE - Required Actor Groupings**

U-EYECARE Actor	U-EYECARE Actor to be grouped with
Patient Registration Source (Note 1)	Appointment Scheduler
Appointment Scheduler	Patient Registration Source

U-EYECARE Actor	U-EYECARE Actor to be grouped with
Charge Processor	Patient Registration Source
	Appointment Scheduler
Patient Registration Consumer	Appointment Consumer
	Department System Scheduler/Order Filler
Appointment Consumer	Department System Scheduler/Order Filler
	Patient Registration Consumer
Department System Scheduler/Order Filler	Patient Registration Consumer
	Appointment Consumer
Image Storage/Display	Department System Scheduler/Order Filler
	Patient Registration Consumer
	Appointment Consumer
Acquisition Modality	None
Acquisition Modality Importer	None

Note 1: There are optional groupings specified to support Charge Posting. See Section 9.2.7.

9.3.1.1 Additional U-EYECARE Required Actor Groupings

For Real World Model II, the DSS/Order Filler Actor SHALL be grouped with the Image Storage/Display Actor.

9.4 Unified Eye Care Workflow Process Flow

9.4.1 Patient Registration, Appointment Scheduling, Charge Posting

The Eye Care administrative process relevant to the patient registration, appointment scheduling and the optional charge posting process flow is shown in Figure 9.4.1-1. The functionality of those data flows is specified within the specific transactions invoked by the EYECARE Technical Framework.
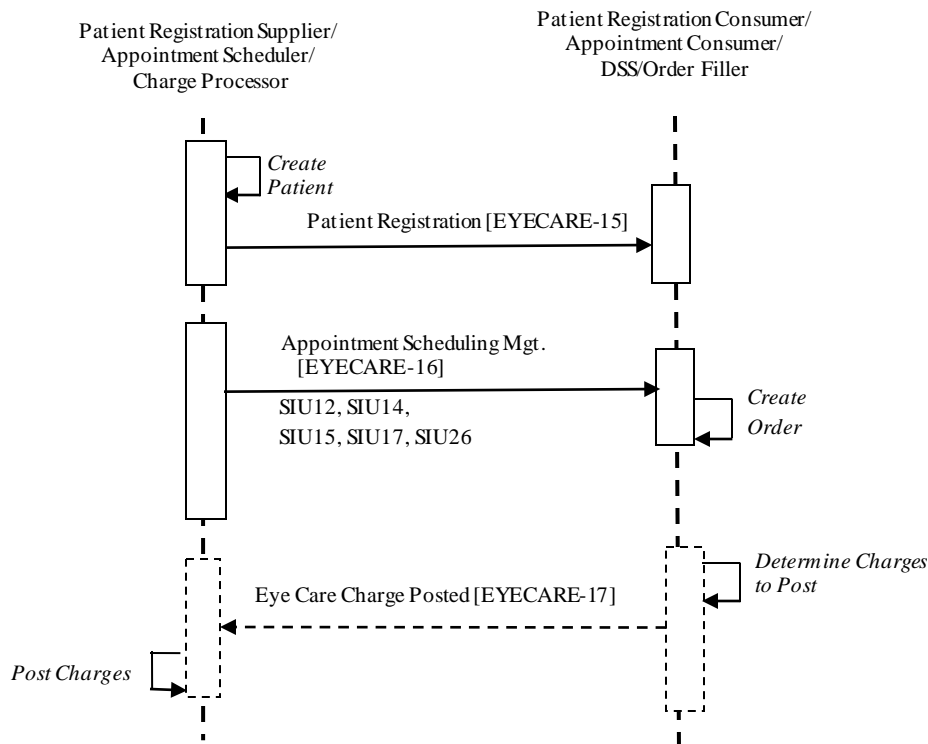
Figure 9.4.1-1: Patient Registration, Appointment Scheduling, Charge Posting Workflow - Administrative Process Flow

1310   The following should be noted in relation to the Administrative process flow:

- *Patient Registration*: New patient demographics and updates are sent to consuming systems.

- *Appointment Scheduling*: The patient's appointment is created/managed and sent to consuming systems. This includes new appointments, updates such as confirmed, arrived,

1315   checked in, complete. It also supports cancel/delete appointments and patient no shows.

- *Create Order*: The DSS/OF creates patient orders internal to its system.

- *Charge Posted*: The DSS/Order Filler provides charging information to the Charge Processor and the Charge Processor post the charges.

9.4.2 Real World Model I - EHR Supports DICOM Modality Worklist and Integrates
1320   ### with a PACS

Real World Model I addresses a scenario where organizations have a Practice Management System (PMS), Electronic Health Record System (EHR), centralized Image Archive, Image Display (PACS) and eye care diagnostic imaging and testing equipment (fundus cameras, slit lamps, refractive measurement devices, visual fields etc.).

1325   The Eye Care administrative process flow relevant to the scenario where the DSS/Order Filler
(i.e., typically an EHR) supports DICOM Modality Worklist and is integrated with an Image
Manager/Image Archive (i.e., typically a PACS). The process flow is shown in Figure 9.4.2-1.
The functionality of those data flows is specified within the specific transactions.
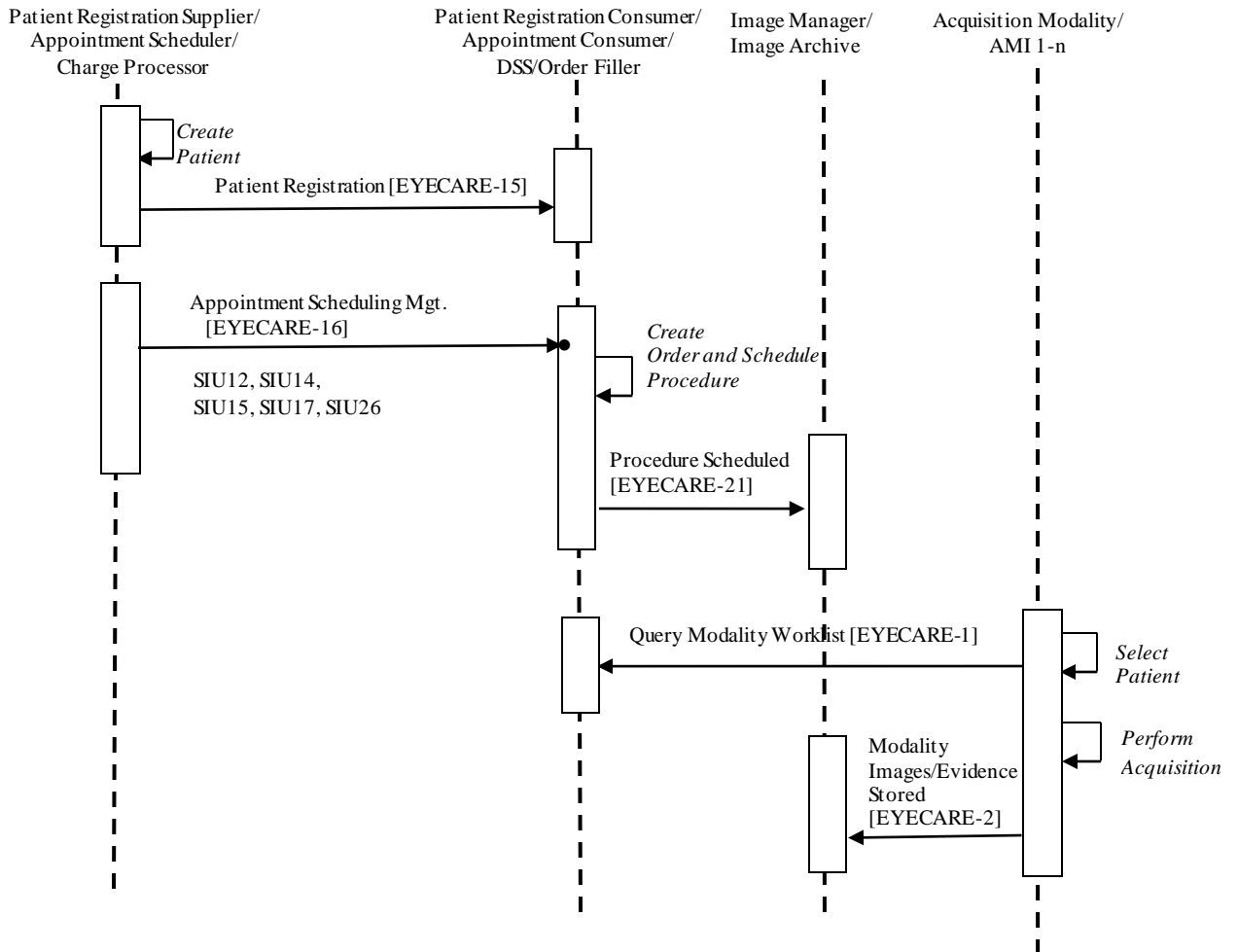
1330   **Figure 9.4.2-1: Real World Model I - Administrative Process Flow**

