Integrating the Healthcare Enterprise

IHE Eye Care User's Handbook

2013 Edition

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Executive Summary

In evaluating alternatives for integrating an electronic medical office, seamless integration of your Electronic Health Record (EHR) with your Practice Management System (PMS) and eye care instruments are critical to success. Experience has demonstrated through numerous examples that proprietary custom solutions typically fail to achieve seamless integration. The American Academy of Ophthalmology (AAO)-sponsored Integrating the Healthcare Enterprise (IHE) Eye Care Initiative has sought to address this problem by leveraging open standards (i.e. DICOM and HL7) to specify an integration approach to meet the needs of Eye Care. IHE is a well established solution to data integration problems, leading to greater interoperability, decreased integration costs, and increased meaningful use associated with greater efficiency and improvements in patient care. It has been used by other specialties such as radiology and cardiology for over ten years. Every clinical specialty has different requirements. IHE Eye Care has developed profiles that meet ophthalmic information requirements.

IHE is an initiative by care providers (including ACC, HIMSS, RSNA and AAO) and vendors to improve the way information systems communicate to support patient care. IHE defines *Integration Profiles* that use established data standards to integrate systems for effective interoperability and efficient workflow. IHE enables the level of systems and information integration required in the era of the electronic health record. Most importantly it empowers the buyer to not be locked-in to a vendor's proprietary solution and allows the most efficient clinical workflow.

What are an IHE Integration Profile and IHE Actor?

Each IHE Integration Profile describes a clinical requirement for systems integration and a solution to address it. A profile defines functional components, called *IHE Actors*, and specifies in careful detail the messages and transactions, based on standards such as Digital Imaging and Communication in Medicine (DICOM) and Health Level 7 (HL7), each Actor must support and perform.

What is a Request for Proposal (RFP)?

Prior to the purchase of any ophthalmic hardware, software or device, we recommend drafting an RFP to establish a purchase requirement to make sure you will be purchasing what you want.

How do you get IHE Integration Profiles?

You specify IHE capabilities as requirements for the information systems (e.g., practice management, electronic health record, instrument, storage, and image display) you are purchasing or upgrading. This is accomplished by specifying in a Request for Proposals (RFP) which IHE Actors and Integration Profiles you require.

What do IHE Integration Profiles cost?

In some cases Integration Profile functionality costs nothing—they are integral to a product's capabilities. In other cases, vendors may package IHE Integration Profile capabilities at an

added cost with new systems or offer them as upgrades to installed systems. IHE Integration Profiles should represent only a small fraction of the total cost of most systems.

What is the business case for implementing Integration Profiles?

Integration Profiles enable you to efficiently manage the array of integrated information systems necessary to support effective healthcare. The alternative —building site-specific interfaces—is more expensive and requires maintaining these custom interfaces for the life of the system involved. Integration via IHE is less costly at the start. It makes future acquisitions easier to plan and execute, as well as more productive in delivering valuable functionality. Integration Profiles give clear definitions, based on widely accepted standards, of how pieces fit together.

What other benefits does IHE provide?

IHE makes it practical for eye care providers to use advanced information technology to improve the quality and efficiency of care. By ensuring the integrity of medical information, IHE enhances patient safety. By reducing the time spent in solving data problems such as lost and mismatched studies, IHE allows the most efficient use of staff time. By providing care providers comprehensive patient information, IHE enables better-informed medical decisions.

What should you do next?

Learn about the IHE Integration Profiles available for Eye Care and other parts of the Enterprise and consider how they meet your organization's goals. Read this IHE Eye Care User's Handbook to learn how to specify these capabilities in an RFP and how to implement them in your setting. These resources and more are available at www.ihe.net and http://one.aao.org/medical-information-technology-guidelines. The current Technical Framework, including Eye Care Workflow (EYECARE), Charge Posting (CHG), Eye Care Evidence Documents (ECED) and Eye Care Displayable Report (ECDR), and the Supplements in Trial Implementation Version, B-EYECARE (B-EYECARE), Eye Care Appointment Scheduling (ECAS) and General Eye Evaluation (GEE), can be found at http://www.ihe.net/Technical_Frameworks/#eyecare.

Connectathon results are published by IHE here: http://connectathon-results.ihe.net/. Also, the IHE Product Registry, http://product-registry.ihe.net/PR/home.seam, provides a way to browse through and find IHE Integration Statements.

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How to Use this Handbook

Assembled by the IHE Eye Care Planning and Technical committees with input from healthcare professionals who have implemented IHE capabilities at their sites, the IHE Eye Care User's Handbook describes the rationale and methods to acquire and implement systems with IHE capabilities.

IHE was designed to make the complex, intricate and time-consuming task of integrating healthcare systems easier, faster and more reliable. This Handbook describes how you can use IHE to improve the way the integration capabilities of your systems are selected, specified, purchased, integrated and deployed. Each chapter presents a scenario: (1) buying and deploying a new instrument, (2) buying and deploying an electronic health record (EHR), and (3) buying and deploying an image storage and display system, referred to as a Picture Archiving and Communications System (PACS). The principles outlined in each scenario can be applied to any systems acquisition or deployment project that involves integration of systems using IHE-defined transactions.

Each scenario includes advice for those selecting and purchasing new systems and for the technical staff who will handle the installation and configuration of a new system. A series of appendices provide advice and information applicable to each scenario—or any other deployment project linking systems via IHE transactions.

Each Chapter/Scenario includes the following sections:

Sections X.1.1 and X.1.2: Selecting IHE Integration Profiles by specifying how specific buyer requested requirements result in specific benefits

Section X.1.3: Writing buyer requested requirements in RFPs to obtain the desired profiles and results (sample text for some recommended profiles is included).

Sections X.1.4 and X.1.5: Identifying and evaluating relevant products

Section X.2.1: Workflow changes that maximize the benefit of the IHE Profiles

Section X.2.2: Installation testing to confirm that IHE capabilities are functioning properly.

Section X.2.3: Issues to consider when installing and configuring IHE-compliant system

Section X.2.4: Identifying and addressing potential problems in order to maximize your benefit despite existing non standard "legacy" systems

This Handbook provides direction on how to make use of the tools developed by the IHE initiative to deploy eye care systems that exchange information for optimal clinical workflow and buyer empowerment without struggling to overcome multiple vendors' proprietary lock-ins... It does not attempt to take into account the many other factors that determine the efficiency and suitability of an application for clinical use. The tools provided by IHE are thus only a part—albeit an essential one—of the full set of resources required selecting, purchasing, deploying and/or upgrading clinical and practice information management systems and devices.

Note: This is the third edition of the IHE Eye Care User's Handbook. Future editions will be expanded and enhanced. The newest edition will always be available at http://one.aao.org/medical-information-technology-guidelines. The Handbook is intended to meet the needs of the eye care community. Comments and suggestions are welcome. Send them by email to flum@aao.org.

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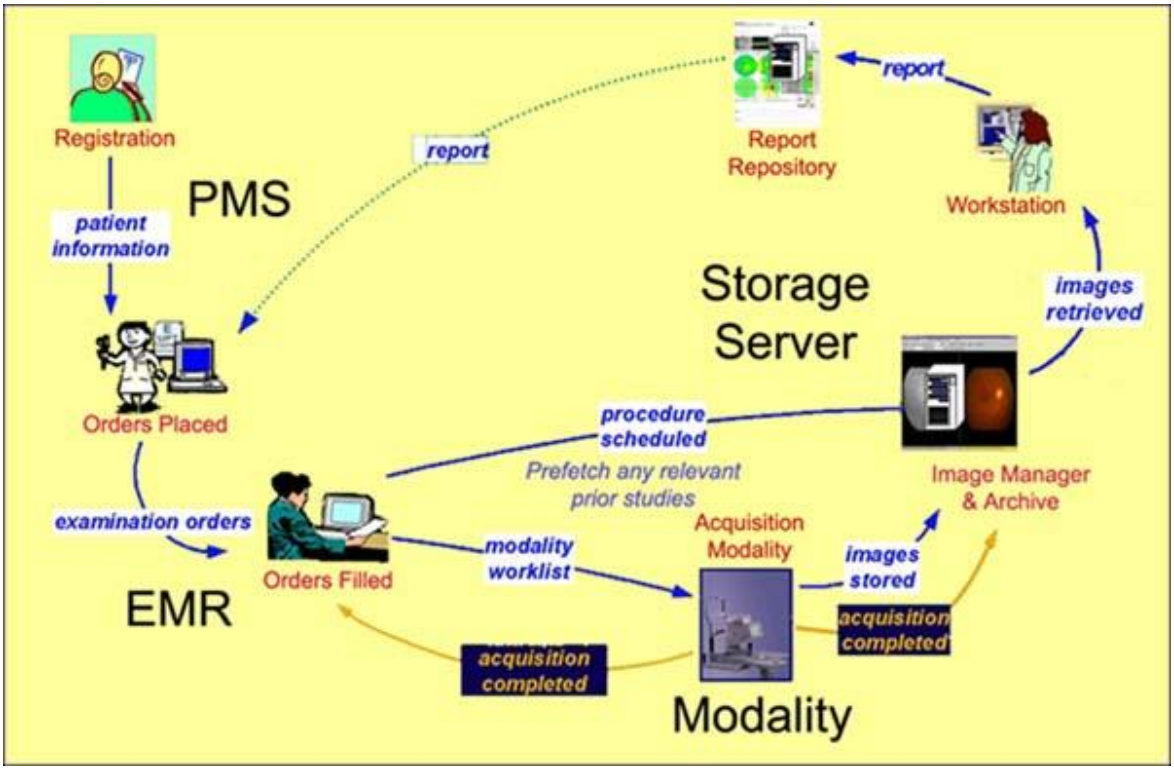
1 IHE EYE CARE SYSTEMS INTEGRATION – GENERAL OVERVIEW

In purchasing the components of an electronic medical office, seamless integration of the Electronic Health Record (EHR), Practice Management System (PMS), and eye care instruments is critical to a successful outcome. IHE Eye Care is specified as an essential requirement for interoperability in the Academy's publication titled "Special Requirements for Electronic Health Records in Ophthalmology." This publication is intended to help ophthalmologists to identify important features when searching for EHR systems, stimulate vendors to recognize and incorporate these functions into systems, and assist federal agencies to develop future guidelines regarding meaningful use of EHRs. More broadly, the Academy believes that these functions are elements of good system design that will improve access to relevant information at the point of care between the ophthalmologist and the patient, enhance timely communications between primary care providers and ophthalmologists, mitigate risk, and ultimately improve the ability of physicians to deliver the highest- quality medical care.

Interoperability is an important concept, representing the ability to exchange data freely among information systems and devices, regardless of the vendor or brand. This will create opportunities for important advances in medical care, data accessibility, clinical research, disease registries, and public health. Even for ophthalmologists who never exchange patient data for referral or consultation outside their practices, interoperability within their practices is required for communication between the EHR system and various ophthalmic imaging devices. Ophthalmology EHRs should conform to accepted, vendor-neutral standards and profiles for representation and transfer of data from ophthalmic instruments and devices. Accessibility to original measurement data will allow ophthalmologists to review and use clinically-relevant findings within the EHR, without the risk of error associated with manual data transcription. The Academy-sponsored IHE (Integrating the Healthcare Enterprise) Eye Care Domain has worked to leverage open standards (i.e. DICOM and HL7) to specify an integration approach to meet the needs of Eye Care. To achieve seamless integration, products must support one or more of the IHE Eye Care (EYECARE) use cases, which are referred to as "profiles".



To achieve seamless integration, products must support one or more of the IHE Eye Care Profiles. This can best be accomplished by having all products support IHE. IHE defines "actors" which vendors implement; these actors have technical names that are simplified by the following table:

COMMON TERMINOLOGY	IHE ACTOR
Practice Management System (PMS)	ADT/Patient Registration
EHR	Department Scheduler/Order Filler
Eye Care Instrument	Acquisition Modality
Non-DICOM Eye Care instrument	Acquisition Modality Importer (converts non DICOM into DICOM/IHE)
Storage System - (PACS)	Image Manager/Image Archive
Display Workstation	Image Display

Vendors may choose to implement one or more of these IHE "actors" in a product. For example, if an EHR is able to store and retrieve images/measurements, the product would support at least three actors (Department System Scheduler/Order Filler, Image Manager/ Image Archive and Image Display). The vendors document their choices in IHE Integration Statements. Don't forget to ask for them.

1.1 IHE PROFILES

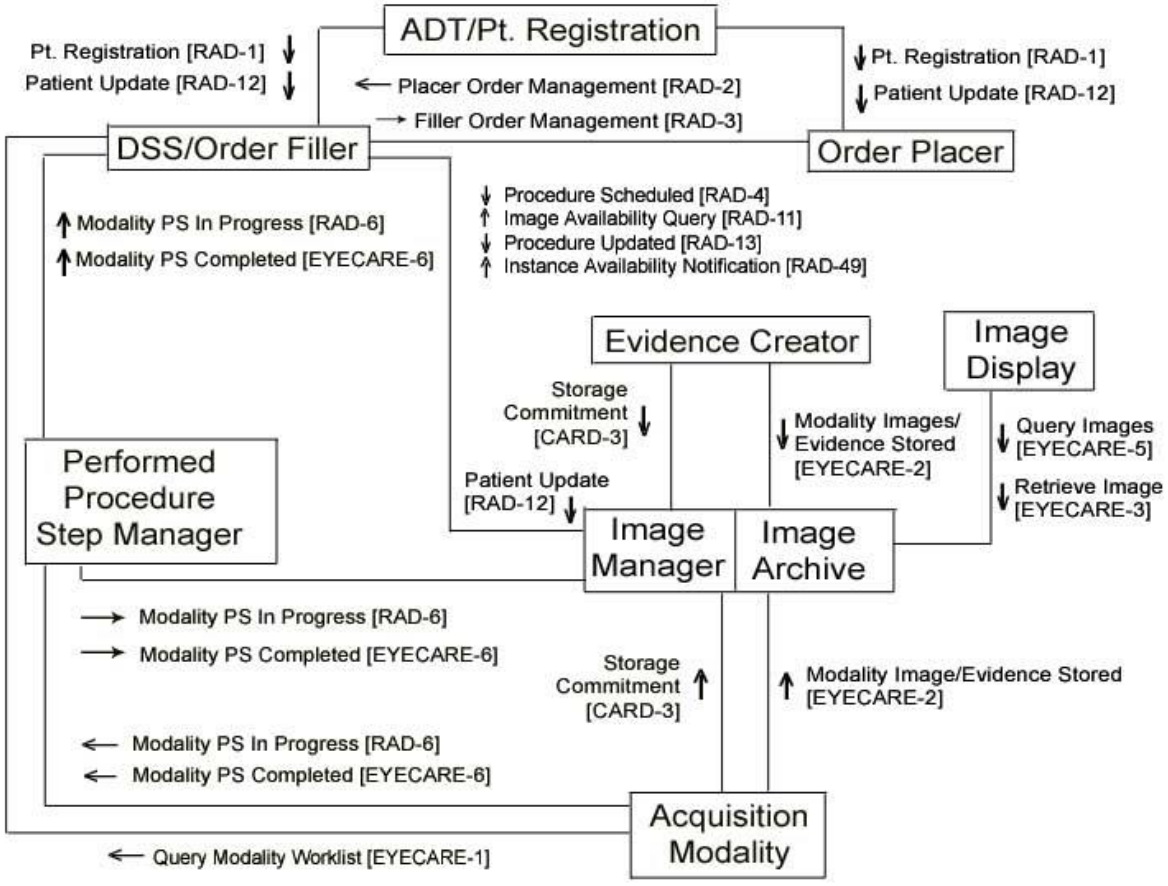
IHE Profiles describe specific solutions to integration problems. A profile documents how standards will be used by each system Actors) to cooperate to address the problem.

Referencing IHE Integration and Content Profiles lets implementers and users be sure they're talking about the same solution without having to restate the many technical details that ensure actual interoperability.

1.1.1 ADVANCED EYE CARE WORKFLOW and BASIC EYE CARE WORKFLOW

Advanced Eye Care Workflow (A-EYECARE) and Basic Eye Care Workflow (B-EYECARE) address three workflow scenarios: stand-alone eye care clinics, large eye care groups, and hospital-based eye care departments. The difference between these two profiles is that B-EYECARE does not include the Performed Procedure Step Manager.

In Eye Care, patients present with a variety of symptoms and complaints, which may or may not result in the need for diagnostic imaging and testing. Some types of imaging and testing may be performed routinely, before patients are seen by a physician. Other types of imaging and testing may be performed only after a physician has determined the need for them while examining the patient. Thus orders may be placed either for a specific procedure, or for a "generic eye care procedure." This requirement of flexibility is paramount.



A-EYECARE actors and Transactions

1.1.2 Charge Posting (CHG)

The Charge Posting Integration Profile specifies the exchange of information from department ordering systems to billing systems regarding charges associated with particular procedures. It also defines the communication between patient registration systems and billing systems about patient demographics, accounts, insurance, and guarantors. The Charge Posted Transaction contains all of the required procedure data to generate a claim. The procedure information is obtained from acquisition modalities via transactions from the *Eye Care Workflow Integration Profile*. The goal of including this transaction in the IHE Technical Framework is to standardize the Charge Posted Transaction to a billing system, thus reducing system interface installation time. Additionally, the Charge Posted Transaction reduces the need of the billing system to have knowledge of the eye care internals. The result is that the billing system will receive more complete, timely and accurate data.

Note: The current version of the IHE EYECARE Technical Framework does not include professional reporting, and therefore has not used the roles of Report Creator and Evidence Creator. This should be addressed in the future and will most likely be part of Charge Posting.

1.1.3 Eye Care Evidence Documents (ECED)

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

This allows detailed information, such as reconstructed or derived images, measurements, post processing results, etc. to be made available as input to the process of generating a Clinical Report, either as additional evidence for the reporting physician, or in some cases for selected items in the Evidence Document to be included in the report. A couple of examples include glaucoma progression analysis performed on visual field analyzers, or the retinal nerve fiber layer (RNFL) analysis performed on an ocular coherence tomography (OCT) device.

1.1.4 Eye Care Displayable Reports (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 ECRD Profile allows the reporting physician to control the "look" of the report, which is important for both clinical and business reasons.

1.1.5 Eye Care Appointment Scheduling (ECAS)

The Eye Care Appointment Scheduling Profile specifies the creation of a scheduling information exchange between a master appointment schedule and a working healthcare provider recognizing that often the master schedule and the personnel who operate it may not be readily available at the provider's location. It also defines the communication between patient registration systems and the appointment scheduling system about patient demographics. The Eye Care Appointment Request contains all of the required data needed to request a patient appointment. The Eye Care Appointment Response has all of the required data to confirm that an appointment with the desired criteria has been created or that the appointment could not be set as requested.

1.1.6 General Eye Evaluation (GEE)

The General Eye Evaluation content profile defines the structure of the data that is often collected during a patient's general eye examination. The American Academy of Ophthalmology (AAO) has created a collection of recommended best practices for this and other aspects of eye care that it terms

the Preferred Practice Patterns (PPP). The information in this document is based upon the "Comprehensive Adult Medical Eye Evaluation October 2010" PPP specification generated by the AAO. The comprehensive eye examination consists of an evaluation of the physiological function and the anatomical status of the eye, visual system and its related structures.

1.2 ACTORS

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise. The following are the actors defined by IHE and referenced throughout the rest of this document, as well as in other domain Technical Framework documents. It is acknowledged that some of the terms used as modifiers for the actor names are not used consistently (e.g., Image Manager, which also manages non-image objects). At this point, the benefit in doing extensive renaming to gain consistency is outweighed by the risk of introducing significant confusion that would result from renaming many of the existing actors that are shared across multiple domains. Therefore the actor names will remain as defined below.

Acquisition Modality – A system that acquires and creates medical images or measurements while a patient is present (i.e., eye care instruments). In eye care, example data Are 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 the Eye Care workflow.

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).

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.

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.).