- *Patient Registration*: New patient demographics and updates are sent to consuming
  systems.

- *Appointment Scheduling*: The patient's appointment is created/managed and sent to
1335   consuming systems. This includes new appointments, updates such as confirmed, arrived,
  checked in, complete. It also supports cancel/delete appointments and patient no shows.

- *Create Order*: The DSS/OF creates patient orders internal to its system.

- *Scheduled 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

1340   prescribes a number of actions that have to be performed by Acquisition Modalities and Acquisition Modality Importers. 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.

1345   • *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). Eye Care procedures may be performed on multiple Acquisition Modalities or Acquisition Modality Importers; therefore, multiple devices may perform the queries.

1350   • *Select Patient*: The patient is selected from the worklist.

    • *Perform Acquisition*: Each Modality may produce a variety of images and other evidence (visual fields, refractive and biometry information, etc.). The DICOM SOP instances are stored to the Image Manager/Image Archive.

9.4.3 Real World Model II - EHR Supports DICOM Modality Worklist, Image
1355   ### Storage and Display (With no PACS)

Real World Model II addresses a scenario where organizations have a Practice Management System (PMS), Electronic Health Record System (EHR) and eye care diagnostic imaging and testing equipment (fundus cameras, slit lamps, refractive measurement devices, visual fields etc.). The EHR performs the storage (not archive) and display of DICOM images, measurements,
1360   etc.

The Eye Care administrative process flow relevant to the scenario where the DSS/Order Filler (i.e., typically an EHR) supports DICOM Modality Worklist, image storage and display. The process flow is shown in Figure 9.4.3-1. The functionality of those data flows is specified within the specific transactions.

1365

Figure 9.4.3-1: Real World Model II - Administrative Process Flow

1370
- *Patient Registration*: New patient demographics and updates are sent to consuming systems.

- *Appointment Scheduling*: The patient's appointment is created/managed and sent to consuming systems. This includes new appointments, updates such as confirmed, arrived, checked in, complete. It also supports cancel/delete appointments and patient no shows.

1375
- *Create Order*: The DSS/OF creates patient orders internal to its system.

- *Scheduled 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 and Acquisition Modality Importers. Actions are specified in Scheduled Procedure Steps

1380
(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). Eye Care procedures may be performed on multiple Acquisition Modalities or Acquisition Modality Importers, therefore, multiple devices may perform the queries.

- *Select Patient*: The patient is selected from the worklist.

- *Perform Acquisition*: Each Modality may produce a variety of images and other evidence (visual fields, refractive and biometry information, etc.). The key DICOM SOP instances are selected and stored to the Image Storage/Display. The Image Storage/Display is highly recommended to support all the object types as specified by the Eye Care Image Option, the Eye Care Measurement Option and the Encapsulated PDF Option (see EYECARE TF-2: 4.2).

- *Store and Display Objects*: The Image Storage/Display Actor stores the DICOM SOP Instances and is able to display them to the user of the system.

9.4.4 Real World Model III - EHR Implements HL7 Only (no DICOM support) and Integrates with a PACS

Real World Model III addresses a scenario where organizations have a Practice Management System (PMS), Electronic Health Record System (EHR), centralized Image Archive, Image Display (PACS) and eye care diagnostic imaging and testing equipment (fundus cameras, slit lamps, refractive measurement devices, visual fields, etc.).

The Eye Care administrative process flow relevant to the scenario where the DSS/Order Filler (i.e., typically an EHR) does not support DICOM transactions (i.e., HL7 messages only), therefore the Image Manager/Image Archive supports DICOM Modality Worklist. The process flow is shown in Figure 9.4.4-1. The functionality of those data flows is specified within the specific transactions.