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.

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.

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.

Integration Profile Actors

Actor \ Integration Profile	Advanced EYE CARE Workflow	Eye Care Charge Posting	Eye Care Evidence Document	Eye Care Displayable Report
Acquisition Modality	X	X	X	
Acquisition Modality Importer	X	X		
ADT Patient Registration	X	X		
Charge Processor		X		
Department System Scheduler/Order Filler	X	X		
Evidence Creator	X		X	
Image Archive	X		X	
Image Display	X		X	
Image Manager	X		X	
Order Placer	X			
Performed Procedure Step Manager	X	X		
Report Creator				X
Report Reader				X
Report Repository				X

2 SCENARIO: BUYING AN INSTRUMENT

IHE integration capabilities can provide many benefits when buying and implementing a new eye care instrument for a typical office or clinic, depending upon the systems (PMS, EHR, picture archiving and communication system [PACS], display workstations) and capabilities (Digital Imaging and Communication in Medicine [DICOM] Instrument Worklist [MWL], soft-copy review) that are already deployed in a practice.

There are many types of instruments supported by IHE and DICOM (e.g., fundus camera, external camera, slit lamp biomicroscope, specular microscope, operating microscope, optical coherence tomography (OCT), retinal thickness analyzer, confocal scanning laser ophthalmoscope, Scheimpflug camera, keratometer, auto refractor, phoropter, lensometer, ultrasound instrument, axial length measurement instrument, and visual field instrument).

The B-EYECARE (B-EYECARE) Profile provides the basic functionality for integrating an instrument with other systems in an office or across an institution. It establishes a seamless flow of information that supports efficient patient care in a typical clinical or imaging encounter. It specifies transactions that maintain the consistency of patient information from registration through ordering, scheduling, image acquisition, storage and viewing. It is strongly recommended that an implementation begin with this Profile.

The Acquisition Modality Importer (AMI) Actor is an interface to a non-standard instrument. It provides functionality similar to an instrument that supports the Acquisition Modality Actor. The configuration and implementation process is the same for an Acquisition Modality and for an AMI.

A common issue when integrating an electronic office is the need to connect to proprietary non-standard instruments to the system. B-EYECARE has a solution. This is accomplished by purchasing an instrument that supports the IHE functions from an AMI Actor. This product interface (Actor) provides the same benefits as ophthalmic instruments that support IHE internally with one difference; it converts the non DICOM output from the ophthalmic instrument into DICOM. The data may be exported in a DICOM PDF document, or a "snapshot" of a DICOM image (called Secondary Capture), or as actual DICOM discrete data. Acquisition Modality Importers may be offered by the device manufacturers as a standalone product or as a part of software suite offering additional capabilities. Acquisition Modality Importers are also available from third-party vendors, frequently combined with other software products, such as Image Managers or Electronic Health Record systems.

2.1 THE PLANNING AND PURCHASING PROCESS

Intended for administrators who make purchasing decisions, this section lists organizational goals to consider when specifying requirements for an eye care instrument, how to select the IHE Integration Profile that will address those goals, how to clearly state IHE requirements in a request for proposals (RFP) and how to interpret vendor responses.

2.1.1 Organizational Goals and Integration Profiles

Clearly identifying organizational goals is important for defining the requirements for equipment acquisition. Each IHE Integration Profile is designed to meet a specific set of

organizational goals. Below is a list of goals an institution might have for acquiring a new instrument and the contributions that the Integration Profile, B-EYECARE, makes in supporting these goals.

Reduce Errors and Enhance Patient Care

- Technicians can select a patient's name from a worklist on the instrument, using data that was supplied by the EHR
    a. Eliminates redundant and often erroneous manual data entry on the instrument
    b. Keeps demographics consistent among PMS, EHR, and instruments
    c. Reduces complications from known patient information such as allergies, as these details can be displayed on the instrument from the EHR
- Patient demographics and procedure information placed into the instrument's images and measurements
    a. Ensures accurate matching between patient and data wherever in the world those images or measurements are used
    b. Eliminates mismatches with EHR
- Create and store data in an open standard format (DICOM)
    a. Eliminates proprietary solutions that may limit or prevent access to existing data when purchasing new software in the future. Empowers user by preventing vendor proprietary lock-in

Improved Throughput

- Saves manual data entry time
    a. Uses Worklists to download patient demographics and study details
    b. Performs "automatic" (no user inputs) orders for data acquisitions such as lensometry, keratometry, etc.
- Prevents wasted time searching for /or duplicating performed studies
    a. Instrument downloads patient demographics to prevent filing of studies under misspelled patient names
- Prevents mis-performed studies from misread paper or verbal orders
    a. Instrument downloads the Worklist of orders from the EHR
- Prevents time wasted manually fixing incorrect demographics for patients
    a. Updates corrected patient demographics on the PMS and automatically synchronizes the EHR and PACS

Reduce Deployment Cost/Time

- Prevents custom interface specification time and expense
    a. IHE TF provides a detailed specification for a powerful interface, supported and tested by many vendors

    b. IHE Integration Profiles are already supported by many vendor products

- Reduces interface compliance testing time and expense
    a. Many combinations of systems have already been directly tested together at IHE Connectathons
- Reduces time and expense consumed for custom interface maintenance
    a. Maintains a single interface (IHE) instead of multiple custom interfaces

The benefits provided by IHE arise from the requirement that the instrument vendors support a software process "actor" called the Acquisition Modality or AMI Actor. The open standard that the instrument supports for this Actor is DICOM.

A-EYECARE not only achieves the benefits of B-EYECARE, but it also expands on those benefits. Below is a list of these expanded benefits from A-EYECARE and other Integration Profiles.

Reduce Errors and Enhance Patient Care

A-EYECARE

- Prevents delays in patient care
    a. Updates the EHR on the procedure status: in progress, completed or canceled electronically
    b. This electronic update reduces the number of manual steps
    c. Prevents complications from known patient history such as patient allergies-- as these details can be displayed on the instrument from the EHR
- Reduces incorrect patient studies resulting from incorrectly selected Worklist entries
    a. The instrument electronically signals the problem to the EHR and PACS
- Reduces incorrect patient studies resulting from incorrectly selected Worklist entries

A-EYECARE (optional features)

- Displays patient specific text instructions to the technician from an ordering physician
    a. Procedure Instructions Option
- Creates standard DICOM PDFs for display of non-DICOM data
    a. Encapsulated PDF Option for Evidence Documents
- Documents stereo relationship between images
    a. Stereo Relationship Option
- Labels images to indicate position in the retina
    a. Relative Image Position Coding Option

Improved Throughput

A-EYECARE

- Saves time wasted manually confirming image transfer to PACS
    a. Instrument automatically confirms PACS receipt of images

- Reduces protocol setup time
    a. Instrument sets initial protocol parameters based on procedure codes provided in the Worklist entry (with Assisted Protocol Setting Option)

Improve Billing Process

A-EYECARE and EYE CARE CHARGE POSTING Profile Benefits

- Avoids lost revenue for additional procedures performed that are not entered into the EHR
    a. Instrument updates the EHR with procedures actually performed
- Prevents payer claim rejection of reported procedures not matching the order
    a. Instrument reports procedures actually performed and flags when they differ so they can be reconciled
- Prevents time spent doing "paperwork" for procedures already cancelled by the instrument
    a. Instrument informs the EHR about cancelled procedures and the reason for cancellation

It is not always possible to address all organizational goals by making a single equipment purchase. There are co-dependencies in IHE that require multiple actors to support the clinical needs described in a Technical Framework. Achieving the full benefit of an IHE Integration Profile requires that the systems interacting with the instrument also play their roles as defined in the Profile. Frequently, partial benefits can be achieved by implementing an Integration Profile on a single Actor, such as the acquisition instrument, in an environment where the interacting systems have some but not all of the functionality described in the Profile. Appendix A provides a general discussion of sequencing requirements and planning individual purchases as part of a long-range plan. There are circumstances in which a current acquisition may anticipate a future acquisition, such as the acquisition of an IHE conforming instrument in the present that will eventually be integrated with a replacement, IHE conforming, PMS sometime in the future.

To track progress toward organizational goals and determine return on investment, a well-defined set of performance metrics is needed—see Appendix I.

2.1.2 Selecting IHE Integration Profiles and Actors

Specifying integration requirements for the system you are purchasing is a simple matter of selecting which IHE Integration Profiles and which IHE Actors you want supported. Some Profiles include options that provide additional functionality. Where options are available, you should consider how the optional functionality could contribute to your operations and productivity and decide which ones to select.

2.1.3 Putting Integration Requirements in Your RFP

To specify IHE support in your RFP you must specify which IHE Integration Profiles (and options) you require your proposed system to support and which IHE Actor roles the proposed system should play in each Profile. To acquire an eye care instrument with the

features described above, the RFP must specify the Eye Care B-EYECARE Integration Profile and must require the instrument to support the Acquisition Modality or Acquisition Modality Importer Actor.

The following is a sample statement that can be used to specify the Profiles and Actors for an acquisition instrument:

- *"The <type of instrument> shall support the IHE **B-EYECARE** Integration Profile as the **Acquisition Modality** Actor."*
- *"The <type of instrument> shall support the IHE **B-EYECARE** Integration Profile as the **Acquisition Modality Importer** Actor."*

This statement requires the instrument to integrate seamlessly with an IHE conforming EHR and PACS system to obtain the functionality discussed above using the DICOM standard.

For further discussion of the RFP process, see Appendix C**.**

2.1.4 Identifying Suitable Products

While you may choose to proceed directly to sending your RFP to a broad group of potential vendors, you may find out which vendors have products with relevant IHE integration capabilities by referring to public sources. For a description of these sources, see Appendix D.

2.1.5 Reading Integration Statements from Vendors

Vendors may respond to your RFP by providing an IHE Integration Statement document. An Integration Statement is a direct statement of which IHE Profiles, Actors and options are supported by a particular product from a particular vendor. IHE Integration Statements are available for many products at the IHE Registry:

http://product-registry.ihe.net/PR/home.seam

For the contents of an Integration Statement, see Appendix E.

2.2 THE CONFIGURATION AND IMPLEMENTATION PROCESS

The following sections are intended for the implementation team. They cover important clinical and IT considerations when deploying an instrument with IHE capabilities, including how to incorporate non-standard "legacy" issues when connecting an instrument to systems that do not support IHE Profiles.

2.2.1 Improvements to Your Workflow

IHE Profiles are designed to implement digital imaging in a streamlined clinical workflow. For instance, they eliminate the need to enter patient information at the instrument, searching for mis-matched studies with the EHR and PACS. They also allow images to be immediately available for viewing. To gain the full benefit of these capabilities, there are several tasks that need to be performed in the correct manner.

2.2.1.1 Workflow (B-EYECARE)

The B-EYECARE Profile helps to ensure that patient demographics and order and procedural information are correct and consistent in all systems. They allow images to be available for review in a timely fashion. Instrument operators use the DICOM MWL to query and retrieve the relevant patient demographics and scheduled procedure information from the EHR (the EHR received the patient demographics from the PMS). Patient name changes should not be made on the instrument. The PMS is the primary information source and is capable of managing name updates, as long as the instrument does not introduce additional unexpected changes. To ensure timely and correct patient information, the Worklist should be re-queried just before starting a new exam in case any patient or order details have changed. The instrument operator should verify that the correct patient is selected for each examination.

2.2.2 Confirming that it's Working

The following sections provide guidance on how to confirm that the instrument is operating according to each IHE Profile implemented. Each section provides elements for testing an individual Profile as it relates to the instrument. Often, there are other ways than the ones described to confirm the data and the transactions—see Appendix H.

2.2.2.1 Workflow (B-EYECARE)

For instruments, it is important that patient demographics and order and procedural information be available to the instrument through the Worklists and be preserved in the images created by the instrument. Verify that the critical information is available for reviewing on the instrument. Confirm that the correct information is maintained by checking information associated with studies on the PACS at the completion of a study and make sure the information matches that in the EHR Worklist.

The following is an example of the high-level list of tests that may need to be run on a new instrument with B-EYECARE:

1) Schedule a procedure through the PMS and review the Worklist information on the instrument using its Worklist features. (MWL)

   Confirming the scenario: Verify that the patient demographics and the procedural information on the instrument match what was scheduled through the EHR. To verify this, compare the EHR scheduled procedures with the MWL on the instrument. See Table 4.5-3 of the IHE TF Vol. 2 for specific information available on the MWL (e.g., patient name, patient ID, AN, instrument, requested procedure ID, protocol name, protocol codes).

2) Archive images from the instrument to the image archival system (either through auto-store or manual storage of images). *(Instrument Image Stored)*
   Confirming the scenario: Verify that the images created on the instrument are stored on the PACS.

For each of these verification tests, detailed test data sets may need to be developed with the appropriate information elements. For example, when an instrument retrieves the MWL from the EHR, the following types of items must be taken into account:

1) What type of MWL queries can the instrument perform?

   Develop tests that ask for the relevant fields of interest (e.g., all of the scheduled procedures for today for this instrument).

2) What information can this instrument display, and what information is stored in the resulting image sets?

Develop tests to review all of the MWL information and determine which can be displayed on the instrument. Verify the capability to review each of the MWL fields returned and displayed on the instrument (patient name, patient ID, AN, etc.). Develop tests to review all of the resulting information, which was generated using the MWL and used in creating the resulting DICOM images.

2.2.2.2 B-EYECARE with Added Features (A-EYECARE)

In addition to testing for B-EYECARE described above, for instruments that have the capability to support A-EYECARE, these tests may also need to be run:

1) Run a scheduled procedure on the instrument and review the procedure information/status updates on the EHR during the procedure. *(MPPS In Progress)*

Confirming the scenario: Verify that the procedure status on the EHR (or PACS) has been updated based on the procedure being performed on the instrument. NOTE: Many instruments do not provide intermediate procedure status. See Appendix A of the IHE TF Vol. 2 for specific information that will be updated based on what is being performed. Also see Section 4.6 of the IHE TF Vol. 2 for the use cases of how the instrument may perform a procedure.

2) Complete a scheduled procedure on the instrument and review the procedure/information status information/ status (complete) on the EHR *(MPPS Complete)*. Also, perform an unscheduled procedure on the instrument where the patient demographics and procedural information will need to be entered (it may be from a bar code or manually), append a new procedure to a scheduled procedure after the ophthalmologist reviews the resulting images and abandon the procedure on the instrument before it is completed.
Confirming the scenario: Verify that the procedure status on the EHR (or PACS) has been updated based on the procedure being performed on the instrument. See Appendix A of the IHE TF Vol. 2 for specific information that will be updated based on what is being performed. Also see Section 4.6 of the IHE TF Vol. 2 for the use cases of how the instrument may perform the procedure. Some of the parameters of particular interest based on the scenario being tested are the AN, requested procedure ID and comparison of the scheduled procedure versus the performed procedure information.

3) Attempt to delete the images from the instrument prior to the image archive claiming possession of the images. *(Storage Commitment)*

Confirming the scenario: Verify that the images on the instrument cannot be deleted because they have not been permanently stored by the PACS system.

4) Attempt to delete the images from the instrument after the image archive claims possession of the images. *(Storage Commitment)*

Confirming the scenario: Verify that the images on the instrument can be deleted after they have been permanently stored by the PACS system.

Additional options in A-EYECARE that can be tested include:

Assisted Protocol Setting Option (in A-EYECARE)

Some instruments have the ability to support Procedure Plans based on Protocol Sequence Codes conveyed to the instrument through the MWL from the EHR and conveyed back to the EHR upon completion of the procedure. The Protocol Sequences are used to drive all steps within a procedure. That protocol sequence can be given a numeric value and each instrument can be configured to respond to that value by performing the appropriate machine protocol.

For enterprises capable of supporting this option, this should be tested on instruments capable of supporting this option. This may be accomplished by adding additional tests to the A-EYECARE and instruments tests.

1) Schedule a procedure using protocol codes through the EHR and review the information through the MWL feature on the instrument.

   Confirming the scenario: Verify that the protocol codes on the instrument match what was scheduled through the EHR. See Table 4.5-3 of the IHE TF Vol. 2 for specific information regarding the Protocol Code Sequences in the MWL. Verify that the instrument uses the protocol codes to control the procedure being performed. Also see Section 4.6.4.1.2.4.2 for additional information on the Assisted Protocol Option.

2) Run the scheduled procedure using the protocol codes specified by the EHR.

   Confirming the scenario: Verify that the instrument uses the protocol codes to control the procedure being performed. See Section 4.6.4.1.2.4.2 for additional information on the Assisted Protocol Option.

3) Run the scheduled procedure with altered protocol codes.

   Confirming the scenario: Verify that the EHR has been updated with the procedures performed by the instrument. See Section 4.6.4.1.2.4.2 for additional information on the Assisted Protocol Option.

Detailed tests sets should be developed with the data sets. A representative set of procedures should be used to test the specific instrument.

PPS Exception Management Option (in A-EYECARE)

Some instruments have the capability to support the provision of an appropriate reason code in case a started procedure needs to be abandoned. For enterprises capable of supporting this option, this should be tested on the instruments. See Section 4.7.4.1.2.2 of the IHE Eye Care TF Vol. 2 for specific requirements. This may be accomplished by adding additional tests to the B-EYECARE and instruments tests.

1) Schedule a requested procedure through the EHR and review the information through the MWL feature on the instrument.

2) Run the scheduled procedure. Acquire a number of images and send to the PACS.

3) Abandon the procedure and fill in the discontinuation reason code.

4) Check that a PPS is created with the discontinuation reason code, which has references to the acquired images sent to the PACS.

Confirming the scenario: Verify that the procedure status on the EHR (or PACS) has been updated based on the procedure being performed on the instrument. See Table 4.7-1 of the IHE TF Vol. 2 for details on the Exception Management Codes.

Detailed test sets should be developed with the data sets. A representative set of procedures should be used to test the specific instrument.

2.2.3 Considering Installation Issues

Even with IHE, installation is not "plug & play"—the systems are not self-configuring. For each instrument integrated into a clinical system, you will likely need to do the following:

2.2.3.1 Workflow (B-EYECARE)

1) Configure the AE Title, IP address, and port for your instrument's DICOM MWL. This information needs to be shared with the EHR vendor so the EHR can be configured to provide your MWL.

2) Configure the AE Title, IP address, and port for your instrument's DICOM Storage. This information needs to be shared with the PACS vendor so the PACS can be configured to provide your storage services.

A significant amount of time goes into creating and keeping various codes in sync between different systems. Codes will need to be established for many parts of your system. These codes may be as simple as a set of protocol codes or may represent a much larger set of data, like procedure codes. Codes are typically kept in sync manually. If codes are out of sync, a receiver may not accept data, as it may not be aware of the supplied coded value.

2.2.3.2 B-EYECARE with Added Features (A-EYECARE)

In addition to the installation issues for B-EYECARE described above, the following are additional configuration issues required for instruments that are able to support "A-EYECARE"

1) Configure the AE Title, IP address, and port for your instrument's DICOM Instrument Performed Procedure Step (MPPS). This information needs to be shared with the PACS vendor (if it is the configured MPPS manager) so they can forward MPPS messages from your instrument to the EHR. Otherwise, if the EHR is acting as the MPPS manager, it will be receiving MPPS messages and forwarding them to the PACS, and the EHR would need your instrument's MPPS configuration information.

2) Configure the AE Title, IP address, and port for your instrument's DICOM Storage Commitment. This information needs to be shared with the PACS vendor so the PACS can be configured to provide your storage services.

2.2.4 Identifying and Addressing "Legacy" Problems

IHE Integration Profiles perform best when all relevant systems support the Profiles. If some systems do not support the Profiles you have selected, but do support the standards a Profile is built upon, it is possible that some benefits of the standards will be achieved. If you have deficient systems, you should consider how to work around identified deficiencies in the short term and strategically consider whether and/or when to replace or upgrade those systems.