1410

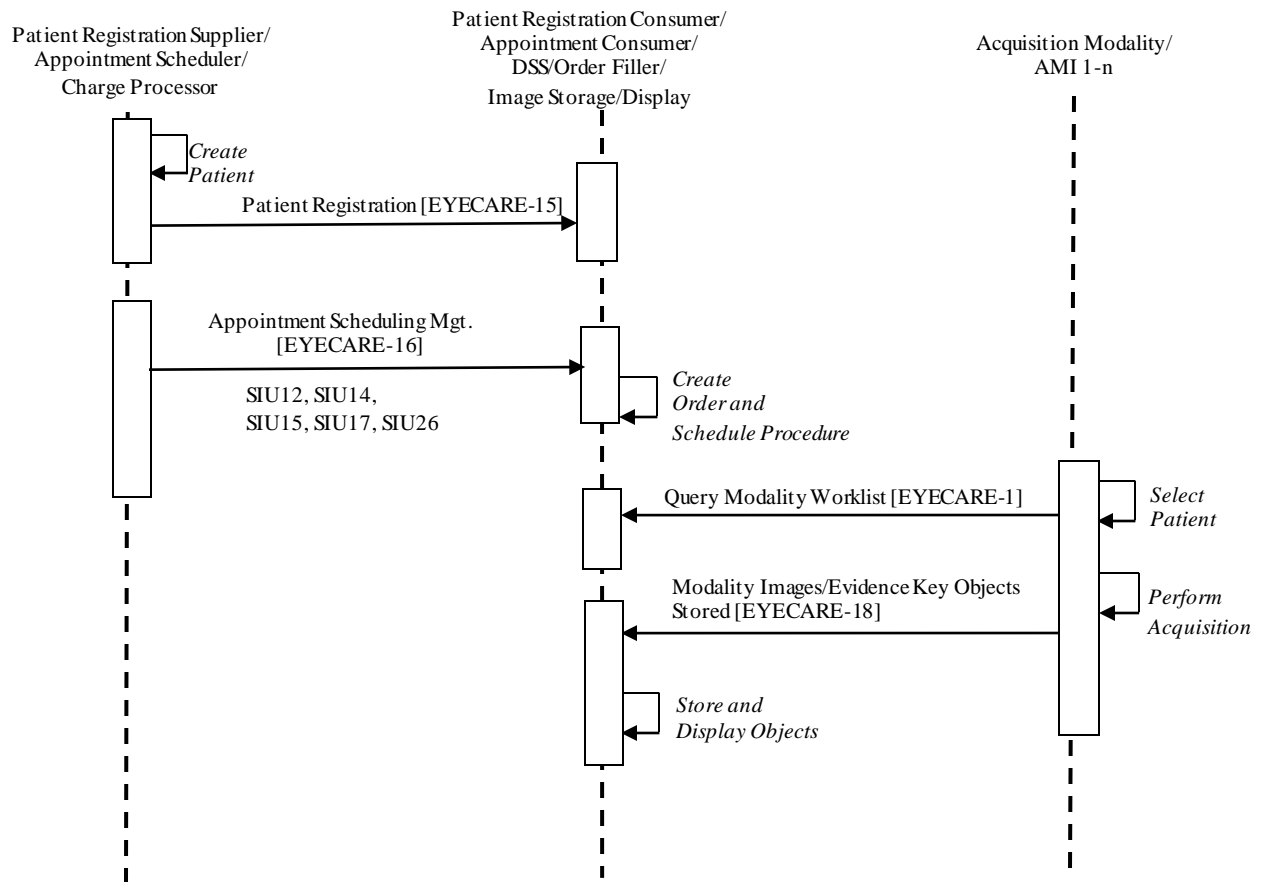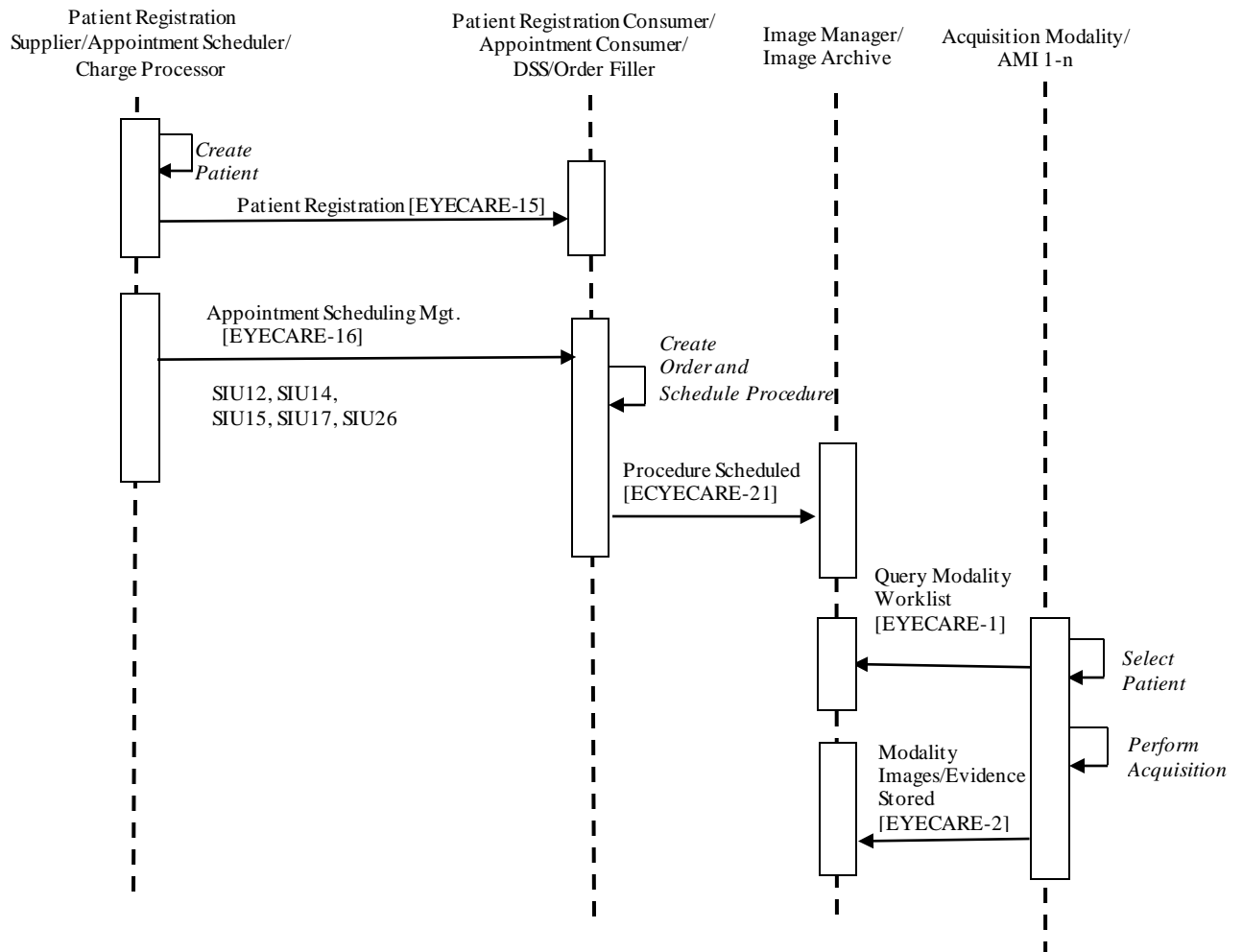**Figure 9.4.4-1: Real World Model III - Administrative Process Flow**

- *Patient Registration*: New patient demographics and updates are sent to consuming systems.

1415
- *Appointment Scheduling*: The patient's appointment is created/managed and sent to consuming systems. This includes new appointments, updates such as confirmed, arrived, checked in, complete. It also supports cancel/delete appointments and patient no shows.

- *Create Order*: The DSS/OF creates patient orders internal to its system.

- *Scheduled Procedure*: The Image Manager/Image Archive associates the order with one
1420 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 and Acquisition Modality Importers. Actions are specified in Scheduled Procedure Steps (SPS) based on timing and sequencing, and on modality.

1425   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). Eye Care procedures may be performed on multiple Acquisition Modalities or Acquisition 1430   Modality Importers, therefore, multiple devices may perform the queries.

- *Select Patient*: The patient is selected from the worklist.

- *Perform Acquisition*: Each Modality may produce a variety of images and other evidence (visual fields, refractive and biometry information, etc.). The DICOM SOP instances are stored to the Image Manager/Image Archive.

1435   **9.4.5 DICOM Storage Commitment and DICOM MPPS Support**

The Eye Care administrative process flow relevant to the scenario where the DICOM transactions such as Storage Commitment and Modality Performed Procedure Step are supported is shown in Figure 9.4.5-1. The patient registration, appointment scheduled, procedure scheduled, modality worklist process flows are omitted as they have been shown above. The 1440   functionality of those data flows is specified within the specific transactions.
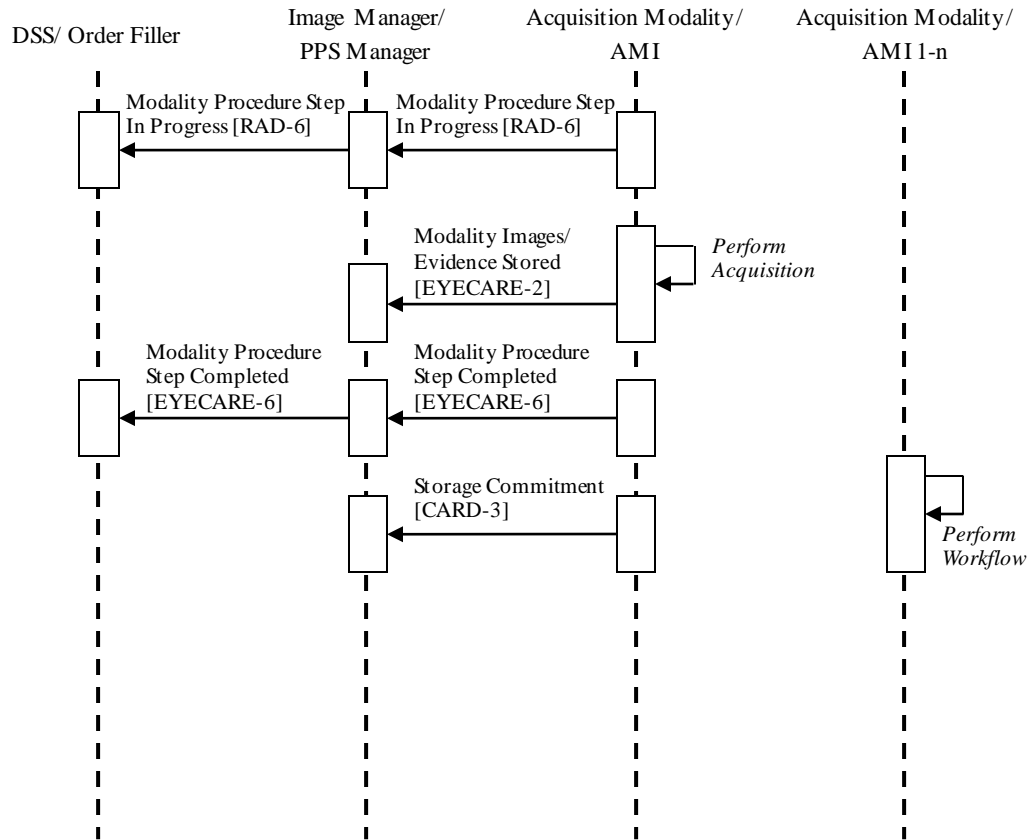
Figure 9.4.5-1: DICOM Storage Commitment and DICOM MPPS Support - Administrative Process Flow

- *Modality Procedure Step In Progress:* This allows the Acquisition Modalities and Acquisition Modality Importers to specify that they have started the procedure step which is linked to the information provided in the Query Modality Worklist transaction.

- *Perform Acquisition*: Each Modality may produce a variety of images and other evidence (visual fields, refractive and biometry information, etc.) that are stored to the Image Manager/Archive. The Image Manager/Archive must support all the object types as specified by the Eye Care Image Option, the Eye Care Measurement Option and the Encapsulated PDF Option (see EYECARE TF-2: 4.2).

- *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 an Acquisition Modality or Acquisition Modality Importer is then available, due to multi-step procedures (diagnostic images, evidence documents) and multi-modality cross-dependencies. It is a function of the DSS/OF (outside the scope of this profile) to determine when to end the procedure step, and declare the Acquisition Modality or Acquisition Modality Importer resources

1465

are available for another procedure step. As part of this transaction, [EYECARE-6] (an extension to [RAD-7]) requires the Acquisition Modality or Acquisition Modality Importer accurately convey the Performed Protocol Code Sequence. This requirement enables the ability to create automatic billing claims for products implementing the *Eye Care Charge Posting Integration Profile.*

1470

- *Storage Commitment:* The Image Manager/Archive accepts responsibility for stored images and evidence, allowing the Acquisition Modality or Acquisition Modality Importer to delete the data from its local storage. The Image Manager/Archive shall support devices that may be intermittently connected to the network and temporarily unable to receive Storage Commitment messages. If Storage Commitment fails, the Acquisition Modality or AMI may need to resend the images to the Image Manager/Image Archive.

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9.4.6 Extension to Query Modality Worklist for Eye Care [EYECARE-1]

9.4.6.1 Issuer of Patient ID

The Patient Registration Supplier Actor transmits information regarding the assigning authority (issuer) of the Patient ID to the Patient Registration Consumer/DSS/OF Actor. However, [RAD-5] (see RAD TF-2: 4.5), does not require the DICOM attribute "Issuer of Patient ID" be filled in by the DSS/OF Actor if asked by the Acquisition Modality or Acquisition Modality Importer (AMI) during a Modality Worklist query. This extension requires support for this attribute; see EYECARE TF-2: 4.1.5 for complete specifications.

1480

A key feature in eye care is that patient identity is a critical issue for the Acquisition Modality itself, because of longitudinal data requirements. For example, visual field analyzers persistently store longitudinal data in order to perform glaucoma progression analysis. Ensuring that all the data comes from one patient, and that all data from that patient is used to calculate the progression, is essential.

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Traditionally, many instruments have used the patient name and date of birth to health record and were unreliable. As electronic health record systems become available to manage patient IDs systematically, these are typically used as the unique key for the identity of the patient record; however, this is within the context of their own "namespace" of IDs. In order for an acquisition modality to confidently determine the identity of its patient records based on the Patient ID, it also must know this context. This can be provided by the "Issuer of Patient ID" attribute.

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Note: When an Issuer of ID is provided to the acquisition modality, it should determine patient identity based on the (Issuer of Patient ID, Patient ID) combination, rather than patient name and date of birth. The acquisition modality should still provide patient reconciliation logic for legacy records.

9.5 Unified Eye Care Workflow Use Cases

This section describes the specific use cases and process flows defined for the Unified Eye Care Workflow Profile.

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Clinical Context: U-EYECARE typically addresses workflow scenarios for an ambulatory eye care clinic.

We are addressing scenarios expecting the patients to be registered, an appointment scheduled (and updated), eye care procedure(s) are ordered and diagnostic imaging/measurements are generated. The following two examples show two typical scheduled workflows that may occur. They are very similar in the IHE transactions performed; however, the difference is whether a manual or automatic order was created for a procedure.

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Note: For the purposes of the Eye Care Technical Framework, the term "order" is to be construed in the most generic sense. The extent to which an order is treated as a healthcare provider's order is to be a function of legal jurisdiction. When the procedure involved is deemed not to require a healthcare provider's order, the "order" may be viewed simply as a requirement to preserve data integrity in the workflow.

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9.5.1 Workflow Example with Manual Procedure Order

The patient has been created in a Patient Registration Supplier Actor, a healthcare provider has written a procedure order manually and a procedure step has been scheduled in the DSS/OF. The technician uses the Acquisition Modality or Acquisition Modality Importer to query for a worklist. This may be either a patient query (using parameters to identify the patient uniquely), or a broad query (for all procedure steps scheduled for the modality). The modalities use the DICOM modality worklist service to query the DSS/OF or Image Manager/Image Archive, which responds with a worklist. This is displayed on the modality. The modality may then use the DICOM query/retrieve service to retrieve longitudinal data to display to the technician prior to the acquisition, or to display to the healthcare provider after the acquisition (for implicit post-processing involving longitudinal data).The technician selects the appropriate worklist item The technician performs the acquisition based upon the scheduled protocol code identified in the worklist, or the technician may determine that the requested protocol code was insufficiently specific, and select a different code for acquiring the information. For example, a visual field may have been ordered and the code to convey the procedure and protocol is Visual Field. This code is not specific enough to choose the algorithm needed. Management of the performed procedure step is an optional feature in U-EYECARE; see Section 9.2.9 Procedure Status Tracking (DICOM MPPS) Option for explanation.