2.2.4.1 Connecting a Non-IHE Instrument

Interoperability between the instrument and other EYECARE systems enables the patient demographics, order and procedural information to be preserved when new or updated information is provided through the PM or EHR System. Additionally, image status can be provided to ensure that images are made available as quickly as possible. Some or all of these capabilities may be available based on the capabilities of the non-IHE instrument.

Instruments with partial or no Digital Imaging and Communications in Medicine (DICOM) capability will need an additional system such as AMI. AMI is an IHE actor which converts non-DICOM instrument data into standardized DICOM output.

Request a current DICOM Conformance Statement (DCS) from your instrument vendor for each of your installed products. See Appendix F.

2.2.4.2 Connecting the Instrument to a Non-IHE PACS

Interoperability between the instrument and the PACS enables the patient demographics and order and procedural information to be preserved and updated when new or updated information is provided through the PMS. Image status can be provided to ensure that images are made available as quickly as possible. Some or all of these capabilities may be available based upon the capabilities of a non-IHE PACS. The following are some guidelines to consider when determining how to integrate an instrument with a non-IHE PACS.

Request a DICOM Conformance Statement (DCS) from your PACS vendor for the current product release installed at your site. See Appendix F.

2.2.4.2.1 Workflow (B-EYECARE)

In the B-EYECARE Profile, the instrument expects the PACS to support several DICOM services, using specific attributes and is expected to respond to messages in specific ways (refer to the TF). The critical DICOM services are:

- DICOM Storage as an SCP
- DICOM Query/Retrieve as an SCP

If your PACS has these two services, the next step is to confirm that critical DICOM attributes provided in the DICOM images (and any other DICOM objects) by the instrument are acted on in the PACS. A summary of the key identifying attributes defined by IHE to ensure information consistency throughout the acquisition workflow is:

- Patient name (0010,0010)
- Patient ID (0010,0020)

- Study Instance Unique Identifier (0020,000D)
- Accession Number (0008,0050)
- Requested Procedure ID (0040,1001)
- Scheduled Procedure Step ID (0040,0009)

For a complete mapping of the key attributes, see the Eye Care TF, Vol. 2, Appendix A. If your PACS does not act on any of these key attributes, your vendor may have an option or upgrade to provide proper support for these attributes.

If your PACS does not support DICOM Storage, IHE integration is not realistically possible, as DICOM Storage is the bare minimum functionality required. If your PACS lacks this bare minimum functionality, consider upgrading or replacing your PACS.

2.2.4.2.2 B-EYECARE with Added Features (A-EYECARE)

The A-EYECARE Profile provides additional features that are not available in the B-EYECARE, which already provides all the relevant features for electronic workflow. In the A-EYECARE Profile, the instrument expects the PACS to support several DICOM services, using specific attributes and responding to messages in specific ways (refer to the TF). In addition to the services provided in the B-EYECARE, the additional DICOM services are:

- DICOM MPPS as an SCP

Support for MPPS on a PACS is useful to "close the acquisition loop" by enabling automated procedure status tracking and billing. Though workflow may be hampered by absence of the MPPS service, data consistency between systems is not endangered in the absence of this service. If your PACS does not have DICOM MPPS, it will not be able to receive study status from the instrument (or the EHR). In this case, reducing the workflow problems this causes in terms of "closing the acquisition loop," tracking procedure status and performing fast and accurate billing can often be accomplished by one of the following means: *(a)* Your PACS may have a "fallback mode" that allows it to guess study status based on heuristics by using Storage and Storage Commitment or other events or triggers from the instrument or the EHR; *(b)* you may also track work status by using a EHR client on or near the PACS to view the status of the acquisition task.

Support for DICOM Storage Commitment on the PACS enables automatic removal of images from the instrument once the PACS has accepted "commitment" of them. If your PACS does not have DICOM Storage Commitment, it will not be able to confirm that the PACS has received and taken ownership of the imaging data. To reduce the problems this may cause: *(a)* Manually confirm all images for each study have been received on the PACS and "committed" to permanent, long term storage before deleting those images from the instrument system; and *(b)* keep copies of all images on the instrument until the reports have been generated and the images archived.

If your PACS does not support DICOM Storage, IHE integration is not realistically possible, as DICOM Storage is the bare minimum functionality required. If your PACS lacks this bare minimum functionality, consider upgrading or replacing your PACS.

2.2.4.3 Connecting the Instrument to a Non-IHE EHR

Request a DICOM Conformance Statement from your EHR vendor for the currently installed system at your site. See Appendix F.

2.2.4.3.1 Workflow (B-EYECARE)

In the B-EYECARE Profile, the instrument expects the EHR to support DICOM services, using specific attributes and is expected to respond to messages in specific ways (refer to the TF). The critical DICOM service is:

- DICOM MWL as an SCP

An EHR should use DICOM MWL to convey patient and order information to instruments. Check the conformance statement to see what kind of attributes it supports for Worklist query and return values, in particular for the extra attributes for which IHE requires support in addition to what is required in the DICOM Standard:

- Requested Procedure ID (0040,1001) as Matching Key,
- Accession Number (0008,0050) as Matching Key,
- Code Meaning (0080, 0104) as Return Key for the Scheduled Procedure Code Sequence (0040,0008)
- Requested Procedure Code Sequence (0032,1064)

If these attributes are not supported, your workflow will be affected because the instrument operator may not be able to search for the required Worklist entry efficiently.

In the absence of the DICOM MWL capabilities on the EHR, some possible workarounds for getting patient and exam information on the instrument are *(a)* using bar-codes (an alternative way of accessing at least essential identification data), and *(b)* manually entering data at the instrument using an EHR terminal or hard copy as a source of patient information. Critical information the instrument needs includes basic patient demographics, the EHR-assigned Accession Number, and if possible the EHR-assigned Study Instance Unique Identifier (to ensure consistent data throughout the Enterprise).

2.2.4.3.2 B-EYECARE with Added Features (A-EYECARE)

In the A-EYECARE Profile, the instrument expects the EHR to support several DICOM services, using specific attributes and responding to messages in specific ways (refer to the TF). In addition to the services provided in the B-EYECARE described above, the additional DICOM service is:

- DICOM MPPS as an SCP.

To close the acquisition workflow loop, instruments issue a DICOM MPPS to the relevant system to track the acquisition status (in progress, completed, discontinued), to notify the occurrence of the single-acquisition group case and to provide additional data on the work done for billing purposes. This is an additional feature that a site can decide to implement

during a later systems integration phase and negotiate accordingly with suppliers of the registration system. The need of this service also depends on whether the institution intends to integrate/automate the billing process into the overall workflow or continue with its unintegrated billing procedures.

If your EHR lacks support for DICOM MPPS, it will not be able to receive study status updates. To reduce problems this causes in terms of being able to close the acquisition loop, track procedure status and perform fast and accurate billing, the MPPS message could be sent to a broker, which could then send an HL7- based update message to the EHR and forward the MPPS to the PACS. An EHR terminal may be available close to the instrument console to manually enter exam updates.

3 SCENARIO: INSTALLING AN EHR

An Eye Care clinic, office or department is planning to install or upgrade their EHR. The department is experiencing an increasing volume of Eye Care procedures, yet not all revenue is realized. There are problems closing orders, and sometimes studies go missing in the reporting and result delivery process.

The institution has an existing source of patient demographics and order management. The department has a PACS, which archives all studies produced by the devices. There are a number of existing DICOM-capable devices and some new devices will be added after the EHR upgrade is complete.

The primary function of the PM system is to register patients, maintain their demographic information, schedule follow up visits and serve as the billing system. The primary function of the EHR will be to place orders for diagnostic tests and procedures, record encounter data and generate reports, as well as capture charges for procedures performed and interpreted in the Eye Care clinic, office or department. The EHR will send copies of diagnostic reports to an enterprise report repository.

3.1 THE PLANNING AND PURCHASING PROCESS

Intended for administrators in charge of making purchasing decisions, this section lists organizational goals to consider when specifying requirements for a PM and/or an EHR system, how to select IHE Integration Profiles that will address those goals, how to clearly state IHE requirements in an RFP and interpret vendor responses.

3.1.1 Achieving Organizational Goals

Clearly identifying organizational goals is an important first step in defining the requirements for any equipment acquisition. Each IHE Integration Profile is designed to meet a specific set of organizational goals. Below is a list of goals an institution might have in acquiring a new EHR and the contributions each relevant IHE Integration Profile makes in supporting these goals.

Reduce Errors and Enhance Patient Care

Scheduled Workflow (EYE CARE WORKFLOW) on the PM and EHR:

- Decreases lost data due to inconsistently identified data because the EHR receives patient demographics from the PM system and provides it to the PACS and devices
- Prevents manual data entry errors because the EHR receives patient demographics and updates from the PM system and Eye Care order details from the order entry system electronically
- Prevents manual data entry errors because the EHR transmits patient and order information to the device using MWL
- Prevents performing incorrect or cancelled procedures because the EHR makes up-to-the-minute Worklists, including recent procedure and schedule changes, available to the device

- Prevents complications from allergies or pregnancy status because the EHR includes details about patient allergies and pregnancy status in the MWL
- Minimizes patient waiting time because the EHR introduces efficiencies in the exam process, as described in the Improve Throughput section below

Improve Throughput

Scheduled Workflow (EYE CARE WORKFLOW) on the PM and EHR:

- Eliminates staff time wasted manually entering patient demographics because the EHR receives the information electronically from the PM system and provides it to the devices
- Reduces staff time wasted waiting or searching for paper orders because the EHR receives the ordered exams electronically from the order placing system and provides them to the devices
- Reduces staff time wasted identifying and correcting errors (in a coordinated fashion) among the PM, EHR, PACS and device because the PM system handles many of the corrections automatically
- Eliminates staff time wasted manually reconciling unscheduled orders because the EHR automatically backfills orders and informs the order placer systems when unscheduled acquisitions are reported by the devices

Increase Revenue/Improve Billing

Scheduled Workflow (EYE CARE WORKFLOW) on the PM and the EHR:

- Prevents loss of revenue for exams performed as ordered that were subsequently either canceled or modified because the EHR provides up-to-date details to the device via Worklists.
- Reduces delays in billing because the EHR receives timely procedure completion information from the device in the PPS messages
- Reduces inaccurate billing because the EHR receives accurate details on procedures cancelled or changed at the device

IHE Eye Care Charge Posting on the PM:

- Reduces billing delays because the PM captures billable events from all systems as they happen, makes the charges quickly and accurately and the results are centrally available

Reduce Operational Costs

Scheduled Workflow (EYE CARE WORKFLOW) and Eye Care Charge Posting on the PM and the EHR:

- Prevents extra head count due to the efficiencies and improvements in throughput and the billing process, as described above

Reduce Deployment Cost and Time

All IHE Profiles on the PM and the

EHR:

- Eliminates custom interface specification time and cost, since the IHE TF provides a detailed specification for a powerful interface, supported and tested by many vendors
- Prevents custom interface implementation time and cost, since many IHE Integration Profiles are already supported by many vendor products
- Reduces interface compliance testing time and cost because many implementation variations have been ironed out in systems tested at the IHE Connectathon
- Reduces intersystem testing time and cost because many combinations of systems have already been directly tested together at the IHE Connectathon
- Reduces custom interface maintenance time and cost by maintaining a single IHE interface instead of multiple custom interfaces

It is not always possible to address all organizational goals by making a single equipment purchase. Achieving the full benefit of an IHE Integration Profile requires that the systems interacting with the PM and the EHR also play their roles as defined in the Profile. Frequently, partial benefits can be achieved by implementing an Integration Profile on a single Actor, such as the EHR, in an environment where the interacting systems have some but not all of the functionality described in the Profile. Appendix A provides a general discussion of sequencing requirements and planning individual purchases as part of a long-range plan.

To track progress toward organizational goals and determine return on investment, a well-defined set of performance metrics is needed—see Appendix I.

3.1.2 Selecting IHE Integration Profiles and Actors

Specifying integration requirements for the system you are purchasing is a simple matter of selecting which IHE Integration Profiles and which IHE Actors you want supported. Note that some Profiles include options that provide additional functionality you may also decide to select. The Integration Profiles relevant to the purchase of a PM system and an EHR and the functionality each provides at the device are given below:

Scheduled Workflow: The EYE CARE WORKFLOW Profile forms the cornerstone of integrating a PM and/or an EHR with other systems in the institution. It establishes a seamless flow of information that supports efficient patient care in a typical imaging encounter and certain exception cases by specifying transactions that maintain the consistency of patient information from registration through ordering, scheduling, imaging acquisition, storage and viewing. It is strongly recommended that you start with this Profile.

Eye Care Charge Posting enables collecting accurate chargeable event information from devices and making it quickly and centrally available to billing systems.

Assisted Protocol Setting Option (in the EYE CARE WORKFLOW Profile) enables sending the initial protocol settings to the device in the Worklist.

IHE Exception Management Option (in the EYE CARE WORKFLOW Profile) allows monitoring of detailed feedback from the device about why studies were halted or may need to be "fixed."

The DSS/Order Filler Actor is the key role played by an EHR system. Additional IHE Actors the EHR can perform include Report Repository to provide permanent storage for diagnostic reports, Report Creator to create diagnostic reports and optionally retrieve Worklist entries for reporting steps, and Report Reader to query for and review reports.

The benefits provided by each Profile and Actor are outlined in the previous section. For further information on the Profiles, see Appendix B.

3.1.3 Putting Integration Requirements in Your RFP

Requiring IHE support in your RFP is as simple as stating which IHE Integration Profiles (and options) you want the system to support and which IHE Actor roles the system should play in each Profile.

The following are sample statements to specify Profiles and Actors for a full-featured EHR:

- *"The EHR shall support the **EYE CARE WORKFLOW Profile** as the **Order Filler** Actor."*
- *"The EHR shall support the **Assisted Protocol Setting Option** and the **Exception Management Option** in the **EYE CARE WORKFLOW Profile** as the **Order Filler** Actor."*
- *"The EHR shall support the **IHE Eye Care Charge Posting Profile** as the **Order Filler** Actor."*
- *"The PM shall support the **EYE CARE WORKFLOW Profile** as the **ADT/Patient Registration and Order Filler** Actor."*
- *"The PM shall support the **IHE Eye Care Charge Posting Profile** as the **ADT** and the **Charge Processor** Actor."*

For further discussion of the RFP process, see Appendix C.

3.1.4 Identifying Suitable Products

While you may choose to proceed directly to sending your RFP to a broad group of potential vendors, you can learn which vendors may have products with relevant IHE integration capabilities by referring to public sources. For source descriptions, see Appendix D.

3.1.5 Reading Integration Statements from Vendors

Vendors may respond to your RFP by providing an IHE Integration Statement document. You may also find IHE Integration Statements for many products at http://product-registry.ihe.net/PR/home.seam

An Integration Statement is a direct statement of which IHE Profiles, Actors and options are supported by a particular model of a particular system from a particular vendor. For the contents of an Integration Statement, see Appendix E.

3.2 THE CONFIGURATION AND IMPLEMENTATION PROCESS

The following sections are intended for the implementation team. They discuss important

clinical and IT considerations when deploying an EHR system with IHE capabilities, including dealing with "legacy" issues when connecting the EHR to systems that do not support IHE Profiles.

3.2.1 Considering Changes to Your Workflow

IHE Profiles are designed to implement digital imaging in a streamlined clinical workflow. For instance, they eliminate the need to enter patient information at the device, searching for lost film folders or reconciling cases in the unmatched study folder on the PACS. They also allow images to be immediately available for viewing. To gain the full benefit of these changes, there are several tasks that need to be performed in the correct manner.

Scheduled Workflow (A-EYECARE and B-EYECARE)

The A-EYECARE and B-EYECARE Profiles ensures that patient demographics and order and procedural information are correct and consistent throughout the enterprise—they must consistently be entered from the same system (PM, EHR, etc.) so the responsible system can maintain and appropriately distribute the information to all interested systems. Clinical and IT personnel will need to identify the owners of certain information elements. The owners distribute the information, while receivers track it. Typically,

- The PM system owns the patient identification. In an emergency case, the PM system is still required to reconcile the patient and update the EHR. Patients should only be registered in the PM system. The IHE workflow will update all other systems below it as needed. There is no IHE workflow to update the PM system if a patient is registered at the EHR.
- The EHR owns the Accession Number and Study Instance Unique Identifier, among other scheduling information. At the device, do not type in the Accession Number if it is unknown.

As a part of identifying information ownership, clinical and IT personnel may want to further review how information is related. For example, IHE supports an Accession Number associated with multiple ordered procedures. Setting up these types of relationships may resolve current workflow inefficiencies.

3.2.2 Confirming That It's Working

The following sections provide guidance as to how to confirm that the EHR is operating according to each IHE Profile implemented. Each section provides elements for testing an individual Profile as it relates to the EHR. Note that in many cases, there are other possible ways than the ones described to confirm the data and the transactions. For an introduction on testing strategies, see Appendix H.

3.2.2.1 Scheduled Workflow (A-EYECARE and B-EYECARE)

It is important that the patient demographics and order information sent from the PM are recorded correctly in the EHR. This information, along with additional patient demographics and order and procedural information, must be correctly forwarded to the device and PACS so that the proper procedures are performed and reported on. Likewise, the status information returned to the EHR from the device and PACS is critical in providing the enterprise with appropriate status on what procedures have been performed and the availability of information,

such as images.

Confirming the EHR interface operation requires checks at several points in the process. Confirm by checking the information of specific patient procedures that have been generated by the HIS and sent to the EHR for scheduling. Confirm the information of specific patient procedures that have been generated by the PM and the EHR and sent to the device to perform the procedure. Confirm by checking the status and update information from the device. Finally, confirm by checking the availability of images on the PACS.

The following are examples of the high-level list of tests that may need to be run on a new EHR with A-EYECARE or B-EYECARE. Some or all may be relevant to a specific enterprise. These test scenarios are based on the use cases identified in Section 4.4 of Vol. 1 of the IHE TF. Along with each scenario is a mechanism to verify that the test scenario is provided. Note that in many cases, there are multiple ways to confirm the data and the transactions.

Patient registration and order fulfillment can occur in a number of ways. This includes:

1) Register the patient and place the orders on the PM. Fill the order through the EHR. (*Patient Registration, Placer Order Management, Filler Order Management)*

   Confirming the scenario: Verify that the critical patient demographics, encounter information (PV-1), etc., entered during patient registration for your operation, appears correctly on the EHR. See Section 4.1.4 of the IHE TF Vol. 2 for specific information sent by the PM as HL7 messages (e.g., patient name, ID, address, class, consulting physician, allergy type). Then, verify that the critical order information entered for your operation appears correctly on the EHR. Make sure that the order can be filled and scheduled on the EHR. See Section 4.2.4 of the IHE TF Vol. 2 for specific information sent by the PM as HL7 messages (e.g., order number, order date/time, universal service ID, ordering provider).

2) Register the Patient on the PM, place the order through the EHR. (Patient Registration, Placer Order Management, Filler Order Management)

   Confirming the scenario: Verify that the critical patient demographics, encounter information (PV-1), etc., entered during patient registration for your operation appears correctly on the EHR through the Patient Management User Interface. See Section 4.1.4 of the IHE TF Vol. 2 for specific information sent by the PM system as HL7 messages (e.g., patient name, ID, address, class, consulting physician, allergy type). Then, verify that the critical order information entered at the EHR for your operation appears correctly on the PM system through the Patient Management User Interface. See Section 4.2.4 of the IHE TF Vol. 2 for specific information sent by the PM system as HL7 messages (e.g., order number, order date/time, universal service ID, ordering provider).

3) Register the patient on the PM system. Prior to placing any orders, update the patient information through the PM system.

   Confirming the scenario: Verify that the critical patient demographics, encounter information (PV-1), etc., reflected on the EHR through the Patient Management User Interface consists only of the updated patient data. See Section 4.1.4 of the IHE TF Vol. 2 for specific information sent by the PM as HL7 messages (e.g., patient name, ID, address, class, consulting physician, allergy type).