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9.5.2 Workflow for Automatic Modality Worklist

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There are often a number of procedures performed on patients when they arrive in the clinic, without need for healthcare provider orders. For example, an eye care order may be created automatically when a patient is scheduled for an eye exam, placing the patient's name and order information on the modality worklist of several different instruments in the eye care clinic. Examples may include a lensometer and an autorefractor, etc. In this scenario, not all of the orders are performed. For example, if the patient does not have glasses, no lensometry measurement is required.

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The patient has been created in a Patient Registration Supplier Actor, and a number of automatic modality worklist entries are generated by the DSS/OF. The technician uses the Acquisition Modality or Acquisition Modality Importer Actor to query the DSS/OF or Image Manager/Image Archive for a worklist. This may be either a patient query (using parameters to uniquely identify the patient), or a broad query (for all procedure steps scheduled for the modality). This is displayed on the Acquisition Modality or Acquisition Modality Importer. At this time, the technician recognizes the automatic modality worklist and therefore determines that he/she needs to select the appropriate protocol code and perform the acquisition. The technician performs an

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1545   acquisition for the patient. When the technician selects to save the acquisition, the modality uses the DICOM storage service to store the acquisition data to the storage server. Additional acquisitions may occur as part of the performed procedure step, each resulting in a DICOM storage command. Management of the performed procedure step is an option in U-EYECARE; see Section 9.2.9 Procedure Status Tracking (DICOM MPPS) Option for explanation.

1550   Not all of the automatically modality worklists will be performed. The DSS/OF and/or Image Manager/Image Archive is responsible to remove all unused worklist items that have not been performed on this patient. The triggering mechanism for removing these automatic modality worklist entries from the device specific Acquisition Modality Worklist will be defined by the DSS/OF and/or Image Manager/Image Archive and configured for the specific needs of the
1555   clinic. This is outside the scope of IHE.

The above workflow may occur on many different modalities for which automatic modality worklist entries were created in the clinic.

This scenario is more completely documented in Appendix A.3 Workflow Examples using Automatic Modality Worklist.

9.6 Workflow Concepts in Practice

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The IHE "Real World" model for Workflow described above offers three major levels of control that can be used to customize a broad range of specific workflow situations:

- **Order**: A request for an Imaging Service

- **Requested Procedure**: Unit of work resulting in one report with associated codified,
1565   billable acts.

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

The DSS/OF uses the Universal Service ID in each order that it receives to determine what specific Requested Procedures are needed, and for each Requested Procedure, what Procedure
1570   Steps need to be scheduled.

A departmental Procedure Plan may be used in the DSS/OF Actor to predefine Orders that may be requested from the eye care department. Definitions will specify both the procedure code and the Scheduled Procedure Steps for each Requested Procedure.

The figure below defines an example of the breakdown of a "rule out glaucoma" Order.

```
┌─────────────────────────────┐
│ Order:                      │
│ R/O Glaucoma                │
└─────────────────────────────┘
        │
        │   ┌──────────────────────────────────────────────┐
        ├───│ Requested Procedure:  Optic Disc Photos       │
        │   └──────────────────────────────────────────────┘
        │           │   ┌──────────────────────────────────────────┐
        │           └───│ Scheduled Procedure Step:                 │
        │               │ Stereoscopic Disc Photographs OU          │
        │               └──────────────────────────────────────────┘
        │   ┌──────────────────────────────────────────────┐
        ├───│ Requested Procedure:  Visual Field             │
        │   └──────────────────────────────────────────────┘
        │           │   ┌──────────────────────────────────────────┐
        │           └───│ Scheduled Procedure Step:                 │
        │               │  30-2 Automated Perimetry                 │
        │               └──────────────────────────────────────────┘
        │   ┌──────────────────────────────────────────────┐
        └───│ Requested Procedure:  Retinal Nerve Fiber Analysis │
            └──────────────────────────────────────────────┘
                    │   ┌──────────────────────────────────────────┐
                    └───│ Scheduled Procedure Step:                 │
                        │ GDx RNFL Analyzer                         │
                        └──────────────────────────────────────────┘
```
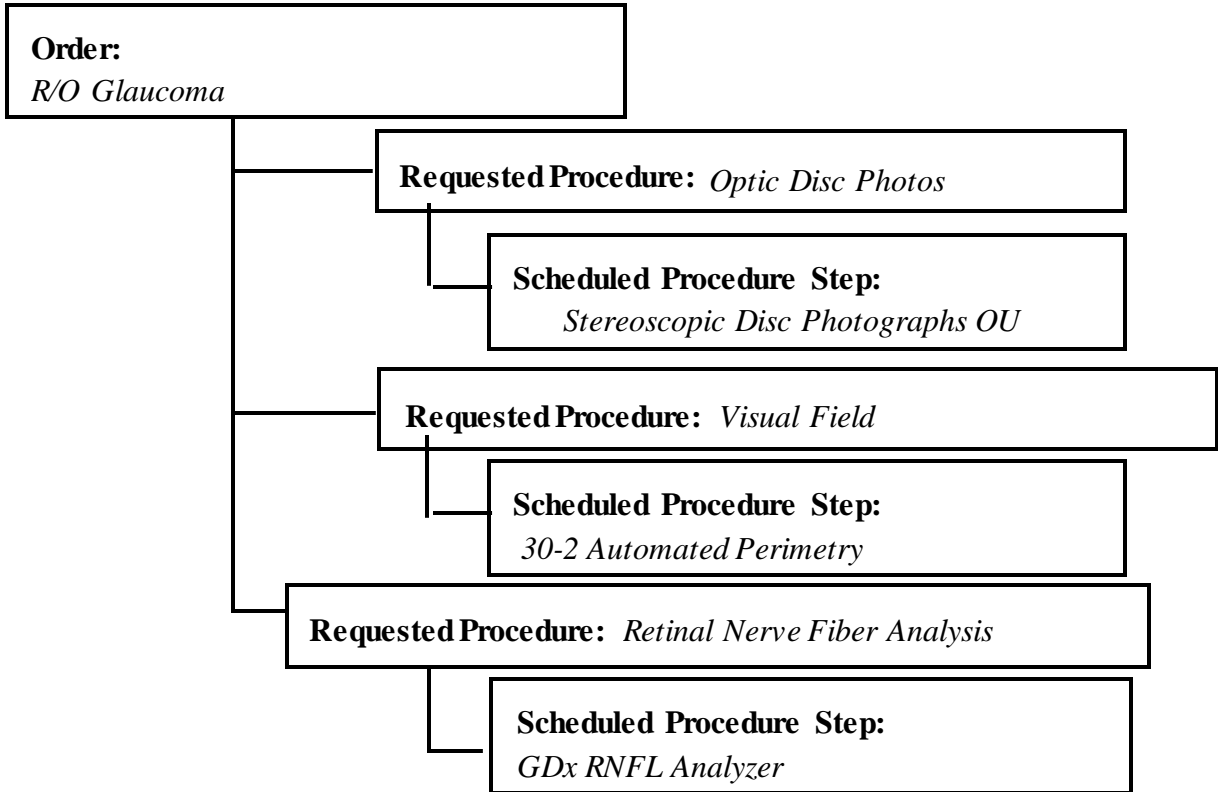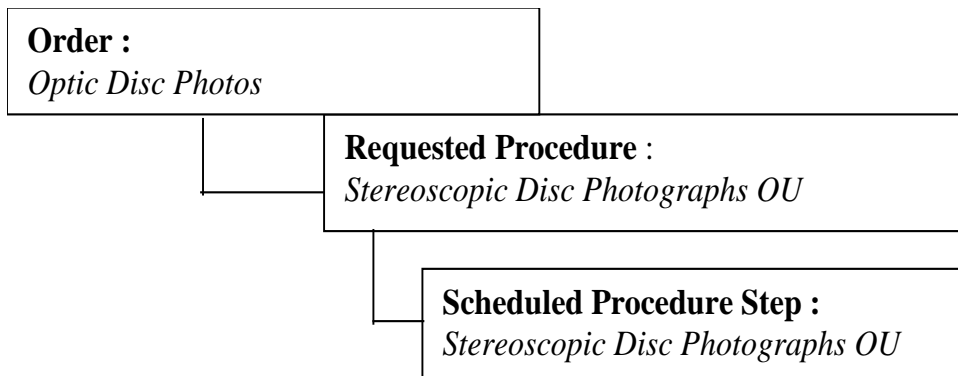
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In this Procedure Plan, for this specific Order, three Requested Procedures are defined. Each Requested Procedure has been scheduled as a separate Scheduled Procedure Step, because the patient may have each one performed at a different time. In addition, more than one ophthalmologist may be involved in the interpretation of the Requested Procedures. This is the 1580 way this institution has decided to handle this Order. Another Institution may choose to require the same ophthalmologist to read some or all of the procedures. In that case, its Procedure Plan would define same Order to have a single Requested Procedure with two or three Scheduled Procedure Steps.

Many Orders processed in an eye care Department would have a simpler breakdown such as this 1585 Optic Disc Photos example.

```
┌─────────────────────────────┐
│ Order :                     │
│ Optic Disc Photos           │
└─────────────────────────────┘
        │
        │   ┌──────────────────────────────────────────────┐
        └───│ Requested Procedure :                          │
            │ Stereoscopic Disc Photographs OU               │
            └──────────────────────────────────────────────┘
                    │   ┌──────────────────────────────────────────┐
                    └───│ Scheduled Procedure Step :                │
                        │ Stereoscopic Disc Photographs OU          │
                        └──────────────────────────────────────────┘
```

Note that the three level Order breakdown has been defined in the IHE Radiology Scheduled Workflow so that any type of Order, from the simple case to the more complex case may be
1590 handled by the same workflow concepts; thus, providing a general approach that can be easily customized by each department in the definition of its Procedure Plan.

In the IHE Radiology Scheduled Workflow, the **Accession Number identifies the Order**. The **Requested Procedure ID** distinguishes among Requested Procedures when an Order requires multiple Procedures. IHE sets a common meaning for these two terms to provide healthcare
1595 providers with a consistent and non-ambiguous access across different vendor products (RIS, PACS and Modalities).

Management of the performed procedure step is optional in U-EYECARE; see Section 9.2.9 Procedure Status Tracking (DICOM MPPS) Option for explanation.

9.7 Patient Record Merging Use Case

1600 **Clinical Context:** Jane Smith is a patient within an eye care clinic. She gets married and her name has been changed to Jane Brown. Her medical records, images, measurements, etc., need updating to reflect her new patient demographics and/or patient ID. Products typically affected include Practice Management Systems (PMS) and Electronic Medical Record systems. The PMS is manually reconciled and the other systems are automatically synchronized with the patient
1605 name/demographics changes.

As part of the reconciliation of the two patient records, the Patient IDs (i.e., records) need to be merged. Merge Patient IDs [EYECARE-20] is an optional transaction that requires support of HL7 ADT-40 (Merge Patient ID) to accomplish the merge. This is an advanced feature that is not easy to accomplish, therefore, if [EYECARE-20] is not supported it is expected that systems
1610 will manually merge the patients internally in each system. How this is accomplished is outside the scope of IHE.

IHE Context: This use case includes the Patient Registration transaction (HL7 A04; this transaction synchronizes patient demographics of the Patient Registration Supplier and Patient Registration Consumer. Followed by the Patient Demographics Update transaction (HL7 A08);
1615 this transaction synchronizes patient demographics of the DSS/Order Filler with the Image Manager/Image Archive. The transaction Merge Patient IDs [EYECARE-20] is an optional transaction which may be supported by all actors; this option is not shown.

The figure below provides an example workflow for merging a patient's records and assumes Jane Smith has already been registered; such as in Figure 9.7-1.

1620
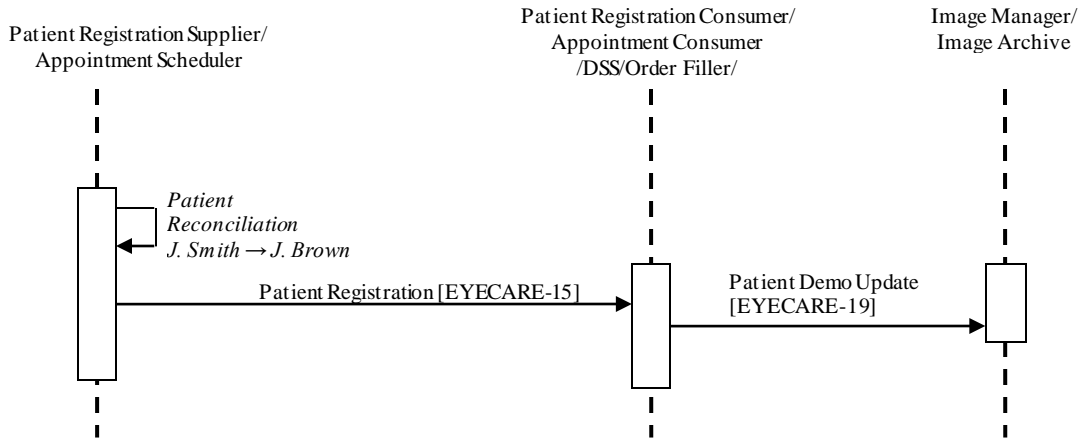
Figure 9.7-1: Patient Record Merging

1625   The above example illustrates how the HL7 ADT A08 message is used to reconcile patient demographics. It is also used to convey additional information or changes to patient information, such as address changes, phone number changes, insurance updates, etc.

9.8 Unified Eye Care Workflow Security Considerations

No security considerations are required.

1630 ## 9.9 Unified Eye Care Cross-Profile Considerations

None.

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 non-interpreted 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 or Encapsulated PDF.

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 healthcare provider 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

DICOM Encapsulated PDF: See DICOM PS3.3

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

1670   **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

1675   **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

1680   **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

1685   **Structured Reporting Templates:** See DICOM PS 3.16

Unique Identifier (UID): See DICOM PS 3.5

HL7 Terms

ADT: See HL7 v.2.5.1

Filler: See HL7 v.2.5.1

1690   **Observation:** See HL7 v.2.5.1

Placer: See HL7 v.2.5.1

Universal Service ID: See HL7 v.2.5.1

Acronyms and Abbreviations

AAO: American Academy of Ophthalmology

1695   **ACC:** American College of Cardiology

ASE: American Society of Echocardiography

EHR: Eye Care Electronic Health Record System or sometimes called Eye Care Electronic Medical Record System

HIMSS: Healthcare Information and Management Systems Society

1700 **HIS:** Hospital Information System

IHE: Integrating the Healthcare Enterprise

IOD: Information Object Definitions

IT: Information Technology

MWL: Modality Worklist

1705 **MPPS:** Modality Performed Procedure Step

NEMA: National Electrical Manufacturers Association

PACS: Picture Archive and Communication System

PPS: Performed Procedure Step

PMS: Practice Management System

1710 **RSNA:** Radiological Society of North America

SCU: Service Class User

SCP: Service Class Provider

SPS: Scheduled Procedure Step

SR: Structured Report

1715 **UID:** Unique Identifier

Appendices

Appendix A – Challenges of Workflow Management in Eye Care

A.1 Clinical Context – Patient Encounter in an Independent Practice

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In eye care, patients present with a variety of symptoms and complaints. Some types of testing may be performed routinely, such as refractive measurements, ocular pressure, etc., before patients are seen by a healthcare provider. Orders are not typically generated for these test. Other types of imaging and testing may be performed only after a healthcare provider has determined

1725 the need for them while examining the patient, such as Visual Field measurements, OCT imaging, B-scans, etc. These tests usually require an order to be placed by a healthcare provider in the DSS/OF (typically an EHR).