4) Based on the orders created by the PM system or the EHR, procedures are then scheduled by the EHR. *(Procedure Scheduled)*

Confirming the scenario: Verify that the procedural information for the registered patient is sent to the PACS. View the order information for the scheduled patient by using the Scheduled Procedure User Interface for the PACS. (Alternatively, there may be subsequent scheduling of activities to ensure that the appropriate information is available for reporting on the completion of the procedure. This includes the retrieval of prior image studies and reports). See Section 4.4.4.1.2 of the IHE TF Vol. 2 for specific information sent by the EHR as HL7 messages (e.g., patient name, ID, universal service ID).

5) In some cases, orders will change prior to performing a procedure. In this case, procedural information updates will need to occur on the EHR. *(Procedure Update)*

Confirming the scenario: Verify that the procedural information for the registered patient has been changed on the PACS by viewing the order information for the scheduled patient by using the Scheduled Procedure User Interface for the PACS. See Section 4.13.1.2 of the IHE TF Vol. 2 for specific information sent by the EHR as HL7 messages (e.g., procedure cancelled, procedure changed, procedure discontinued).

Procedures may be scheduled for devices. The systems performing procedures need to interact with the EHR, as they may need to retrieve scheduled procedures and provide updates. A representative number of systems should be tested to ensure all of the required order and procedural information is transmitted.

6) Devices may retrieve lists of procedure schedules on the EHR. *(Device Worklist Provided)*

Confirming the scenario: Verify that the patient demographics and order and procedural information for the scheduled procedure are displayed correctly on the device by viewing the MWL. See Table 4.5-3 of the IHE TF Vol. 2 for specific information sent by the EHR as DICOM (e.g., patient name, ID, requested procedure, AN).

7) As the device performs procedures, status updates are provided to the EHR. *(MPPS In-Progress, MPPS Complete in A-EYECARE*)

Confirming the scenario: Verify that the procedure according to the EHR matches what was performed on the device. The following is a list of outcomes. See Table 4.7-1 of the IHE TF Vol. 2 for specific information sent from the device in the case of procedure discontinuation and Section 4.6.4.1.2.4 for Assisted Protocol Option.

Outcomes: Device/workstations perform single scheduled procedure, device/workstations abandon procedure, device/workstations, device performs procedures different than scheduled, device performs unscheduled procedures, device performs procedures scheduled with protocol codes (if *Assisted Protocol Option* supported).

8) Workstations used to create additional images for reporting may also be required to notify the EHR of performed procedures. *(Creator Procedure Step In Progress, Creator Procedure Step Complete in A-EYECARE*)

Confirming the scenario: Verify that the procedure according to the EHR matches what was performed by the Evidence Creator. Below is a list of outcomes.

The EHR provides status updates to other components within the enterprise, including the PACS, during the acquisition phase of the procedure.

9) The EHR maintains not only procedural status, but also status on the images associated with the procedure. PACS reporting systems may schedule the reporting phase based on the status of not only the procedure, but also the availability of the images associated with the procedure. *(Image Availability*)

Confirming the scenario: Verify the status of the procedure during acquisition at the device and up through the time that the procedure is ready to report on. As images become available on the PACS, verify that the EHR status for the procedure is updated to reflect this.

For each of these areas, detailed sets of tests need to be developed with the appropriate data sets. The EHR is in the center of the Eye Care clinic, office or department, so this set may need to be fairly extensive. These data should include:

1) Development of HL7 records to be sent from the PM system to the EHR. *(a)* These records should include all HL7 messages, which will be sent from the PM system to the EHR to generate such items as patient demographics and patient orders. This includes HL7 messages, such as Admission, Discharge and Transfer (ADT) messages A01 (patient admission), A04 (patient registration), A05 (preadmission) and general order messages (ORMs). See the IHE TF for the specific transactions being tested. *(b)* These records should include all of the fields, which will be propagated to the devices (through MWLs), and PACS systems (through DICOM images). patient demographics/patient orders include critical fields such as patient name, ID, sex, requested procedure ID, Accession Number and performed procedure ID.
2) Development of HL7 records to be sent from the EHR to the PM system. (These may be data, created as part of the tests.) *(a)* These records should include all HL7 Messages, which will be sent from the EHR to the PM system to generate such items as patient demographics and patient orders. *(b)* These records should include all of the fields, which will be propagated to the devices (through MWLs), and PACS (through DICOM images). patient demographics/patient orders include patient name, ID, AN, requested procedure ID, scheduled location, device, scheduled protocol codes, and scheduled protocol description. See IHE TF Vol 2 Table 4.5-3 for a full list of parameters.
3) Development of codes and mappings on the EHR to be used within the Eye Care department. HL7 to DICOM mapping may need to occur as part of the system setup. This is necessary for such things as MWLs. If the Assisted Protocol Code Option is supported within A-EYECARE or B-EYECARE, protocol codes will need to be developed and set up both on the EHR and the devices.

3.2.3 Considering Installation Issues

Even with IHE, installation is not "plug & play"—the systems are not self-configuring. For the EHR, you will likely need to do the following:

3.2.3.1 Scheduled Workflow (A-EYECARE AND B-EYECARE)

- Configure the AE Title, IP address, and port for your DICOM MWL. This information needs to be shared with all the device vendors so they can be individually configured to query your EHR's MWL.
- Configure the AE Title, IP address, and port for your EHR's DICOM MPPS. This information needs to be shared with the PACS vendor (if it is the configured MPPS Manager) so they can forward MPPS messages from devices to your EHR. Otherwise, if your EHR is acting as the MPPS manager, it will be receiving MPPS messages and forwarding them, so all devices would need your EHR's MPPS configuration information.
- For your HL7 interfaces, configure the IP address and port for your ADT and order interfaces. These may or may not be the same. This information should be shared with your HIS so it knows where to send the HL7 messages. Locate the IP address and port for the PM system so procedure update messages can be sent from your EHR. Finally, for HL7 procedure messages, you will need to get the IP address and port for HL7 orders from your PACS vendor to allow your EHR to send orders and patient demographics to your PACS.

There is a significant amount of time that goes into creating and keeping various codes in sync between different systems. You will need to establish codes for many parts of your system—as simple as a set of gender codes to a much larger set of data, like provider codes. These codes are typically kept in sync manually, and if they are out of sync, the receiver may not accept data, as it may not be aware of a coded value.

3.2.4 Identifying and Addressing "Legacy" Problems

IHE Integration Profiles are built assuming that all relevant systems support these Profiles. If some systems do not support the Profiles you have selected but do support the standards the Profile is built on, some benefit is still possible. If you have deficient systems, consider how to work around the deficiencies in the short term and when you plan to replace or upgrade those systems.

3.2.4.1 Connecting the EHR to a Non-IHE PACS

Interoperability between the EHR and the PACS enables the patient demographics and order and procedural information to be preserved when new or updated information is provided through the PM system or EHR. Image status can be provided to ensure that images are made available as quickly as possible. Some or all of these capabilities may be available based on the capabilities of the non-IHE PACS. The following are some guidelines consider when determining how to integrate the EHR with a non-IHE PACS.

Request a current DCS and HL7 "interface specification" from your PACS vendor. See Appendices F and G.

3.2.4.1.1 Scheduled Workflow (A-EYECARE and B-EYECARE)

In the A-EYECARE and B-EYECARE Profiles, the EHR expects the PACS to support several DICOM and HL7 services, using specific attributes and responding to messages in

specific ways (refer to the TF). The critical DICOM and HL7 services are DICOM MPPS as an SCP, DICOM Query/Retrieve as an SCP, DICOM Instance Availability Notification as an SCP, and HL7 ORMs.

Your PACS should be able to receive DICOM MPPS status updates from a device. These updates include status on when acquisition is started and completed, as well as information related to the study and exam (Study Instance Unique Identifier and AN). In the absence of the DICOM MPPS capabilities on your PACS, your new EHR should be set up as the PPS Manager so your EHR will receive status updates.

Your PACS receives HL7 "procedure scheduled" messages (refer to Eye Care TF Vol. 2 4.4) from the EHR when exams have been scheduled. This includes patient demographics, scheduled procedure steps, and EHR-created Accession Number and Study Instance Unique Identifier. This allows the PACS to associate received images with the correct patient and exam and prefetch relevant prior images. In the absence of the ability to receive the HL7 "procedure scheduled" messages, the PACS operator would be required, when a device stores images that don't match the order, to manually handle reconciliation by entering patient demographics and exam-specific information, such as AN. The PACS would then start prefetching relevant prior images as soon as it starts receiving current images rather than when it receives the HL7 message. A broker/interface engine may be used to receive HL7 messages and convert these orders to a message the PACS does support. These workarounds obviously take time, and depending on how non-standard they are, may be expensive to implement.

3.2.4.2 Connecting the EHR to a Non-IHE Device

The interoperability between the EHR and the device enables the patient demographics and order and procedural information to be passed to the device from the PM system and/or EHR. Procedure status is provided by the device to ensure that images are made available as quickly as possible. Some or all of these capabilities may be available based on the capabilities of the non-IHE device. Some guidelines to consider when determining how to integrate the EHR with a non-IHE device are listed below.

Request a current DCS from your device vendor for each of your installed products. See Appendix F.

3.2.4.2.1 Scheduled Workflow (A-EYECARE and B-EYECARE)

In the A-EYECARE and B-EYECARE Profiles, the EHR expects the device to support several DICOM services, using specific attributes and responding to messages in specific ways (refer to the TF). The critical DICOM services are DICOM MWL as an SCU in A-EYECARE and B-EYECARE and DICOM MPPS as an SCU in A-EYECARE. Devices should use DICOM MWL to retrieve patient and order information from the EHR. IHE extends the required attributes to be displayed on the device. Check to see that all of the following IHE extended attributes are available for display in the Worklist on the device: Scheduled Procedure Step start date/time, device, Scheduled Procedure Step description, requested procedure description, requested procedure ID, AN, referring physician's name, and patient name, ID, birth date, and sex.

The devices could issue a DICOM MPPS (A-EYECARE) to the EHR system to track the acquisition status (in progress, completed) to close the acquisition loop and provide additional

data on the work done for billing purposes. This can be implemented in a later phase and negotiated accordingly with suppliers of both devices and registration system. If your device is missing support for one or both of these DICOM services, see the next section on connecting the EHR to a non-DICOM device.

3.2.4.3 Connecting the EHR to a Non-DICOM Device

Since your device does not support DICOM MWL and/or DICOM MPPS, there is no standards-based conformance statement to request of your vendor. Ask your device vendor for a proprietary mechanism for querying/receiving patient and exam information. In the absence of DICOM MWL capabilities on acquisition devices, possible workarounds for querying/receiving patient and exam information are: using bar codes (an alternative way of accessing at least essential identification data), using a device gateway from (semi-) proprietary interfaces to DICOM (might add some burden with additional costs and/or maintenance), and manually entering data at the device by reading at a EHR terminal or on hard copy.

Critical information for the device to have includes basic patient demographics, EHR-assigned AN, and if possible, EHR-assigned Study Instance Unique Identifier (to ensure consistent data throughout the enterprise). In the absence of DICOM MPPS capabilities on acquisition devices, possible workarounds for reporting study status are *(a)* "broker" systems or PACS options that can send MPPS on behalf of the device, *(b)* the PACS may have a "fallback mode" that allows it to guess study status based on Storage and Storage Commitment or other events or triggers from the device or the EHR, and *(c)* you can put a EHR terminal near each of the devices to manually enter the study status update.

3.2.4.4 Connecting the EHR to a Non-IHE PM system

The interoperability between the EHR and the PM system enables patient demographics and order information to be passed to the EHR and the rest of the Eye Care enterprise. Some or all of these capabilities may be available based on the capabilities of the non-IHE PM system. Some guidelines for consideration when integrating the EHR with a non-IHE PM system follow. Request a current HL7 "interface specification" from your PM vendor—see Appendix G.

3.2.4.4.1 Scheduled Workflow (A-EYECARE AND B-EYECARE)

In the A-EYECARE and B-EYECARE Profiles, the EHR expects the PM system to support several HL7 message types, using specific attributes and responding to messages in specific ways (refer to the TF). The critical HL7 message types are *(a)* HL7 patient registration messages, including at a minimum (depending on your facilities functions) the following ADT messages: *(i)* A01, registration of an inpatient visit; *(ii)* A04, registration of an outpatient visit; A08, update patient information, and *(iii)*, A40, patient merge; and *(b)* HL7 procedure-ordering messages, including at a minimum *(i)* new ORM and *(ii)* cancel ORM.

This minimal set of HL7 messages should provide the basic ability to pass patient demographics and visit information from your PM system to your EHR. These messages should also support any updates to the patient demographics and the ability to merge two patients together. For a complete set of IHE-defined HL7 messages required, see Eye Care TF Vol. 2 4.1-4.4 and 4.12.

Procedure-ordering messages should allow the PM system to create orders and send ORMs to the EHR for scheduling. Without this basic HL7 support, patient and/or exam identification may not be consistent throughout the enterprise. For example, if the PM system cannot notify the EHR of patient updates or merges via HL7 messages, the EHR may have the ability to perform the patient updates or merge operations directly.

Typically, there is an interface engine between a PM system and an EHR, which can be used to transform any of these messages. This may include minor changes to HL7 messages shared between the EHR and PM system, or if the PM system does not support HL7, the interface engine may allow proprietary messages to be converted to HL7 messages and vice versa. IHE also requires the PM system to support a bidirectional interface to receive order updates. Without the bidirectional interface, the following issues will arise: *(a)* an order may need to be re-entered at the PM system if it is placed at the EHR. *(b)* The PM system is not going to be up-to-date on patient and exam information. This has clinical and billing implications. *(c)* When the order is placed at the EHR, there is HL7 message handshaking (General Order Response Message) to allow the EHR to get the order number from the PM system. If the PM system does not support HL7, ask the vendor for interface specifications. Provide this to the EHR vendor or the interface analysts to determine how to manipulate the proprietary data to/from HL7. See Appendix G.

4 SCENARIO: INSTALLING A HIGHLY INTEGRATED PACS

An Eye Care clinic intends to install a new large-scale integrated Picture Archiving and Communication System (PACS). Increasing study sizes, rising numbers of studies, and the desire to better integrate with the practice management (PM) system and electronic order entry system are key issues. The new PACS will serve the eye care clinic for the purpose of digital archiving of images, diagnostic interpretation, and reporting.

Most instruments will archive studies to the PACS. Instruments with partial or no Digital Imaging and Communications in Medicine (DICOM) capability will need an additional system such as Acquisition Modality Importer (AMI). AMI is an IHE actor which converts non-DICOM instrument data into standardized DICOM output. . Reading will be done on soft-copy review workstations with a limited amount of printing images and reports for evaluation, referrals and teaching.

The PACS serves as the imaging source for both soft- and hard-copy interpretation. Long-term archiving will eventually shift from printed documents to digital. The Eye Care clinic also offers Eye Care interpretation services to other medical facilities in the region—i.e., reading studies from other institutions sent to the PACS for a second opinion or specialized diagnosis. The results of studies (images and reports) should be distributed to referring sites electronically or as printed materials or CDs.

4.1 THE PLANNING AND PURCHASING PROCESS

Intended for administrators in charge of making purchasing decisions, this section discusses organizational goals to consider when specifying requirements for a PACS system, how to select Integrating the Healthcare Enterprise (IHE) Integration Profiles that will address those goals, how to clearly state IHE requirements in a Request for Proposal (RFP) and how to interpret vendor responses.

4.1.1 Achieving Organizational Goals

The AAO has a resource page that highlights benefits of deploying IHE in a clinical practice, success stories, vendor integration statements, etc. For more details, visit: http://www.iheeyecare.org/resources.asp

Clearly identifying organizational goals is an important first step in defining the requirements for any equipment acquisition. Each IHE Integration Profile is designed to meet a specific set of goals. Below is a theoretical list of goals when acquiring a new PACS and the contributions that each relevant IHE Integration Profile makes in supporting these goals.

Reduce Errors and Enhance Patient Care

- Prevents mistaken patient identification because the PACS monitors orders from the electronic health record system (EHR) (which include patient demographics, in addition to order details) and checks the corresponding images received from the instrument for consistency
- Reduces image availability delays because the PACS responds to image availability queries from the EHR

Increase Throughput

Workflow (B-EYECARE) on the PACS:

- Improves efficiencies for viewing studies because the PACS centralizes storage of images and measurements from ALL instruments and is able to display ALL studies (old and new)

Reduce Operational Costs

Workflow (B-EYECARE) on the PACS:

- Reduces personnel requirements due to the efficiencies and improvements in throughput described above
- Largely eliminates document printing, management and storage costs because the PACS display presents images for soft-copy review instead of printed copies.

Reduce Unnecessary Imaging

Workflow (B-EYECARE) on the PACS:

- Prevents repeat imaging due to lost studies by reducing lost studies, as described in the above section on throughput.

Reduce Deployment Cost/Time ***All IHE Profiles on the PACS:***

- Prevent custom interface specification time and cost—IHE Eye Care Technical Framework (TF) provides detailed specifications for a powerful interface, supported and tested by many vendors
- Prevent custom interface implementation time and cost—many IHE Integration Profiles are already supported by numerous vendor products
- Reduce interface compliance testing time and cost—many implementation variations have been ironed out in systems tested at IHE Connectathons
- Reduces intersystem testing time and cost—many combinations of systems have already been directly tested together at IHE Connectathons
- Reduces custom interface maintenance time and cost by maintaining a single IHE interface instead of multiple custom interfaces

It is not always possible to address all organizational goals by making a single equipment purchase. Achieving the full benefit of an IHE Integration Profile requires that the systems interacting with the PACS also play their roles as defined in the Profile. Frequently, partial benefits can be achieved by implementing an Integration Profile on a single Actor, such as the PACS, in an environment where the interacting systems have some but not all of the functionality described in the Profile. Appendix A addresses sequencing requirements and planning individual purchases as part of a long-range plan. To track progress toward organizational goals and determine return on investment, a well-defined set of performance metrics is needed; see Appendix I.

A-EYECARE not only achieves the same benefits as B-EYECARE (see Section 3.1.1) but also it expands on those benefits. Below is a list of these expanded benefits for A-EYECARE and other Integration Profiles.

Reduce Errors and Enhance Patient Care

B-EYECARE with possible additional Features (Which may be included A-EYECARE products) on the PACS:

- Prevents inaccurate diagnosis due to missing images because the PACS uses MPPS and Storage Commitment to confirm with the instrument the list of images in the study sent to the PACS
- Reduces reporting delays because the PACS notifies reporting and other interested systems when imaging data become available (Instance availability notification option)
- Prevents misread studies caused by ophthalmologists doing initial reads before all images are available because the PACS notifies the review system when the complete study is available (Instance availability notification option)

Evidence Documents (in EYE CARE EVIDENCE DOCUMENTS) on the PACS:

- Prevents incomplete clinical data because the PACS stores and provides evidence documents containing clinical measurements

Increase Throughput

B-EYECARE with possible additional Features (Which may be included A-EYECARE products) on the PACS:

- Improves efficiencies for viewing studies because the PACS centralizes storage of images and measurements from ALL instruments and is able to display ALL studies (old and new)
- Prevents losing studies due to instrument deletion after presumed transmission to the PACS because the PACS explicitly confirms to the instrument that it has taken ownership of the images with Storage Commitment
- Eliminates technicians time wasted manually confirming successful storage on the PACS by using the Storage Commitment service
- Reduces postprocessing delays—the PACS notifies the Postprocessing Manager as soon as the images are available for postprocessing (Instance Availability Notification option)
- Reduces reporting delays—the PACS notifies the Reporting Manager when the images are available (Instance Availability Notification option)
- Reduces delays in initial reads because the PACS monitors the acquisition in progress and completes messages so ophthalmologists can keep abreast of the current status

Evidence documents (EYE CARE EVIDENCE DOCUMENTS) on the PACS:

- Reduces ophthalmologist time spent accessing multiple workstations—the PACS allows the review of non-image data, such as refractive instrument measurements

Reduce Operational Costs

B-EYECARE with Added Features (A-EYECARE) on the PACS:

- Reduces personnel requirements due to the efficiencies and improvements in throughput described above
- Largely eliminates document printing, management and storage costs because the PACS display presents images for soft-copy review instead of printed media.