Orders may be modality specific, e.g., a Visual Field machine is used to produce Visual Field measurements; a B-Scan ultrasound device produces an ultrasound image, etc. However, the

1730 result of one test may indicate a need for additional testing and evaluation to make a diagnosis, or determine an appropriate management plan. Additionally, some tests are performed preparatory to a procedure after the diagnosis is made. The ordering process is just not often structured and the need for flexibility while maintaining accuracy is paramount.

A.2 The Current Workflow

1735 Even in the best eye care practices, there is currently potential for error and inefficiency because of the multitude of players in a practice. Consider a practice that has an electronic health record (EHR) system, a practice management system (PMS) and numerous types of devices/instruments for diagnostic purposes.

For example, a potential patient calls the practice for an appointment, either because they have a

1740 concern about their eyes/vision, or because another practitioner has discovered a problem and suggested a consultation or a procedure. If another healthcare provider refers the patient and the referring healthcare provider makes the appointment, then a reasonable amount of information is transferred from the referring healthcare provider to the healthcare provider that is going to see the patient, although this is not the most common scenario. If the patient calls, usually a

1745 minimum of patient information is retrieved from the phone call and entered into the PMS. An appointment is scheduled, usually in the PMS.

When the patient arrives at the clinic, additional information is entered into the PMS system and forms are filled out and signed. At this time the clinic has all the necessary information so the healthcare provider and/or staff can see the patient. The information gathered at this point

1750 becomes automatically available to the rest of the information systems and devices if the practice utilizes IHE compatible products. Under the most optimized of practices that do not use IHE compatible products, this information would flow from the PMS to the EHR and potentially to each device/equipment as a result of a specific custom interface written. In the case where the information isn't available automatically, patient information is re-entered by hand by the

1755 technician into the device or application that is going to be used to help diagnose the patient.

After completion of paperwork, the patient is taken to a work up area by a technician, who will

perform initial tests and measurements based on the type of exam that has been requested and on the complaints of the patient. Results are entered into the EHR, either by hand, or through a custom interface from some diagnostic equipment (e.g., auto refractors, lensometers). The healthcare provider is directed to the readied patient and arrives to examine the patient.

After initial review and evaluation, the practitioner may choose to have one or more tests performed, either immediately or at a later time. This is often expressed verbally to a technician, particularly if it is to be done in the office that day. The technician or the scribe may enter the order for a test into the EHR system. This increases accountability, but still leaves room for error and provides no real means for reporting back, other than the arrival in the EHR of the resulting test data or image.

The patient is then sent or guided to the diagnostic technician. In the integrated, but non-IHE environment, there will likely be an EHR workstation in the technician's area to indicate the healthcare provider's order and to capture the result. In the paper based office (no EHR), the chart travels with the patient and the documents are added to the stack, or the fact that the images are available in the storage repository of the diagnostic device is recorded. The practitioner is then informed that the test is done. The healthcare provider reviews and documents the interpretation of the results of the tests and makes an assessment, or decides that additional testing is needed and orders those tests. Once all testing and interpretation have been completed, the practitioner reviews the total exam, documents all relevant diagnoses, including the primary diagnosis, and reviews the findings and proposed plan with the patient. A final plan is produced and documented, and needed communications are generated, usually in the form of reports and/or letters to referring healthcare providers and the patient.

A.3 Workflow Example using Automatic Modality Worklist

A.3.1 The Use Case

A patient pre-registers in a clinic over the phone. An appointment is created for a future date, the patient selects a healthcare provider and the registration person finds an open slot in that healthcare provider's schedule.

The clinic has a protocol defined for patient visits that involves several diagnostic procedures. These diagnostic procedures are designed to give the healthcare provider base line information about the patient's general ophthalmic health. The ophthalmic technician normally performs these diagnostic tests. The types of tests done may vary from clinic to clinic and many possible examples include:

- An objective or auto-refraction device is commonly employed to create a starting point for the patient's refraction

- A lensometer device will measure the patient's existing corrective glasses

- A keratometer, topographer, wavefront analyzer, and pachymeter may be used to measure the shape and thickness of the cornea

- One or several baseline fundus photos are taken with a non-mydriatic camera

- A manifest refraction on an all-in-one refraction station device

A.3.2 Example of how IHE Could Be Used for this Use Case

The DSS/OF (i.e., EHR) is notified by the Patient Registration Supplier (i.e., PMS) system that the patient has been registered. The DSS/OF processes the patient identifier and demographic information. This would be accomplished using an A04 Outpatient Registration message. This list of "predefined" diagnostic procedures is clinic defined and will be different from clinic to clinic.

The Appointment Consumer (joined with the DSS/OF) is notified by the Appointment Scheduler (joined with the Patient Registration Supplier) that a patient is present at the clinic. This is accomplished via the HL 7 SIU message (either a SIU^12 or SIU^14) with the Filler Status Code set to "Arrived" or "Checked In" or "Started".

An Appointment Scheduler is able to convey many statuses while the patient is at the organization. "Arrived", "Checked In" and "Started" may all be conveyed but also only one or two may be sent via the HL7 SIU message. Therefore, the DSS/Order Filler manages all three statuses to determine a patient is within an organization. It will offer an automatic modality worklist entry only once for each patient (i.e., if statuses "Arrived" or "Checked In" or "Started" are received only one match is returned for that specific patient). This is accomplished via the DICOM Modality Worklist message.

The automatic modality worklist (via the DICOM Modality Worklist query message) is available to the Acquisition Modalities and Acquisition Modality Importers devices based upon the choice of the clinic (devices that the clinic does not wish to create specific orders for, such as refractive devices, tonometer, etc.).

Not all of the diagnostic procedures defined by the clinic will be performed. For instance the lensometer that measures the patient's glasses will not be used for someone who does not wear glasses. The DSS/OF is responsible to remove all unused worklist entries that have not been performed on this patient. The triggering mechanism for removing these patient worklist entries will be defined by the DSS/OF and configured for the specific needs of the clinic. This is outside the scope of IHE.

Some examples could be, the Appointment Scheduler notifies the DSS/OF that the patient's appointment has been completed and that information can be used to remove any unused Modality Worklist entries for this patient that have not been fulfilled. The DSS/OF could also expire these entries some time beyond the scheduled appointment date for that patient or the clinic could require human intervention to notify the DSS/OF to expire these entries, or all of the above.

A.3.3 Continued Use Case Example with Manual Orders

The patient sees the healthcare provider after all necessary above tests are completed. The healthcare provider reviews the results of the diagnostic tests and then performs a physical exam of the patient. The healthcare provider may determine that further testing is required, for example the healthcare provider see signs of Diabetic Retinopathy and orders Fluorescein Angiography Fundus Photos to document the locations that are bleeding.