Reduce Unnecessary Imaging

B-EYECARE with Added Features (A-EYECARE) on the PACS:

- Prevents repeat imaging due to lost studies by reducing lost or incomplete studies, as described in the above section on throughput

4.1.2 Selecting IHE Integration Profiles and Actors

Specifying integration requirements for the system you are purchasing is a simple matter of selecting which IHE Integration Profiles and which IHE Actors you want supported. Some Profiles include options that provide additional functionality. Where options are available, you should consider how the optional functionality could contribute to your operations and productivity and decide which ones to select. The Integration Profiles relevant to the purchase of a PACS and the functionality each provides are given below:

- *B-EYECARE*
- *A-EYECARE*
- *Eye Care Charge Posting*
- *Eye Care Evidence Documents*
- *Eye Care Displayable Reports*

The Image Manager/Archive Actor is the key role played by a PACS system. Most PACS also play the roles of the Image Display Actor and the PPS Manager Actor. Additional Actors the PACS can perform include:

- *Evidence Creator Actor* to generate reprocessed images or additional measurements
- *Report Creator Actor* to create and export reports containing interpretations of imaging and other evidence
- *Report Repository Actor* to archive and distribute diagnostic reports

The benefits provided by each Profile and Actor are outlined in the previous section. For further information, see Appendix B.

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It is strongly recommended that you start with this Profile or the A-EYECARE.

4.1.3 Putting Integration Requirements in Your RFP

To specify IHE support in your RFP, you must specify which IHE Integration Profiles (and options) you require the system to support and which IHE Actor roles the system should play in each Profile.

4.1.3.1 Workflow (B-EYECARE)

To acquire a PACS with the B-EYECARE features described above, the RFP must specify the B-EYECARE Integration Profile and must require the PACS to support the appropriate actors, e.g., Image Manager and Image Archive Actors.

This statement requires the PACS to integrate seamlessly with an IHE conforming EHR and PM system and instruments to obtain the functionality discussed above using the DICOM standard.

The following are sample statements to specify Profiles and Actors for a full-featured PACS:

- *"The PACS shall support the **Image Manager/Image Archive Actor** in the following IHE Integration Profiles: **B-EYECARE**."*

4.1.3.2 Workflow (A-EYECARE and Other Profiles)

To specify IHE support in your RFP, you must specify which IHE Integration Profiles (and options) you require the system to support and which IHE Actor roles the system should play in each Profile. To acquire a PACS with the features described above, the RFP must specify the A-EYECARE Integration Profile or other Profiles and must require the PACS to support the appropriate actors, e.g., Image Manager and Image Archive Actors.

The following are sample statements to specify Profiles and Actors for a full-featured PACS:

- *"The PACS shall support the **Image Manager/Image Archive Actor** in the following IHE Integration Profiles: **A-EYECARE, Eye Care Evidence Documents**."*
- *"The PACS shall support the **Evidence Creator Actor** and the **Image Display Actor** in the following IHE Integration Profiles**: A-EYECARE**, **Eye Care Evidence Documents**."*
- *"The PACS shall support the **Report Creator, Report Repository, and Report Reader actors** in the following IHE Integration Profile: **Eye Care Displayable Reports**.*

This section only discusses B-EYECARE; however there are many other IHE useful profiles such as:

- Eye Care Evidence Documents
- Eye Care Displayable Reports

For further discussion of the RFP process, see Appendix C.

4.1.4 Identifying Suitable Products

While you may choose to proceed directly to sending your RFP to a broad group of potential vendors, you may get an idea of which vendors may have products with relevant IHE integration capabilities by referring to public sources. For a description of these sources, see Appendix D.

4.1.5 Reading Integration Statements from Vendors

Vendors may respond to your RFP by providing an IHE Integration Statement document. You may find IHE Integration Statements for many products at the IHE Registry:

http://product-registry.ihe.net/PR/home.seam

An Integration Statement is a direct statement of which IHE Profiles, Actors and options are supported by a particular model of a particular system from a particular vendor. For the contents of an Integration Statement, see Appendix E.

4.2 THE CONFIGURATION AND IMPLEMENTATION PROCESS

The following sections are intended for the implementation team. They discuss important clinical and IT considerations when deploying a PACS system with IHE capabilities, including how to approach "legacy" issues when connecting the PACS to systems which do not support IHE Profiles.

4.2.1 Considering Changes to Your Workflow

IHE Profiles are designed to implement digital imaging in a streamlined clinical workflow. For instance, they eliminate the need to enter patient information at the instrument, searching for lost image folders or reconciling cases in the unmatched study folder on the PACS. They also allow images to be available immediately for viewing. To gain the full benefit of these changes, there are several tasks that need to be performed in the correct manner.

4.2.1.1 Workflow (B-EYECARE)

The B-EYECARE Profile will be used to ensure that patient demographics, order and procedural information are correct and consistent throughout the enterprise. Additionally, internal system status updates provide access to clinical data in a more timely fashion. Ophthalmologists will be able to rely on patient demographics, order and procedure information, as the PMS and EHR system updates will be provided to the PACS.

4.2.1.2 B-EYECARE with Added Features (A-EYECARE)

The A-EYECARE Profile will be used to ensure that patient demographics, order and procedural information are correct and consistent throughout the enterprise. In addition to the features of the B-EYECARE described above, ophthalmologists will be provided with current image status for a particular study.

4.2.2 Confirming that it's Working

The following sections provide guidance on how to confirm that the PACS is operating within the system. Each section provides elements for testing an individual Profile as it relates to the

PACS. Note that in many cases, there are multiple ways to confirm the data and the transactions. This method is only one way. For an introduction on testing strategies, see Appendix H.

4.2.2.1 Workflow (B-EYECARE)

For the PACS, it is important that the DICOM images and related DICOM objects from performed procedures and subsequent workstation renderings are permanently stored. Furthermore, it is critical that workstations may inquire for available images and retrieve them for use within the postprocessing and reporting phases. The following is an example of the high-level list of tests that may need to be run on a new PACS System for B-EYECARE:

1) For each instrument type on the enterprise, display images from the PACS. *(Query Images, Retrieve Image)*

   Confirming the scenario: Verify that the images can be retrieved from the PACS and properly displayed. Then verify that the patient demographics, order and procedural information on the EHR match those on the images.

2) Create new post-processing images (images that have been adjusted or had additional quantitative analysis after the procedure) and archive them to the PACS. *(Modality Images/Evidence Stored)*

   Confirming the scenario: Verify that the images can be retrieved from the PACS and properly displayed.

For each of these areas, detailed sets of tests need to be developed with the appropriate data sets. These data will need to include development of images to be sent from the instruments to the PACS; scheduled procedures created for each instrument, so that the DICOM images created from the instruments include all of the critical patient demographics and procedural information; and DICOM images created on workstations for each post-processed image.

4.2.2.2 B-EYECARE with Added Features (A-EYECARE)

In addition to testing for B-EYECARE described above, for PACS that have the capability to support A-EYECARE, these tests may need to be run:

1) Complete scheduled procedures for each of the relevant instruments as scheduled on the instrument, with verification of the availability of the images *(MPPS Complete, Image Availability)*. Also, *(a)* perform an unscheduled procedure on a instrument where the patient demographics and procedural information will be entered (it may be from a bar code or manually), *(b)* append a new procedure to a scheduled procedure after the ophthalmologist reviews the resulting images, and *(c)* abandon the procedure on an instrument before it is completed.

   Confirming the scenario: Verify that the procedure status and procedure type on the EHR (or PACS) has been updated based on the procedure being performed on the instrument. Make sure the number of images available matches the number of images acquired.

2) Archive the images from the instrument to the PACS System (either through auto-store or manual storage of images). *(Storage Commitment)*

   Confirming the scenario: Verify that the images created on the instrument are stored on

the PACS system. Then verify that the procedure status on the EHR (or PACS) has been updated based on the procedure being performed on the instrument. Make sure the number of images available matches the number of images acquired.

3) Attempt to delete the images from the instrument prior to the PACS claiming possession of the images. *(Storage Commitment)*

   Confirming the scenario: Verify that the images on the instrument cannot be deleted because they have not been permanently stored through the PACS system.

4) Attempt to delete the images from the instrument after the PACS claims possession of the images. *(Storage Commitment)*

   Confirming the scenario: Verify that the images on the instrument can be deleted because they have been permanently stored through the PACS system.

4.2.3 Considering Installation Issues

Even with IHE, installation is not "plug & play"—the systems are not self-configuring. For PACS, this is a list of configuration and installation items that will need to be considered. Configure the PACS with the AE Title, Integration Profile address, and ports for all instruments and workstations with DICOM Storage Services.

1) Configure the AE Title, Integration Profile address, and port for your PACS' DICOM print services.
2) Configure the above parameters for other media output such as a CD with the patient's images and records

A significant amount of time goes into creating and keeping various codes synchronized between different systems. Codes will need to be established for many parts of your system. The codes may be as simple as a set of protocol codes or may entail a much larger set of data, like procedure codes. These codes are typically synchronized manually. If codes do not match up, a receiver may not accept data, as it may not be aware of the supplied coded value.

In addition to testing for the B-EYECARE described above, for the PACS that have the ability to support A-EYECARE, these installation issues will need to be considered:

1) Configure the PACS with the AE Title, Integration Profile address, and port for the instrument's DICOM MPPS (if it is the configured MPPS Manager) so the PACS can forward MPPS messages from the instrument to the EHR. Otherwise, if the EHR acts as the MPPS Manager, it will receive MPPS messages and forward them to the PACS.

4.2.4 Identifying and Addressing "Legacy" Problems

IHE Integration Profiles perform best when all relevant systems support the Profiles. If some systems do not support the Profiles you have selected, but do support the standards a Profile is built upon, it is possible that some benefits of the standards will be achieved. If you have deficient systems, you should consider how to work around identified deficiencies in the short term and strategically consider whether or when to replace or upgrade those systems.

4.2.4.1 Connecting the PACS to a Non-IHE Instrument

Interoperability between the instrument and the PACS enables the patient demographics,

order and procedural information to be preserved when new or updated information is provided through the PM or EHR System. Additionally, image status can be provided to ensure that images are made available as quickly as possible. Some or all of these capabilities may be available based on the capabilities of the non-IHE instrument.

Instruments with partial or no Digital Imaging and Communications in Medicine (DICOM) capability will need an additional system such as Acquisition Modality Importer (AMI). AMI is an IHE actor which converts non-DICOM instrument data into standardized DICOM output.

Request a current DICOM Conformance Statement (DCS) from your instrument vendor for each of your installed products. See Appendix F.

4.2.4.1.1 Workflow (B-EYECARE)

In the B-EYECARE Profile, the PACS expects the instrument to support several DICOM services, using specific attributes and responding to messages in specific ways (refer to the IHE Eye Care Technical Framework documents. The critical DICOM services are DICOM Storage as a Service Client User (SCU), and DICOM Modality Worklist (MWL) as an SCU.

If your instrument has all of these services, confirm that critical DICOM attributes that the instrument stores to the PACS are being provided in the DICOM images (and any other DICOM objects). A summary of the key identifying attributes defined by IHE to ensure information consistency throughout the acquisition workflow is the following

- Patient Name (0010,0010)
- Patient ID (0010,0020)
- Accession Number (0008,0050)
- Requested Procedure ID (0040,1001)
-

If one or more of your current instrument systems is missing any of the services listed above, your vendor may have an option or upgrade to provide these attributes.

If your instrument cannot retrieve DICOM MWLs but does support DICOM Storage, it will not be able to automatically get accurate patient, order and procedure information as scheduled by the EHR. Although this interaction is defined in IHE as occurring between the instrument and the EHR, it does have a bearing on the quality of integration between the instrument and the PACS. The Acquisition Modality Importer should be used if DICOM MWL is not supported on the instrument.

4.2.4.1.2 B-EYECARE with Added Features (A-EYECARE)

In the A-EYECARE Profile, the PACS expects the instrument to support several DICOM services, using specific attributes and responding to messages in specific ways (refer to the IHE Eye Care TF). In addition to the critical DICOM services for the B-EYECARE described above, the critical DICOM services are DICOM MPPS as an SCU, and DICOM Storage Commitment as an SCU.

If one or more of your current instrument systems is missing any of the services listed above, your vendor may have an option or upgrade to provide these attributes. Support for MPPS

on instruments is useful to "close the acquisition loop" by enabling automated procedure status tracking and billing. Though workflow may be hampered by absence of the MPPS service, data consistency between systems is not endangered in the absence of this service.

If your instrument does not have DICOM MPPS, it will not be able to report study status to the PACS (and the EHR). In this case, reducing the workflow problems this causes in terms of "closing the acquisition loop," tracking procedure status and performing fast and accurate billing can often be accomplished by one of the following means: *(a)* "Broker" systems or PACS options may be available that can send MPPS on behalf of the instrument. Such systems frequently also provide Worklist functions to the instrument. *(b)* Your PACS may have a "fallback mode" that allows it to guess about study status based on Storage and Storage Commitment or other events or triggers from the instrument or the EHR. *(c)* You may also track the work status by using an EHR client on or near the instrument—e.g., by manually "signing off" the acquisition task.

Support for DICOM Storage Commitment on instruments enables automatic removal of images from the instrument once the PACS has accepted "commitment" of them. If your instrument does not have DICOM Storage Commitment, it will not be able to confirm that the PACS has received and taken ownership of the imaging data. To reduce the problems this may cause, manually confirm all images for each study have been received on the PACS and "committed" to permanent, long-term storage before deleting them from the instrument system. Keep copies of all images on the instrument until reports have been generated and images archived.

4.2.4.2 Connecting the PACS to a Non-DICOM Instrument

As mentioned in the section on integrating a PACS with a non-IHE instrument, the ability to transmit and store instrument-generated images to a PACS using DICOM is a necessity to achieve even the most basic level of integration, because all IHE-capable PACS systems will expect to receive images via DICOM. It is recognized that legacy non-DICOM instruments still exist within healthcare environments. To address the situation where one or more of your instruments does not support DICOM Storage, one of the following approaches can be taken to correct this situation until such time where these outdated instruments can be replaced.

1) The instrument vendor may have a software upgrade or option that adds DICOM Storage capability to the instrument. In addition, there may be upgrades/options available from the instrument vendor that enable DICOM MWLs, Storage Commitment and/ or Modality Performed Procedure Step (MPPS).
2) Instruments with partial or no DICOM capability for which a software upgrade is not available will need an additional system such as AMI. AMI is an IHE actor which converts non-DICOM instrument data into standardized DICOM output.

4.2.4.3 Connecting the PACS to a Non-IHE EHR

Interoperability between the PACS and the EHR enables the patient demographics, order and procedural information to be preserved and updated when new or updated information is provided through the PM system or EHR. Image status can be provided to ensure that images are made available as quickly as possible. Some or all of these capabilities may be available based on the capabilities of the non-IHE EHR. Some guidelines to consider when

determining how to integrate the PACS with a non-IHE EHR follow.

Request a current DCS and HL7 "interface specification" from your EHR vendor. See Appendices F and G.

Note that this deployment scenario considers integrating a PACS to a separate EHR system. A combined PACS-EHR product handles the PACS and EHR communication internally, but any communication with other PACS systems still requires a thorough interface review.

4.2.4.3.1 Workflow (B-EYECARE)

In the B-EYECARE Profile, the PACS expects the EHR to support several DICOM and HL7 services, using specific attributes and responding to messages in specific ways (see the IHE Eye Care TF). Critical DICOM and HL7 services are:

- DICOM Query/Retrieve as an SCU, HL7 ORMs
- HL7 ADT messages

Verify that the EHR can provide the following key patient, order and procedure identifying attributes in the HL7 ORMs it sends to the PACS:

- Patient Identification Segment (PID)
  - Information such as Patient Name, Patient ID, Patient Date of Birth, Patient Sex, etc.
- Filler order number, Accession Number, etc.

The EHR often plays a key role in departmental workflow management. As such, it is important for the EHR to be aware when all images for a procedure are available so that subsequent workflow steps, such as reporting or additional image postprocessing, can begin. Support in the EHR for the DICOM Query Service is useful to provide this awareness. If the EHR does not support DICOM Query as an SCU, the EHR will not have an automated way to determine when all images from a procedure are available. To reduce the problems this causes, you may use a PACS client for querying to determine if all images are available. An interfacing mechanism may be able to perform the DICOM query on behalf of the EHR.

The PACS uses the HL7 order (procedure scheduled) messages it receives from the EHR to streamline image review workflow by enabling the prefetching of relevant prior studies. If the EHR does not send HL7 ORMs, the ability of the PACS to perform prefetching may be limited. To reduce the problems this causes, a broker/interface engine may be used to convert the proprietary order/procedure scheduled message provided by the EHR into an HL7-based ORM, or the EHR vendor may have a software upgrade or option that adds HL7 capability, including the transmission of HL7 ORMs.

The PACS uses the HL7 ADT messages it receives from the EHR to keep patient and encounter data current in the PACS' DICOM objects. This is especially important for correctly handling instances of unidentified patients and misidentified patients. If the EHR does not send HL7 ADT messages, the ability of the PACS to maintain consistency of patient and encounter data may be limited. To reduce the problems this causes, a broker/interface engine may be used to convert the proprietary patient or encounter message provided by the EHR into an HL7-based ADT message, or the EHR vendor may have a software upgrade or option that

adds HL7 capability, including the transmission of HL7 ADT messages.

4.2.4.3.2 B-EYECARE with Added Features (A-EYECARE)

In the A-EYECARE Profile, the PACS expects the EHR to support several DICOM and HL7 services, using specific attributes and is expected to respond to messages in specific ways (see the IHE Eye Care TF). In addition to the critical DICOM and HL7 services for B-EYECARE described above, critical DICOM services for A-EYECARE are:

- DICOM MPPS as an SCU
- DICOM Instance Availability Notification as a

  Service Class Provider (SCP)

If your EHR has these two services, confirm that the EHR can accept the critical DICOM attributes that are being provided in the DICOM MPPS messages. Key identifying attributes defined by IHE to ensure information consistency throughout the acquisition workflow are:

- Patient Name (0010,0010)
- Patient ID (0010,0020)
- Accession Number (0008,0050)
- Requested Procedure ID (0040,1001)
- PPS ID (0040,0253)

For a complete mapping of the key attributes, see the IHE Eye Care TF, Vol. 2, Appendix A.

Support for MPPS between the EHR and instruments (or PACS) is useful to "close the acquisition loop" by enabling automated procedure status tracking and billing. If your EHR does not support DICOM MPPS, it will not be able to receive study status updates from an instrument, nor will it be able to forward them to the PACS. In this case, reducing the workflow problems this causes in terms of "closing the acquisition loop," tracking procedure status and performing fast and accurate billing can often be accomplished by one of the following means

In the absence of the DICOM MPPS capabilities on your EHR, your new PACS should be set up as the PPS Manager so your PACS will receive these status updates.

The EHR often plays a key role in departmental workflow management. As such, it is important for the EHR to be aware when all images for a procedure are available so that subsequent workflow steps, such as reporting or additional image postprocessing, can begin. Support in the EHR for the DICOM Instance Availability Notification Service or DICOM Query Service is useful to provide this awareness. If the EHR does not support either DICOM Query as an SCU or DICOM Instance Availability Notification as an SCP, the EHR will not have an automated way to determine when all images from a procedure are available. To reduce the problems this causes, you may use a PACS client for querying to determine if all images are available, an interfacing mechanism may be able to perform the DICOM query on behalf of the EHR, and an interface converter may receive, route or process a DICOM Instance Availability message for enabling automated availability notifications (e.g., by converting the

DICOM message into a message the EHR can understand and process).