A new order is created (i.e., internal to the DSS/OF). The DSS/OF associates the order with one or more Requested Procedures that have to be performed to satisfy the order. These procedures

scheduled would most likely be very specific, as the healthcare provider has determined exactly what needs to be performed on the patient.

Each Requested Procedure prescribes a number of actions that have to be performed by an
1840 Acquisition Modality or Acquisition Modality Importer. 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 via DICOM MWL.

After each modality performs its function, it conveys a DICOM MPPS back to the DSS/OF (if
1845 supporting the Procedure Status Tracking (DICOM MPPS) Option) with the appropriate protocol information filled in (i.e., it lets the DSS/OF know it completed its job and identifies the actual protocol performed on its system). Now the DSS/OF knows exactly what was performed for this patient from each device that was used.

The unfulfilled procedure steps for these manually scheduled items will most likely be removed
1850 by human action, but again this is outside the scope of IHE and up to the clinic. The clinic can be configured to direct the DSS/OF to send charges to the Charge Processor based on information obtained from the modality that, in this case, is the Fundus Photography Device.

Appendix B – The Eye Care Procedure in Perspective

1855 Eye care procedures occur within a typical clinical context: a patient has a clinical presentation, and an eye history and physical exam are performed with input by both support staff and eye care professionals. Diagnostic procedures are performed preliminary to, during, and after the history and physical exam by an eye care professional. They may be performed on the same day as the initial history and physical exam, or during another visit.

1860 Healthcare providers may use the terms such as "case," "encounter," "appointment" or "visit" to refer to this broader scope. To help avoid confusion with other standards documents and nomenclature, this Appendix introduces the term "Episode of Care".
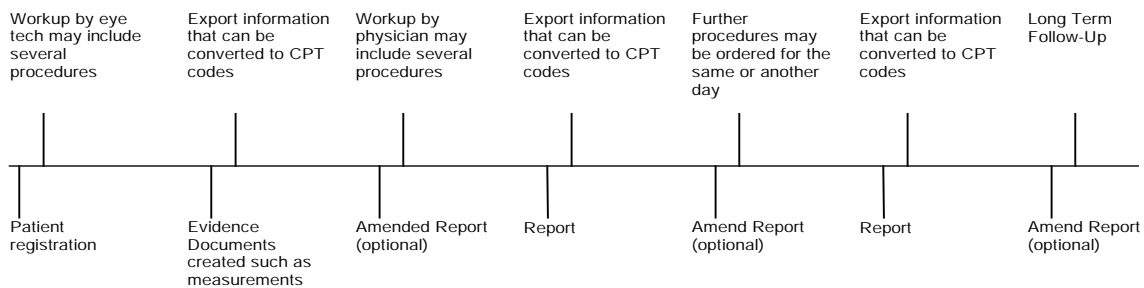

Figure B-1: Eye CARE Workflow Example

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The clinical activities associated with eye care Procedures are shown schematically above. As detailed in other parts of this document, there are several actors in the process. Although most healthcare providers aren't familiar with breaking down their procedures into what may appear to be an artificial number of steps, these actors have specific tasks to perform, any one of which 1870 may be taken on by one or more pieces of hardware or software in use within the practice.

In the timeline above, a patient calls or shows up at the clinic and is registered. The IHE actor is the Patient Registration Source. This task can be taken on in a number of places, depending on the information flow and sometimes the size of the facility, however the typical system would be a Practice Management System (PMS). The patient demographics information is sent to other 1875 information systems, typically an EHR. The actor receiving the patient demographics is the Patient Registration Consumer.

Next an appointment is scheduled (and managed) for the patient. The IHE actor is the Appointment Scheduler and again typically a PMS. Information systems that wish to learn about patient appointments do so via the role of the Appointment Consumer (typically the EHR).

1880 Once the patient is in the clinic, the technician performs various procedures before the doctors see the patient such as lensometry, auto-refraction, keratometry, etc. These measurements are captured and help determine if other procedures should be performed on the patient.

The patient sees the healthcare provider after all necessary above tests are completed. The healthcare provider reviews the results of the diagnostic tests and then performs a physical exam

1885 of the patient. The healthcare provider may determine that further testing is required. When this occurs an order is created (i.e., internal to the DSS/OF IHE Actor, which is typically an EHR). The DSS/OF associates the order with one or more Requested Procedures that have to be performed to satisfy the order. These procedures scheduled would most likely be very specific, as the healthcare provider has determined exactly what needs to be performed on the patient

1890 (visual field measurements, Fundus photo, OCT imaging, etc.).

> Note: The advantages of using the DSS/OF as opposed to the time honored tradition of "yelling for the tech" are the
> following: it can take less time to create a task in an order than to find the appropriate person, the task can be
> more exact, and the tracking and notification with regard to the completion of the task are automated, making the
> healthcare provider's job easier, faster and more effective. That said, this would probably be the biggest
1895 > conceptual leap in the process, as it mostly impacts the healthcare provider.

These orders are coordinated with the equipment devices via the DSS/OF. This is called DICOM Modality Worklist. The equipment devices receive patient and order information, display this information to the healthcare provider, and then capture the images and/or measurements based upon the specific order. The IHE actor which performs the acquisition is called an Acquisition

1900 Modality.

The output from these Acquisition Modalities (i.e., DICOM images, measurements, etc.) are often stored on an image storage system as an IHE actor called the Image Manager/Image Archive (typically a PACS). This enables a central location to securely store the images/measurements and offers the ability for them to be queried and retrieved.

1905 The images/measurements may be viewed via many locations, an image viewer is the IHE actor Image Display. Anywhere that the data is needed is a potential place to implement the image viewer, i.e., as part of an image management system (PACS), within the EHR system, at the acquiring equipment, even as a stand-alone image viewer. There have even been some recent examples of healthcare providers using a hand held device as an image viewer, although

1910 software would need to be more thoroughly designed to work well within the IHE framework.

Billing software capture charges, this is accomplished by the DSS/OF (i.e., EHR) conveying procedure and possibly CPT information to an IHE Actor called a Charge Processor (typically the PMS). It is the responsibility of the Charge Processor to post charges.

A similar process is performed for the patient over many episodes of care encounters.

1915 By breaking down the actors to this level of granularity, all of the tasks which must be performed to integrate the information in a well-run practice can be defined and then taken on by different vendors. In any practice, through IHE, the process of knowing that all steps have been handled, and the responsible party for each step, is systematized. Ultimately, by using the steps, the clinic achieves the goal of efficiently and smoothly managing a patient episode of care.

1920 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 Section 2 of the Technical Framework).

1925 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.).

1930 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 Connectathon, 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 Connectathon, and
1935 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 UNDERSTAND: Vendors have sole responsibility for the accuracy and validity of their IHE Integration Statements. Vendors' Integration Statements are made
1940 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
1945 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

1950 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:
1955   "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.
1960 Profiles, Actors and Options shall use the names defined by the IHE Technical Framework Volume I. (Note: The vendor may also elect to indicate the version number of the Technical Framework referenced for each integration profile.)

Note that implementation of the integration profile presumes implementation of all required transactions for an actor; options include optional transactions or optional functions for required 1965 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, 1970 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.

1975 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 2015
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**	
Unified Scheduled Workflow	Image Manager/Image Archive – Models I and III	none	
	Image Display – Models I and II	none	
	Department System Scheduler/Order Filler – Models I, II, III	Patient Record Merging Imaging Procedure Instructions Imaging Procedure Status Update (HL7) Charge Posting	
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

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Appendix D – 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.

2020

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.

2025

- 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.

2030

- 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.

2035 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.

2040