4.2.4.4 Connecting the PACS to a Non-IHE Workstation

The interoperability between the workstation and PACS enables the viewing and manipulation of images and other objects that are stored on the PACS. The workstation may be able to create new images derived from the images originally acquired at the instrument and store these to the PACS. The workstation may also be able to store information to the PACS indicating various viewing parameters and image manipulations that were performed. Some or all of these capabilities may be available based on the capabilities of the non-IHE Workstation. Some guidelines to consider when determining how to integrate the PACS with a non-IHE workstation follow.

Request a current DCS from your workstation vendor for each of your installed products. See Appendix F.

4.2.4.4.1 Workflow (B-EYECARE)

In the B-EYECARE Profile, the PACS expects the workstation to support several DICOM services, using specific attributes and responding to messages in specific ways (see the IHE Eye Care TF). The critical DICOM services are:

- DICOM Query/Retrieve as an SCU
- DICOM Storage as an SCU (in cases where the workstation can create derived images)

A workstation in the B-EYECARE Profile is expected to query for images and retrieve them from the PACS for the purpose of displaying them and performing postprocessing, which may not have been scheduled. If your workstation does not support DICOM Query/Retrieve, it will be more difficult to view and post process the images stored on the PACS. In this case, you will need to find alternate ways to identify the images and get them to the workstation for viewing and/or postprocessing. This can be accomplished in the following ways: *(a)* the workstation may be capable of receiving DICOM images sent to it. Identify the images by using an integrated PACS workstation. Send them to your legacy workstation for further viewing/processing. *(b)* Your PACS may be able to transfer the images to the workstation by using a piece of media your workstation is able to read (e.g., the PACS could create a DICOM-formatted CD that the workstation is capable of reading). *(c)* Your workstation vendor may have a software upgrade or option that enables DICOM Query/Retrieve functionality. *(d)* An additional software that enables DICOM Query/Retrieve functionality may be offered by other vendors or publishers.

A workstation that can post process images and create derived images is expected to store them to the PACS as part of the B-EYECARE Profile by using the DICOM Storage Services.

If your instrument does not support DICOM Storage, you may want to use an interface box temporarily to provide it. However, DICOM Storage is a minimum requirement.

4.2.4.4.2 B-EYECARE with Added Features (A-EYECARE)

In the A-EYECARE Profile, the PACS expects the workstation to support an additional DICOM service, using specific attributes and responding to messages in specific ways (see the IHE Eye

Care TF). In addition to the critical DICOM services for B-EYECARE, the critical DICOM service for A-EYECARE is:

- DICOM Storage Commitment as an SCU (in cases where the workstation can create derived images)

A workstation that can post process images and create derived images is expected to store them to the PACS and request that the PACS take ownership for the images as part of the A-EYECARE Profile by using the DICOM Storage and Storage Commitment Services. Support for DICOM Storage Commitment on the workstation enables automatic removal of images from the workstation once the PACS has accepted "commitment" of them.

If your workstation does not have DICOM SC, it will not be able to confirm that the PACS has received and taken ownership of the imaging data. To reduce the problems this may cause: Manually confirm that all images for each study have been received on the PACS and "committed" to permanent, long-term storage before deleting them from the workstation. Keep copies of all derived images on the workstation until the images have been archived.

5 SCENARIO: INTEGRATING CLINICAL DOCUMENTS INTO YOUR EHR

The ability to document patient care is an essential part of an electronic office. It's not only important to capture such information but also vital to exchange this information between EHR systems using open standards based solutions. One example of this type of situation might be where your clinic is contracted to perform follow up care for patients that have been seen in the local hospital emergency room for an eye related problem. The HL7 Clinical Document Architecture (CDA) provides the open standard for capturing patient care in clinical documents.

The CMS Final Rule for stage 1 and stage 2 Meaningful Use (MU) adopted the HL7 CDA standard to exchange a patient's summary of care record. For example, one document specified is HITSP C32-Summary Document using HL7 Continuity of Care Document (CCD). This HL7 based clinical document incorporates many IHE standards such as the definition of Chief Complaint, Medications, Active Problems, Allergies, etc. Certified EHRs are required to create and receive this clinical document.

IHE Eye Care expects further requirements for standardized exchange of patient information and these will likely rely upon CDA document standards. As a result we have begun development of appropriate CDA document standards for eye care.

The **first** type of CDA document defined by IHE Eye Care is called **General Eye Evaluation (GEE).** Its purpose is to capture data recorded by physicians in the course of an encounter with a patient.

Following GEE, IHE Eye Care has defined CDA documents related to eye care surgery. They are:

- **Cataract Pre-Operative Note (Cataract-PreOp) –** it defines the data that is collected during a patient's pre-operative eye examination for cataract surgery. This includes an ocular history and exam as well as relevant ancillary testing.

- **Cataract Operative Note (Cataract-Op) –** it defines the data that is collected during a patient's cataract surgery. It is a comprehensive description of the cataract surgery and associated procedures. This may include pre-and postoperative diagnoses, procedure, findings and unusual occurrences, fluids administered, implant(s), complications, postoperative expectations, and management plan, etc.

- **Cataract Post-Operative Note (Cataract-PostOp)** – it defines the data that is collected during a patient's post-operative cataract surgery eye examinations. It is a provider note that describes data such as post-operative findings, complications, medications and care plan.

- **General Eye Care Operative Note (Eye-Op)** – it defines data that is collected during patient's eye surgery. It is a general operative note that can be used for all types of eye care surgeries but is not intended to replace or substitute for a specific eye care operative

note (e.g., Cataract Operative note, Glaucoma operative note, etc.). This may include pre- and postoperative diagnoses, procedure, findings and unusual occurrences, length of procedure, estimated blood loss, fluids administered, implant(s), specimen removed (if any), complications, postoperative expectations, and management plan.

While GEE and the surgery CDA documents follow the architecture and standards chosen by MU, there is no current requirement for them since eye care exams and surgeries have not yet been addressed in this regulation. However, the published MU strategy suggests that this is likely forthcoming so IHE Eye Care is preparing in our best judgment what is likely to be needed to satisfy future MU standards specific to eye care.

5.1 HL7 CLINICAL DOCUMENT ARCHITECTURE – A BRIEF EDUCATION

HL7 specifies the CDA standard for exchange of clinical documents. The CDA defined six characteristics of a clinical document, they are; persistence, stewardship, potential for authentication, content, wholeness and human readability.

- **Persistence** – documents exist in an unaltered state that can be queried and accessed (how long they exist is based upon policy, government regulations, etc.).

- **Stewardship** – documents are maintained by responsible organizations. That means responsible organizations must be able to produce the clinical documents for many years and not lose any clinical data captured. The CDA header requires the name of the steward organization be recorded at the time the document is created.

- **Potential for Authentication** – include the ability for the legally responsible provider to attest to the document with a signature. CDA supports the use of electronic signatures.

- **Content** – a clinical document tells a story about care being provided to the patient. This information is stored in the CDA header and provides default context for all the information in the body of the document. Information includes:
  - Document identifier
  - Relevant dates and times
  - Type and author of document
  - Legal authenticator
  - Patient whose care is describes
  - The clinical encounter(s)
  - Preceding document it may replace or amend (if they exist)
  - Intended recipient of the information (when the document was first written)
  - Sources of information contained with the document
  - Identity of clinicians providing the care documented

- **Wholeness** – the information contained within the document is expected to be understood in the context of the whole. For example, it may contain information about medication that the patient has been prescribed, but that may not be fully understood without also providing the specific diagnosis for which the medication was described.

- **Human Readability** – documents are read by humans, this mean there must be a way to display the content in a way that allows humans to read it (how this is accomplished is quite often proprietary implementation strategy).

CDA documents are implemented via the XML standard and the CDA model maps closely to HTML and XHTML. These standards are widely supported across all medical specialties and therefore a large set of implementation tools are readily available to manage CDA documents.

5.1.1 CDA Document Structure

The CDA clinical document is comprised of a document header (sets the context for the document) and the body of the document (contains the human readable narrative text) and potentially machine readable semantic content.

5.1.1.1 CDA Header

The header contains metadata about the document, including the type of document, its identifier and the creation date. It also describes participants in the encounter being documented, including the author, patient, and legal authenticator (signer). It documents the encounter during which service(s) were performed, relates the document to the service and relates the document to any prior documentation of that encounter or those services (such as amendments or complete new document with additional information).

5.1.1.2 CDA Body

The body of a CDA clinical document contains narrative (human readable) data in sections of the document and machine readable data within section entries. The narrative content uses XML markup to identify paragraphs, lists, tables, multimedia content, and other common structures for communication of narrative information. The body of the document may be structured or unstructured.

Examples of unstructured data include external files such as MS RTF documents, PDFs, etc. This provides little if any semantic interoperability if unstructured data is used, as this is a human readable display solution only (i.e. not machine computable). However the CDA header provides some required context and minimum management metadata for its required data.

Structured data is encoded as XML structured content. This is the primary usage of IHE clinical documents such as GEE.

Clinical documents are organized into sections and subsections. Sections contain categories of information pertaining to a single specified concept; therefore the list of Sections within a document can be quite large. Examples include problems, medication, immunizations, vital signs, procedures, encounters, allergies, diagnosis results, assessment, plan of care, etc.

5.1.1.3 Sections

The list of Sections for GEE is defined in table shown below. GEE specifies constraints with respect to the sections that must be present and others which may be present (required, conditional, or optional). Certain sections in GEE are text only while others include machine readable data (i.e. coded terms to define the context such as SNOMED codes). The coded data in

a CDA document is contained in Entries, which are further described below.

5.1.1.4 Entries

Entries are used to document clinical observations. They are collections of data elements pertaining to a single instance of the specific concept. For example a refractive measurements entry describes all the data elements for one refractive measurement (sphere and cylinder power, cylinder axis, reading addition power, distance power, interpupillary distance, etc.)

A refractive measurement Section is a collection of Entries pertaining to all the refractive measurements for one eye of a patient at a particular point in time. For example, there may be one entry for the left eye and a second entry for the right eye.

5.1.1.5 Vocabulary

A vocabulary (also known as a terminology) is a collection of concepts along with their relationships to each other. In some vocabularies, the relationships are hierarchical (such as SNOMED, LOINC, ICD 9-CM, etc.

5.1.1.6 Templates

A general strategy for constraining clinical documents being used by IHE and HL7 is to create templates. A template can apply to a whole CDA document or to Sections and/or Entries within a document. It is common to define the Sections/Entries that are required for a specific document in a template. It is also common to define specific vocabulary restrictions.

IHE Eye Care has defined the "templates" for GEE, therefore enhancing interoperability of eye exam documentation for exchange between EHR systems.

5.2 IHE ACTORS AND ROLES

An EHR implementing an IHE CDA document can chose to create and/or consume the clinical document. IHE assigns actor names to those roles so it is clear what the EHR supports. The names of the actors are:

- Content Creator – a system that is able to create the IHE clinical document
- Content Consumer – a system that is able to consume (use) the IHE clinical document

The Content Creator builds CDA documents based upon the IHE eye care specifications. As discussed above both narrative and machine readable data are included. There should also be a "style sheet" to ensure a consistent rendering of the document content by the Content Consumer Actor. It is envisioned that the data will be captured as a by-product of routine physician documentation of care.

5.2.1 Content Consumer Actor Import options

EHRs that are able to consume IHE are required to document "how they consume" the document. IHE defines four options and it is important to understand which option(s) are implemented by the EHR you purchase. The options include:

- **View Option –** Able to render the document in human readable format. The Content Consumer Actor must be able to present a view of the document using the style sheet presented by the Content Creator and optionally can choose to render the document with its own style sheet. If it supports its own style sheet it must provide a mechanism to view the source style sheet. It also must be able to print the document to paper.
- **Document Import Option** – This Option requires that the View Option be supported. In addition, the Content Consumer that supports the Document Import Option must be able to support storage of the entire document. Proper tracking of the document origin is required. Once a document has been imported, the Content Consumer shall offer a means to view the document without the need to retrieve it again from the network.
- **Section Import Option** - This Option requires that the View Option be supported. In addition, the Content Consumer that supports the Section Import Option must be able to support the import of one or more sections of the document. Proper tracking of the section origin is required. Once sections have been selected, a Content Consumer shall offer a means to copy the imported section(s) into local data structures as free text. This is to support the display of section level information for comparison or editing in workflows such as medication reconciliation when discrete data import is not possible.
- **Discrete Data Import Option** - This Option does not require that the View, Import Document or Section Import Options be supported. The Content Consumer that supports the Discrete Data Import Option must be able to support storage of the structured content of one or more sections of the document. This Option requires that the user be able to import select structured content (e.g. a visual acuity or an allergy in a list) into the local patient record with proper tracking of its origin.

5.3 IHE EYE CARE GENERAL EYE EVALUATION (GEE)

Comprehensive eye care deals with a broad spectrum of specialty disciplines each with its own lexicon, examination techniques, and procedures. The highest volume and most central component of this is the routine adult eye examination. A patient presents for a general eye examination and demographic data is either created, retrieved from existing databases, or updated. The patient provides a chief complaint and historical information relevant to the eye,

and a partial or complete examination of the eye and visual system is performed using various optical devices. Multiple people may contribute to this process including receptionist, technician, and physician.

The nature of the data varies widely and may be discrete and defined by existing terminology standards (e.g., visual acuity, intra ocular pressure) or narrative and available only as free text (e.g., description of a lesion, description of morphology). After this data is collected the clinician will arrive at an assessment and management plan. All of this must be recorded in a fashion that will allow subsequent transfer across diverse information platforms without loss of content or meaning using existing standards and protocols.

The General Eye Evaluation (GEE) HL7 CDA Content Profile defines the structure for data that is collected during examination of a patient's by an eye care practitioner (i.e. exam note). The AAO has created a collection of recommended best practices for this and other aspects of eye care that it terms the Preferred Practice Patterns (PPP). The information in this document is based upon the "Comprehensive Adult Medical Eye Evaluation October 2010" PPP specification generated by the AAO. The comprehensive eye examination consists of an evaluation of the physiological function and the anatomical status of the eye, visual system and its related structures.

The following table provides a brief description of the data content in GEE:

GEE Data Content (Sections)	Brief Description
Header Module	Patient demographic data, eye care organization, contributing providers, author, creation date/time, etc.
Healthcare Providers and Pharmacies	Identity of the patient's other pertinent health care providers
Chief Complaint	Chief complaint
Functional Status	Present status of visual function
History of Present Illness	History of Present Illness
Ocular History	Ocular specific past history
History of Past Illness	Systemic history: pertinent medical conditions and previous surgery
List of Surgeries	
Coded List of Surgeries	
Review of Systems	Responses to questions about the function of various body systems
Medications	Systemic medication currently used
Ophthalmic Medications	Ophthalmic specific medications
Allergies and Other Adverse Reactions	Allergies or adverse reactions to medications
Active Problems	Problems currently being monitored for the patient
Family Medical History	Genetic relatives in terms of possible or relevant health risk factors
Coded Family Medical History	
Social History	Occupational, personal (e.g. lifestyle), social, and environmental history that have a potential impact on the patient's health
Coded Social History	

GEE Data Content (Sections)	Brief Description
Ocular Physical Exam	Detailed eye examination information
Assessment and Plan	Assessment of the patient condition and expectations for care

The ocular physical exam is often coded using vocabularies such as SNOMED, LOINC and DICOM. The data content is a follows:

- Visual Acuity
- Vision Testing
- Refractive Measurements
- Lensometry Measurements
- Intraocular pressure
- Confrontation Visual Field
- Eye External
- Lacrimal
- Pupils
- Ocular alignment and motility
- Anterior segment
- Posterior segment
- Ancillary testing

5.3.1 How to specify GEE in an RFP

In order to require an EHR to be able to create the IHE Eye Care General Eye Evaluation (GEE) document the following wording should be included in your RFP (request for proposal):

"The EHR shall support the IHE Eye Care General Eye Evaluation (GEE) Content Profile as a Content Creator."

In order to require an EHR to be able to consume the IHE Eye Care General Eye Evaluation (GEE) document the following wording should be included within your RFP (request for proposal):

"The EHR shall support the IHE Eye Care General Eye Evaluation (GEE) Content Profile as a Content Consumer with the following options supported:

<pick one or more of the import options (View Option, Document Import Option, Section Import Option and/or Discrete Data Import Option)>

Note – if the RFP requires the Section or Discrete Data Import options then it should document which sections and/or discrete data attributes are desired.

5.4 IHE EYE CARE CATARACT SURGERY DOCUMENTS

The IHE Eye Care Cataract Surgery profiles provide documentation of a process that occurs along a temporal continuum connecting planning, execution, and short-term and long-term

follow-up components. The constituent events of this continuum may take place in different locations (referring provider's office, surgeon's office, hospital/surgery center), can involve different staff using different information systems for different purposes (health care planning and service delivery, QA auditing, research) and can involve unanticipated changes that redirect outcome and workflow (change or termination of surgery, referral for alternate care, etc.). For this reason the clinical documents must provide the ability to transfer information between multiple systems.

In general, the cataract surgery process begins in the surgeon's office with a pre-operative assessment that produces a large amount of disparate data that is used to plan the cataract surgery, but may also be used to accommodate unplanned intraoperative events. This information (i.e., CDA pre-operative note) must be available in the operating room, but may also be needed by QA auditors at the surgical hospital or elsewhere to support outcome assessment.

Upon completion of the surgery the surgeon creates an operative note (i.e., CDA operative note) that must be available at the surgeon's office, hospital/surgical center, and QA auditor's office. During surgery events may occur that cause the surgery to be terminated and the patient to be referred to another site and provider who needs all pre-operative, operative, and post-operative data.

In the short-term following surgery the patient is evaluated by one or multiple providers in the same or separate sites, on one or several occasions, and a post-operative note is generated. These providers must refer to the pre-operative and operative documents and the string of documents which encapsulate the cataract surgery process would be accessible for planning future cataract or other ocular surgery. An auditor with access to these records can assess outcome in this and other instances of cataract surgery, and a researcher can address particular questions about the cataract process by evaluating aggregated data in documents derived from numerous cataract procedures.

In order to document this information IHE Eye Care has specified three clinical documents. The content profiles are:

1. Cataract Pre-Operative Note (Cataract-PreOp)
2. Cataract Operative Note (Cataract-Op)
3. Cataract Post-Operative Note (Cataract-PostOp)

The following table provides a brief description of the data content in Cataract-PreOp:

Cataract-PreOp Data Content (Sections)	Brief Description
Header Module	Patient demographic data, eye care organization, contributing providers, author, creation date/time, etc.
Operative Eye	Which eye (right or left) is the operative eye
Target Refraction	Planned post-operative refraction
Ocular Axial Length	Ocular axial length measurement value
Intraocular Lens	Narrative description and detailed information regarding the planned intraocular lens.
Planned IOL Cylindrical	The axis at which a toric IOL is intended to be placed in surgery

Cataract-PreOp Data Content (Sections)	Brief Description
Axis	
Assessment and Plan	Assessment of the patient condition and expectations for care
Ophthalmic Surgical Risk Factors	Describes risk factors that may impact choice of surgical technique, risk of intraoperative complications, or expectations for a good outcome
Ocular History	Ocular specific past history
History of Past Illness	Systemic history: pertinent medical conditions and previous surgery
List of Surgeries	
Coded List of Surgeries	
Medications	List of current medications
Ophthalmic Medications	Ophthalmic specific medications
Allergies and Other Adverse Reactions	Allergies or adverse reactions to medications or other allergens
Active Problems	Problems currently being monitored for the patient
Ocular Physical Exam	Detailed eye examination information
Visual Acuity	Best corrected visual acuity for the patient
External Document Reference	External document references

The following table provides a brief description of the data content in Cataract-Op:

Cataract-Op Data Content (Sections)	Brief Description
Header Module	Patient demographic data, eye care organization, contributing providers, author, creation date/time, etc.
Preoperative Diagnosis	Records the surgical diagnosis or diagnoses assigned to the patient before the surgical procedure that indicate the reason for the surgery
Postoperative Diagnosis	Records the diagnosis or diagnoses discovered or confirmed during the surgery
Operative Eye	Which eye (right or left) is the operative eye
Surgery Description	Records the particulars of the surgery with an extensive narrative. Local practice often identifies the level and type of detail required based on the procedure or specialty.
Cataract Coded Surgery Description	Records the particulars of the cataract surgery using coded terms.
Surgical Operation Note Findings	Records clinically significant observations confirmed or discovered during the surgery
Anesthesia	Records the type of anesthesia (e.g., general or local) and may state the actual agent used.
Estimated Blood Loss	Records the approximate amount of blood that the patient lost during the surgery. It may be an accurate quantitative amount, e.g., 250 milliliters, or may be descriptive, e.g., "minimal" or "none."
Complications	Records problems that occurred during surgery, the complications may have been known risks or unanticipated problems
Specimens Removed	Records the tissues, objects, or samples taken from the patient during

Cataract-Op Data Content (Sections)	Brief Description
	surgery, the narrative may include a description of the specimens
Medications	Records the medications used during the surgery
Planned Procedure	Records the procedure(s) that the surgeon thought would need to be done based on the preoperative assessment.
Indications	Further details about the reason for the surgery
Disposition	Records the status and condition of the patient at the completion of the surgery, it often also states where the patent was transferred to for the next level of care
Plan	Used to indicate follow-up that the patient needs including any planned or potential future surgeries
Operative Note Fluids	Record fluids administered during the surgical procedure.
Operative Note Surgical Procedure	Used to restate the procedures performed if appropriate for an enterprise workflow
Surgical Drains	Record drains placed during the surgical procedure.
Implants	Record implants placed during the surgical procedure
External Document References	External document references

The following table provides a brief description of the data content in Cataract-PostOp:

Cataract-PostOp Data Content (Sections)	Brief Description
Header Module	Patient demographic data, eye care organization, contributing providers, author, creation date/time, etc.
Operative Eye	Which eye (right or left) is the operative eye
Post-Operative Complications	Records problems that have occurred after a surgical procedure has been performed
Assessment and Plan	Assessment of the patient's condition and expectations for care
Ophthalmic Medications	Ophthalmic specific medications
Active Problems	Problems currently being monitored for the patient
Ocular Physical Exam	Detailed eye examination information
External Document Reference	External document references

5.4.1 How to specify the Cataract Surgery Documents in an RFP

In order to require an EHR to be able to create the IHE Eye Care Cataract Surgery documents one or more of the following statements should be included in your RFP (request for proposal):

"The EHR shall support the IHE Eye Care Cataract Pre-Operative Note (Cataract-PreOp) Content Profile as a Content Creator."

"The EHR shall support the IHE Eye Care Cataract Operative Note (Cataract-Op) Content

Profile as a Content Creator."

"The EHR shall support the IHE Eye Care Cataract Post-Operative Note (Cataract-PostOp) Content Profile as a Content Creator."

In order to require an EHR to be able to consume the IHE Eye Care Cataract Surgery documents, one or more of the following statements should be included within your RFP (request for proposal):

"The EHR shall support the IHE Eye Care Cataract Pre-Operative Note (Cataract-PreOp) Content Profile as a Content Consumer with the following options supported:"

"The EHR shall support the IHE Eye Care Cataract Operative Note (Cataract-Op) Content Profile as a Content Consumer with the following options supported:"

"The EHR shall support the IHE Eye Care Cataract Post-Operative Note (Cataract-PostOp) Content Profile as a Content Consumer with the following options supported:"

<pick one or more of the import options (View Option, Document Import Option, Section Import Option and/or Discrete Data Import Option)>

Note – if the RFP requires the Section or Discrete Data Import options then it should document which sections and/or discrete data attributes are desired.

5.4.2 IHE Eye Care General Eye Care Operative Note (Eye-Op)

The General Eye Care Operative Note (Eye-Op) document defines the data that is collected during a patient's eye surgery. It is a general operative note that can be used for all types of eye care surgeries but is not intended to replace or substitute for a specific eye care operative note (e.g., Cataract Operative note, Glaucoma operative note, etc.). This may include pre-and postoperative diagnoses, procedure, findings and unusual occurrences, length of procedure, estimated blood loss, fluids administered, implant(s), specimen removed (if any), complications, postoperative expectations, and management plan.

The purpose of this document is to enable transfer of data found in an operative note for any type of eye surgery. This profile would preferably not be the one used when a more structured CDA profile is available for the procedure that was done.

In general, the eye care surgery process begins in the surgeon's office with a pre-operative assessment that produces disparate data that is used to plan the eye care surgery, but may also be used to accommodate unplanned intraoperative events. This information (i.e., CDA clinical document) must be available in the operating room, but may also be needed by QA auditors at the surgical hospital or elsewhere to support outcome assessment.

Upon completion of the surgery the surgeon creates an operative note (i.e., CDA operative note) that must be available at the surgeon's office, hospital/surgical center, and QA auditor's office.

During surgery events may occur that cause the surgery to be terminated and the patient to be referred to another site and provider who needs all pre-operative, operative, and post-operative data.

The following table provides a brief description of the data content in Eye-Op:

Eye-Op Data Content (Sections)	Brief Description
Header Module	Patient demographic data, eye care organization, contributing providers, author, creation date/time, etc.
Preoperative Diagnosis	Records the surgical diagnosis or diagnoses assigned to the patient before the surgical procedure that indicate the reason for the surgery
Postoperative Diagnosis	Records the diagnosis or diagnoses discovered or confirmed during the surgery
Operative Eye	Which eye (right or left) is the operative eye
Surgery Description	Records the particulars of the surgery with an extensive narrative. Local practice often identifies the level and type of detail required based on the procedure or specialty.
Surgical Operation Note Findings	Records clinically significant observations confirmed or discovered during the surgery
Anesthesia	Records the type of anesthesia (e.g., general or local) and may state the actual agent used.
Estimated Blood Loss	Records the approximate amount of blood that the patient lost during the surgery. It may be an accurate quantitative amount, e.g., 250 milliliters, or may be descriptive, e.g., "minimal" or "none."
Complications	Records problems that occurred during surgery, the complications may have been known risks or unanticipated problems
Specimens Removed	Records the tissues, objects, or samples taken from the patient during surgery, the narrative may include a description of the specimens
Medications	Records the medications used during the surgery
Planned Procedure	Records the procedure(s) that the surgeon thought would need to be done based on the preoperative assessment.
Indications	Further details about the reason for the surgery
Disposition	Records the status and condition of the patient at the completion of the surgery, it often also states where the patent was transferred to for the next level of care
Plan	Used to indicate follow-up that the patient needs including planned or potential future surgeries
Operative Note Fluids	Record fluids administered during the surgical procedure.
Operative Note Surgical Procedure	Used to restate the procedures performed if appropriate for an enterprise workflow
Surgical Drains	Record drains placed during the surgical procedure.
Implants	Record implants placed during the surgical procedure
External Document References	External document references

5.4.2.1 How to specify the Eye-Op Document in an RFP

In order to require an EHR to be able to create the IHE Eye Care General Eye Care Operative the following statement should be included in your RFP (request for proposal):

"The EHR shall support the IHE Eye Care General Eye Care Operative Note (Eye-Op) Content Profile as a Content Creator."

In order to require an EHR to be able to consume the IHE Eye Care General Eye Care Operative document the following wording should be included within your RFP (request for proposal):

"The EHR shall support the IHE Eye Care General Eye Care Operative Note (Eye-Op) Content Profile as a Content Consumer with the following options supported:" <pick one or more of the import options (View Option, Document Import Option, Section Import Option and/or Discrete Data Import Option)>

Note – if the RFP requires the Section or Discrete Data Import options then it should document which sections and/or discrete data attributes are desired.

5.5 TRANSPORT OF THE CLINICAL DOCUMENT BETWEEN DIFFERENT HEALTH CARE INSTITUTIONS

IHE content profiles define the ability to create and consume clinical documents. IHE has defined various Integration Profiles that apply to exchange of all types of clinical documents (i.e. not just eye care specific).

Meaningful Use Stage 2 uses IHE for defining the exchange of HL7 CDA clinical documents. It is called "Direct Messaging" and is specified in a document called "XDR and XDM for Direct Messaging Specification".

Below are the IHE profiles defining document exchange:

Cross-Enterprise Document Sharing (XDS) – provides standards based specification to manage the sharing of clinical documents (CDA) among healthcare enterprises. XDS provides the ability to register, query, and store/retrieve documents utilizing document registries and repositories. It is based upon Web services.

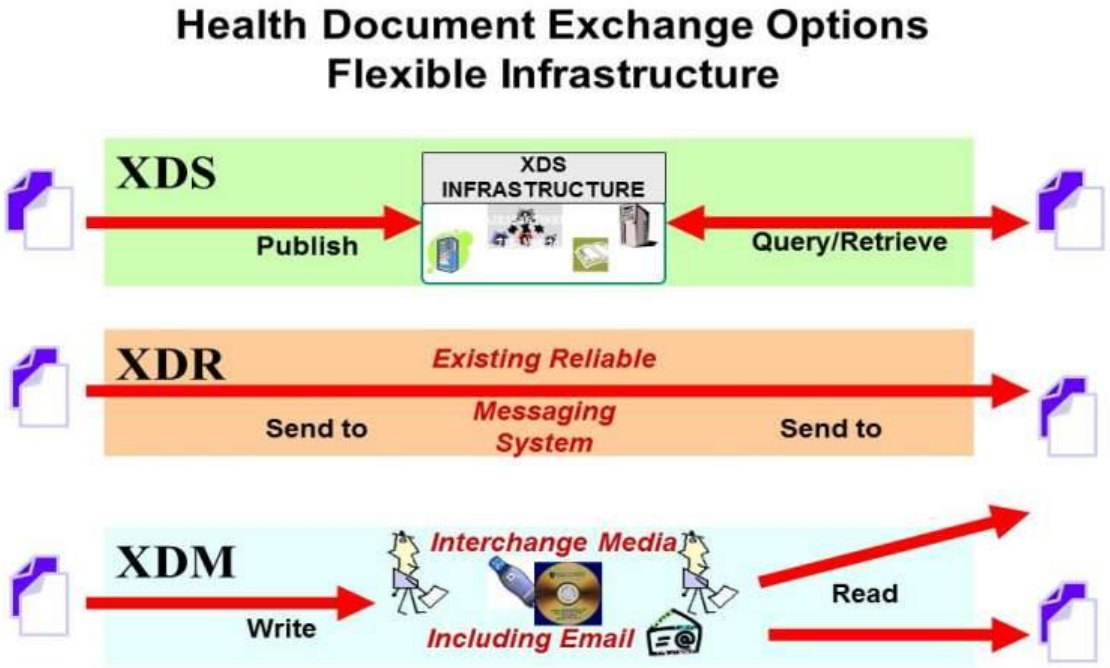
Cross-Enterprise Document Reliable Interchange (XDR) – permits clinical document interchange between EHRs, PHRs, and other health IT systems in the absence of XDS infrastructure. It utilizes the same web service used in XDS to "publish and register" the document; however exchange may be accomplished by connecting directly to a system that holds the documents (i.e. point to point document exchange). It is based upon Web services.

Note – The final stage 2 of Meaningful Use has defined the use of IHE XDR to exchange clinical documents.

Cross-Enterprise Document Media Interchange (XDM) - provides document interchange using a common file and directory structure over several standard media. This permits the patient to use physical media to carry medical documents. This also permits the use of person-to-person secure email to convey medical documents.

Note – The final stage 2 of Meaningful Use has defined the use of IHE XDM ZIP over E-Mail option to exchange clinical documents.

Below is a simple illustration of the exchange options.



5.5.1 How to specify Transport Options in an RFP

In order to require an EHR to be able to exchange GEE using IHE standard web services the following wording should be included within your RFP (request for proposal).

For exchanging documents which this EHR has created (as a GEE Content Creator Actor), one or more of the following statements:

- ***"The EHR shall support IHE Cross-Enterprise Document Sharing (XDS) as a Document Source"***
- ***"The EHR shall support IHE Cross-Enterprise Document Reliable Interchange (XDR) as a Document Source"***
- ***"The EHR shall support Cross-Enterprise Document Media Interchange (XDM) as a Portable Media Creator supporting the ZIP over Email option"***

For receiving documents created elsewhere (as a GEE Content Consumer Actor), one or more of the following statements:

- ***"The EHR shall support IHE Cross-Enterprise Document Sharing (XDS) as a Document Consumer"***

- ***"The EHR shall support IHE Cross-Enterprise Document Reliable Interchange (XDR) as a Document Recipient"***

- ***"The EHR shall support Cross-Enterprise Document Media Interchange (XDM) as a Portable Media Importer supporting the ZIP over Email option"***

APPENDIX A DEVELOPING AN INTEGRATION STRATEGY

Integration does not begin and end with the purchase of a single piece of equipment. Integration involves all the systems in the department or enterprise contributing efficiently and intelligently to the overall flow of work and information. It is important to develop an overall departmental or enterprise strategy for integration. Envision what the completed integration will look like and how it will work, and consider what steps will lead you from where you are now to that destination. This will help dictate what integration interfaces and capabilities your current purchase should support to play its part in the grand scheme.

Information technology is a crucial component of an efficient workflow process. The implementation of such a process usually requires purchasing new equipment or upgrading existing equipment. IHE provides a useful vocabulary for writing the integration portions of purchasing specifications.

On rare occasions, an opportunity arises to outfit a complete healthcare enterprise with all new equipment. In these situations, it is relatively easy to implement a fully integrated system. Usually however, a complete or nearly complete suite of partially integrated information systems and instruments already exists, and a pragmatic stepwise development and integration strategy is easier to manage and fund.

In either case, the planning method is the same: Focus on integrating operational workflow processes. Start by understanding the basic process flow, and then include "tributaries" and special cases. Next, identify the systems and transactions involved in those processes. Then, for each system involved in the process and already existing in the enterprise, determine whether the product can be upgraded to implement the required transactions. For existing product upgrades or new products to be purchased, include the requirement to implement the necessary IHE transactions in the purchasing specification.

There are two ways to specify the required transactions: the hard way and the easy way. The hard way is to understand each of the transactions defined in the IHE TF, decide which specific transactions are required to meet the objectives of the current phase of the project, and require in the purchasing specification that the purchased product or upgrade implement those transactions. The easy way is to systematically use IHE Integration Profiles and the detailed use case and solutions specified in these Integration Profiles, which offer a smooth evolution path toward higher interoperability.

Unless you purchase all your equipment at once, a single purchase will not achieve all the goals but will typically result in incremental benefits immediately, and the integration features will bear additional fruit as other components are added and integrated in the future. As an example of a stepwise integration strategy in an Eye Care department (which demonstrates that incremental benefits are possible), consider the following:

Assume that at the start, the situation in the Eye Care clinic, office or department is such that there are some instruments connected to a printer, and there is no EHR to control the workflow in the department. What IHE brings you in this situation is the vision, blueprint and strategy for the quest toward optimal clinical workflow and patient care.

One step is to use a PM system and to introduce an EHR and connect the instruments to the EHR by means of the DICOM MWL. IHE has a Profile available for this step, the EYE CARE

WORKFLOW Profile, which brings all the benefits of an automatic transport of patient ID and patient demographics, and in addition specifies exactly what the behavior of the EHR and the instruments must be to prepare for the next phase, when the department is ready to introduce a PACS.

The next step then would be the introduction of a PACS. In this phase, the full power of the IHE TF comes to play, with the following relevant Integration Profile: the full EYE CARE WORKFLOW. See the applicable sections in this Handbook about benefits to expect from these IHE Profiles.

Sometime after PACS introduction, the department will be ready for the next phase: Introduce in the workflow the tasks for the creation and use of additional productivity-enhancing objects like measurement. IHE has the following Integration Profile available in this phase: Eye Care Evidence Documents. See the applicable sections in this Handbook about benefits to expect from these IHE Profiles.

To close the loop for the patient's imaging procedures in the Eye Care department, reporting and billing need to be addressed. The workflow will be extended to include the reporting tasks and the preparation of the procedure billing. For this, IHE has the following Integration Profile available: Eye Care Charge Posting.

In summary, with the IHE approach to enterprise integration, one may expect a reduction of the integration costs, which could represent 20%–25% of the total IT budget. As a result, more funding becomes available for healthcare-specific investments. The reduction is caused by using standard protocols in products according to IHE specifications and prevents specific proprietary non-interoperable lock-ins. These products are tested at regular interconnectivity sessions (Connectathons), where most healthcare vendors participate. Reduced product prices can also be expected owing to the market dynamics of products based on open and mature standards.

IHE provides a proven and pragmatic roadmap for integrating existing IT systems within and among offices and hospitals. The roadmap covers new clinical domains, such as Eye Care, Patient Care Instruments and Laboratory, and the infrastructure for the patient's Electronic Health Record and Clinical Pathways in a Regional Health Information Network.

The user- and iteration-driven standardization process ensures that IHE specifications address real-world integration problems. The IHE roadmap is divided into 1-year iterations, where each iteration provides self-contained integration solutions.

The availability of IHE-compliant products from multiple vendors is ensured, since IHE is endorsed by a growing number of healthcare IT vendors. As a result, a hospital can choose from a large variety of available products to build best-of-breed IHE-based systems and reduce its dependencies on single vendors. The interoperability among IHE products from different vendors is improved because of the detailed message description, the validation of IHE implementations at multi-vendor testing sessions (Connectathons) and the publication of "ISs" describing specific IHE capabilities of a product.

That this strategy is successful in practice is shown by the many IHE success stories available at

www.ihe.net/Resources/user_success_stories.cfm. You will not be the first to start this integration journey—many others paved the way for you. Along the way, you can set a baseline and measure progress toward your goals (see a discussion of metrics in Appendix I).

A.1 INTEGRATION APPROACHES IN IT ENVIRONMENTS WITH LEGACY SYSTEMS

Interoperability between systems in the IHE means that the systems use precisely defined interfaces for data exchange. In addition, essential system behavior on how to compose data to be exchanged or how to process data received in such an exchange is often defined. This reduces installation or configuration efforts and realizes communication of essential data in a defined quality.

In legacy systems that do not follow such integration mechanisms, specific adaptation of existing interfaces may help to establish data exchange in a less comprehensive but potentially transitionally sufficient manner. Therefore, common legacy integration approaches are described here that may be a viable step to connect non-IHE-capable equipment to IHE-capable machines to match integration needs at your institution.

In the "non-IHE" integration scenarios described above, the communicating systems provide at least the most important standards-based interfaces, mainly DICOM, HL7 v2.x interfaces. This should ease integration efforts because defined messages with a limited variability need to be adapted.

The "non-DICOM," non-HL7 integration scenarios are based primarily on proprietary interfaces between communicating systems, which may complicate the integration effort. In these cases, interface adaptation may work.

Interface adaptation or conversion can be a tedious but valuable effort. Check relevant interfaces, including data structures, content meanings and configuration options or variability on each side of the systems to be prepared for communication. If the message types, structures or contents do not match between sending and receiving systems (e.g., different message versions, data differently structured, different codes used), the receiving system cannot accept or understand the sent message. A message conversion mechanism may solve this communication and integration problem (either by the primary or third-party vendor). Depending on the purpose, scope of the involved systems, and your organization or equipment, there are different approaches to interface adaptation:

1) Individual mapping of interfaces ("manual interfacing"): The adaptation is done for this specific case and for the two communicating systems only. Such a non-reusable solution can only be recommended for peripheral systems with specific usage in a limited organizational scope

2) Specific adaptation mechanisms for certain system types ("broker," "interface converter"): Such integration systems sit between specific system types (e.g., PM-EHR, EHR-PACS) and translate a certain set of messages, often with considerable preconfigured message translations. They allow easier legacy integration for specific scenarios, mostly on a departmental level—e.g., an EHR-PACS converter may translate an EHR's HL7 data into DICOM MWL services that it can offer to instruments. Such a mechanism may be appropriate if you need to implement a rather dedicated message conversion for specific

imaging purposes or in your imaging department.

3) General, multipurpose, high-throughput message adaptation system ("interface engine"): Such a system has highly configurable message conversion mechanisms, often combined with different message distribution functions—e.g., routing, broadcasting. It can connect many system types and is normally offered as a central service in an enterprise. For instance, an EHR may get laboratory data via the interface engine from a legacy laboratory system. If your enterprise operates such a central interface engine, it may be possible to use it for your imaging integration scenario instead of installing separate interfacing software in your imaging department.

If the cost/benefit ratio of above described interface adaptation does not seem satisfying to you, a newer software version of one or both of the communicating systems may be an alternative in solving the integration problem at hand, and possibly additional integration problems with other systems.

APPENDIX B UNDERSTANDING IHE INTEGRATION PROFILES

There are several sources of additional information for understanding the Integration Profiles, depending on the depth you are interested in.

B.1 INTEGRATION PROFILE SUMMARIES AND TUTORIALS

Presentations and documents providing summaries and tutorials on IHE and its Profiles are available at *www.ihe.net*.

The Integration Profiles document provides a basic description and graphics for each of the Profiles (*www.ihe.net/pdf/iheyr3_integration_Profiles.pdf).*

The "What Does IHE Offer" presentation from the SCAR 2003 workshop provides a brief graphic overview of the basic Profiles *(www.ihe.net/presentations/ihe_scar_2003.html).*

Presentations from the 2004 IHE Workshop provide a more detailed presentation for each of the Profiles *(www.ihe.net/participation/workshops/workshop_2004/index.html).*

Ultimately, the most detailed description of each Profile is contained in Vol. 1 of the IHE TF, which a chapter for each Profile, outlining the problem has solved, the Actors involved in the solution and the transactions they use to interact. Specifically, Section 2.1 provides an overview of the current Profiles, Section 2.2 describes the current Actors, Table 2.2-1 shows which Profiles each Actor is involved in, and Chapter 3 and onward document each Profile in detail. If you wish to dig deeper, explore the IHE TF documents. Refer to the section below on reading the IHE TF.

B.2 USER SUCCESS STORIES

Another source of relevant information is the collection of user success stories available at http://www.ihe.net/User_Success_Stories/. These case studies were submitted by sites that have deployed IHE Profiles. Each document is a concise one-page summary of the experience of the site, the Profiles they deployed and the specific products involved.

B.3 READING THE IHE TECHNICAL FRAMEWORK

The complete IHE TF is available for download at http://www.ihe.net/Technical_Frameworks/#eyecare.

Each IHE domain publishes a separate TF; however, they are completely compatible and interoperable. In fact, domains often make use of transactions and Profiles from other domains, and products often implement Profiles from more than one domain. The TF published covers the domains of Eye Care, Radiology, IT Infrastructure, Laboratory and Cardiology. Others will likely be added soon.

When new Profiles are published for trial implementation, they will appear on the site as Supplement documents. Once a Profile has been tested and judged stable and correct enough for final text, the Profile Supplement document is merged into the next release of the appropriate TF document. A TF is broken down in roughly the same way in each of the domains: Vol. 1 of the TF has a chapter for each Integration Profile. It explains what problem the Profile is intended to solve and then outlines a solution in terms of Actors (the different roles to be played in the solution) and Transactions (how the Actors are required to communicate and behave). Vol. 2 of the TF specifies in detail how each Transaction is performed. This volume describes the use of the relevant standards in great detail. It is essentially an implementation guide for the vendor engineers. Technical staff at healthcare sites that wish to understand the operation of IHE in detail may also find it useful. In some domains, where the number of transactions is large, Vol. 3 is added to include additional transactions. Vol. 4 of the TF, when required, includes any variations required to meet the particular needs of individual countries. These are referred to as National Extensions. Since the goal of IHE is to serve common global needs, Vol. 4 is generally brief.

APPENDIX C WRITING INTEGRATION CAPABILITIES INTO AN RFI/RFP

Integration Profiles provide precise shorthand communication between purchasers and vendors of medical equipment. A purchaser can include a requirement for a particular Profile, and IHE provides several hundred pages documenting what the vendor needs to do to claim conformance to that requirement. Referencing an IHE Profile has the advantage of being both brief and precise. When using IHE Integration Profiles to express your requirements, you may want to reference the IHE Eye Care TF and include a link to http://www.ihe.net/Technical_Frameworks/#eyecare in your RFI/RFP. The simplification of using IHE leaves the details of the TF for the vendors to implement in their products. You may want to specifically request that vendors provide the IHE Integration Statement for applicable products either before or in response to the RFI/RFP.

RFI versus an RFP

An RFI asks a vendor to describe their technology and how it would solve your problems. An RFP is a proposal of what you plan on doing and includes a project schedule, budget, and statement of need. This Appendix describes an RFI. To make this RFI into an RFP, your timetable and budget will be added to the RFI.

Methodology for Ranking Vendors on Integration

Integration is key for evaluating and ranking competing systems. For each area of integration, the buyer will need to determine their "Limits": Like to haves, Intend to haves, and Must haves. For each IHE Integration Profile, identify the integration problem it solves for you and internally assign a rating of how important this integration is for you to accomplish successful implementation in your facility: Use 1 for Like to haves, 3 for Intend to haves, and 5 for Must haves.

Perform this task internally and then decide if you want to share this prioritization of integration features with your vendors. For each Integration Profile, provide a brief description of what you intend to accomplish through integration and ask how the vendor's solution can solve that problem. Rate the answers from the vendors on the following scale: 0 points if they cannot perform that integration, 1 point if they integrate through proprietary methodologies, 3 points if they integrate through DICOM/HL7 but not according to IHE specifications, 4 points if they use IHE but not with all the options you want, and 5 points if they integrate fully through IHE methodologies. An evaluation of integration features might look like the following example for a PACS:

Internal Rating	**Vendor Capability**	**Rank***
5	4	20
5	3	15
3	0	0
		35

Integration Profile	**Problem**
Scheduled Workflow (ADVANCED EYE CARE WORKFLOW)	Integration of orders into scheduling and acquisition process, providing a on the instrument and procedure status information back on the EHR a or PACS. Synchronizing the EHR, PACS and HIS databases automatically to patient demographics changes.

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Summing the total product of the all the ranks together with their respective vendor capability will provide an objective metric for the vendor's ability to integrate to your individual needs.

Example Vendor RFI Scorecard

The following is an example scorecard. It does not contain all available Profiles from the IHE Eye Care domain and includes a few from IHE IT Infrastructure domain. You should create your own scorecard to reflect the Profiles that interest you.

Integration Profile	Problem	Internal Rating	Vendor Capability	Rank*
Scheduled Workflow (BASIC OR ADVANCED EYE CARE WORKFLOW)	Integrates orders into scheduling and acquisition process, providing a MWL on the instrument and procedure status information back on the EHR and or PACS.			
Eye Care Charge Posting	Allows for more accurate billing. The instrument communicates back to the billing system regarding procedures that have been performed.			
Evidence Documents	Enables image measurements to be acquired with the instrument and stored on the PACS.			
Eye Care Displayable Reports	Enables the creation, query/retrieve and reading of display –ready eye care reports. It allows use of a DICOM 460 Encapsulated Document.			

The Language of the RFP

For your Must-haves and perhaps your Intend-to-haves, use "shall" terminology in your RFP, as shown in the following examples:

"The PACS system shall support the BASIC EYE CARE WORKFLOW Integration Profile as the Image Manager/Image Archive Actor."

"The PACS system shall support the BASIC EYE CARE WORKFLOW Integration Profile as the Evidence Creator Actor and the Image Display Actor."

"The PACS System shall support the Instance Availability Notification Option of the ADVANCED EYE CARE WORKFLOW as the Image Manager/Image Archive Actor."

For your Like-to-haves and especially for newer Integration Profiles, vendors may not yet be able to comply with shall language, as they may not currently offer that functionality in their product offering. Decide how you will include promissory components of a contract negotiation to include future roadmaps. A vendor should not be expected to deliver functionality if it is not incorporated in the contract.

APPENDIX D IDENTIFYING SUITABLE PRODUCTS

There are several ways to find vendors and products involved in IHE.

D.1 IHE CONNECTATHON RESULTS

IHE Connectathon results indicate which vendors are developing and successfully testing which Integration Profiles. IHE Connectathons are annual testing events that vendors participate in on a voluntary basis. They allow vendors to test the IHE integration capabilities of their products with those of many other vendors in a structured and supervised environment. The results indicate which vendors have demonstrated proficiency in implementing a given Actor in a given Profile.

The results do not list specific products or versions. Vendors are not required to participate in the Connectathon to claim support for IHE in their products. The Connectathon should not be considered a certification of a vendor or product; rather, published results can be considered a useful litmus test. When a vendor that has successfully tested a given Profile at a Connectathon makes a direct claim that their product has implemented said Profile, you have some evidence they know what they are talking about. For direct claims of conformance to IHE for a specific version of a specific product, refer to the IHE Integration Statement published by the vendor, which is discussed in the next section.

IHE Connectathons are held each year in North America, Europe and Asia. Obtain Connectathon Results from *http://connectathon-results.ihe.net/*. The results are generally laid out with a row for each vendor and a dot showing which Actors in which Profiles the vendor was judged to have tested successfully at the Connectathon. Success is judged by the Connectathon Project Management Staff, who are independent technical experts hired by the sponsoring professional society (e.g., AAO, HIMSS, RSNA, ACC). Success generally means a vendor successfully tests their product with products from at least three other vendors.

D.2 IHE INTEGRATION STATEMENTS

IHE Integration Statements are declarations by vendors of support for specific IHE Integration Profiles in specific products. Many vendors post product Integration Statements on their Web sites. These are linked to a single index page at *www.ihe.net/Resources/ihe_integration_statements.cfm*. Vendors who wish to have a link to their Integration Statements on this page can follow the instructions there for submitting a request.

An Integration Statement is a claim made by the vendor to the consumer. Vendors are not required to test the system in question at a Connectathon before publishing an Integration Statement. See Appendix E for details on interpreting the contents of an Integration Statement.

APPENDIX E READING INTEGRATION STATEMENTS

IHE Integration Statements are simple statements (frequently a single page) of which IHE Integration Profiles are supported by a product and which IHE Actor roles the system plays in those Profiles. Vendors may publish Integration Statements on their Web sites or provide them in response to an RFP. Here's an example:

IHE Integration Statement			
Vendor	**Product Name**	**Version**	**Date**
Integrated Medical Systems	Mega CT	V3.2	17 Oct. 2002
This product implements all transactions required in the IHE TF to support the IHE Integration Profiles, Actors and Options listed below:			
Integration Profiles Implemented	**Actors Implemented**	**Options Implemented**	
Scheduled Workflow	Acquisition Instrument	Patient-based Worklist Query, Assisted Acquisition Protocol	
Web address for vendor's IHE information:			
Links to Standards Conformance Statements for Implementation			
HL7	N/A		
DICOM	*www.integratedmedicalsystems.com/dicom/MegaCT-DCS.pdf*		
Links to general IHE information			
www.ihe.net	In Europe: *www.ihe-europe.org*	In Japan: *www.jira-net.or.jp/ihe-j*	

Integration Statements are discussed in more detail in the IHE Eye Care TF, Vol. 1, Appendix D.

The first part of the statement indicates that it applies to version 3.2 of the Mega CT System from a vendor called Integrated Medical Systems, and it was published on 17 Oct. 2002.

The middle part of the statement indicates that this CT System supports the IHE Scheduled Workflow Profile as the Acquisition Instrument Actor and it supports two options within Scheduled Workflow (i.e. Patient Based Worklist Query, and Assisted Acquisition Protocol Setting).

APPENDIX F OBTAINING AND READING DICOM CONFORMANCE STATEMENTS

Vendors will generally provide a DICOM Conformance Statement (DCS) for each product at the customer's request. Frequently, these documents can be found on the vendor's Web site for download. Otherwise, ask a salesman to obtain a DCS from engineering. A DCS provides a detailed description of the DICOM capabilities of a vendor's product.

Because DICOM leaves many details up to the vendor and many things are optional, the vendor must document what their product does in a detailed DCS. DICOM recently updated

the documentation on what should be included in a DCS and its format. For further details, see Part 2 of the DICOM Standard, available at *dicom.nema.org*.

The DCS will describe:

- which services the vendor has implemented such as: DICOM Storage or DICOM MWL Management), whether they have implemented support for the service as a client (SCU) of the service, a server (SCP) or possibly both; and
- what objects are supported for certain key services (e.g., storage of the CT object, the enhanced MR object or cath lab procedure reports).

Often, key details such as finding out if the product supports a particular service as an SCU or an SCP can be found by looking on the title page or in the table of contents. Often, a search for the phrase "SOP Class Unique Identifier" will answer questions about the specific objects supported by a product.

Although an IHE Integration Statement provides a much simpler approach to some of the issues addressed by DCSs, the Integration Statement does not replace the DCS. Further, the DCS will be particularly useful when handling legacy integrations with non-IHE systems. Detailed analysis of the contents of DCS documents is beyond the scope of this Appendix.

APPENDIX G OBTAINING AND READING HL7 INTERFACE SPECIFICATIONS

Although vendor claims of conformance to HL7 are not as widely distributed or as strictly formatted as DCSs, it is often possible to ask the vendor to provide an HL7 "interface specification" that details the types of messages their system produces and accepts, the fields in those messages, when the messages are sent or expected and how the fields are filled. Often, HL7-based systems can be quite flexible, and their HL7 interface behavior can be adapted to your needs. Depending on the complexity of your needs, you may want to hire someone experienced with these sorts of interfaces to help you in the process of evaluating and customizing your HL7 interfaces.

If your vendor asks you to provide some details on what you want their interface to do, you may find it useful to provide the vendor with a pointer to the IHE TF and tell them which Profile and Actor roles you expect their system to fulfill. While this does not address the full use to which you will put their system, it will at least provide detailed specifications for part of the functionality.

APPENDIX H CONDUCTING ACCEPTANCE TESTING

Sites are strongly encouraged to include Acceptance Testing as part of the implementation phase. This requires developing an Acceptance Plan, which includes the Acceptance Tests to be performed, specification of what constitutes a pass or failure and some kind of a schedule. Typically, Acceptance Tests to be included in the plan are agreed on by the vendor and the customer. Acceptance Tests can be developed once the systems to be integrated have been identified. It is preferable to run the Acceptance Tests only after all of the physical systems are installed and properly connected to the network. It may be possible to

do Acceptance Tests on a subset of the systems, but that may require additional analysis and test setup.

The development of the Acceptance Plan requires technical staff (consultants or internal development resources). Note that this Handbook deals only with Acceptance Testing of interoperability features and not all the other features provided by the individual systems. Also, the testing here focuses on functionality, not on performance issues such as speed.

Once all of the IHE Profiles, Actors and transactions involved in the installation have been identified, a list of Acceptance Tests can be written for each of the systems involved. Using Vol. 1 of the IHE TF, a high-level list of transaction tests can be developed by reviewing the Table of Actors/Transactions for each of the relevant Profiles. Using Vols. 2 and 3 (and 4 for country-specific changes) of the IHE TF (along with your project specifications, HL7 specifications and DCSs), details of Acceptance Test data sets and expected results of running the tests can be developed.

Once all of the test specifications are brought together, the test plan is developed. The test plan should include the following components:

What systems are required to perform the testing?

What is the list of tests that should be run?

What data are required to perform the testing?

How will the operation of the test be verified (e.g., What test tools are

required?) What are the expected results for each of the tests?

Each of the components is critical, and time should be dedicated to developing them.

Test System Suite: The Test System Suite needs to include all of the systems that interconnect. In some cases, a separate test environment will need to be set up to ensure that the live environment is not impacted by testing. In other cases, the live environment may be used, but the timing and the data used to test the system will need to be carefully thought through. Development of Tests: Test strategies will depend on which systems are being integrated. Likewise, confirmation of the results will depend on the capabilities of the systems being deployed and the workflow of the institution itself. Note that if non-IHE systems are involved in the Enterprise, additional evaluation is needed to determine what the expected results should be, since they may deviate from what would happen in a full IHE environment.

Some test specifics are listed in the Acceptance Testing section of each chapter/scenario in this Handbook. Additionally, many of the Profiles documented in Vol. 1 of the TF include use cases, which detail variations addressed by IHE that you may want to include in your tests—e.g., unscheduled acquisitions, simple single-step scheduled acquisitions, appended acquisitions and "group case" acquisitions.

Test Data: Specific test data will depend on the use cases being tested and what data are relevant to the operations of the site. The data should be representative of real cases and include complete sets of patient demographics and order and procedural information. In some cases, it may be necessary to have representative "canned results," such as DICOM images and reports. An array of instrument systems from several manufacturers with specific data

fields may be required to fully test interoperability features.

Not all IHE use cases may be relevant to implementation for a given site. For example, a site may always construct their procedures so that there is only a single procedure step per requested procedure. In this case, IHE functionality dealing with multiple scheduled procedure steps is not relevant.

Test Tools: Verification of results may require the use of tools and multiple systems. For example, HL7 tools, DICOM tools, the use of the instrument to display result images, or alternatively the use of a PACS system to verify that the information within the DICOM images contains all of the retrieved MWL information. The following are classes of tools that may be used to validate results:

HL7 Parsers: Parse out the fields of HL7 messages and present the components in a more human-readable way.

DICOM Validators: Check the content of DICOM Image Headers for conformance to the DICOM standard. (See *www.dclunie.com/* for freeware.)

DICOM Sniffers: Watch traffic on a TCP/IP network, identify DICOM-related traffic and provide a way to assemble and store the contents of DICOM communications for review. (See *www.dclunie.com/* for freeware.)

MESA Tools: As a part of the IHE testing process, HIMSS and RSNA commissioned the development of a set of software tools by the Electronic Eye Care Laboratory at the Mallinckrodt Institute of Radiology, Washington University of St. Louis. They provide communication partners, test data and test plans to allow vendors to perform baseline testing as they implement the IHE TF. These tests are limited in scope but may be useful in the development of test plans. (See *www.erl.wustl.edu/mesa/index.html.)*

In some cases, it may be advantageous to use multiple tool sets to verify different system behaviors. Your vendors may also provide tools to test their systems. It should be noted that IHE does not promote specific vendor tools.

APPENDIX I PERFORMANCE METRICS

Use of relevant performance metrics is extremely important to any process you intend to effectively manage and improve. The workflow and other processes of Eye Care are no different. Selecting relevant metrics, collecting measurements and responding to resulting feedback can make the difference between informed management and ad-hoc intervention. Even considering what metrics to measure is a useful exercise in reflecting on your current priorities and goals and what they should be.

Diligently selecting, measuring and tracking relevant metrics has proven to be easier said than done. One argument in favor of IHE is that by facilitating the shift from paper to electronic workflow, collecting many relevant values automatically is more practical than manually collecting measurements, which disrupts and diverts the actual work (the Heisenberg Principle in action).

When considering an integration project, the time to start collecting metrics is now. Metrics are particularly useful when planning changes. Good metrics help with establishing a baseline measurement of your current practice, making the case that there is room for improvement,

estimating the impact from the proposed process and technology changes, tracking the potential initial disruption caused by the changes and the return to equilibrium, and confirming/revising the impact on the process and ultimately the success of the project.

Additionally, metrics are useful for the healthcare industry at large, as they deal with pressures to improve care, reduce costs and effectively apply new technologies for those goals. Sites that collect metrics are strongly encouraged to share results. In particular, AAO is interested in publishing comparative studies of before-and-after IHE implementations.

I.1 WHAT TO MEASURE

Choosing what to measure and optimize can be a non-trivial task. Systems and the people in them will adapt to optimize to reach the chosen target. Although not all clinical benefits can be boiled down to a representative measurable value, many can, and metrics are a valuable way of establishing targets and measuring progress toward those targets. Some values to consider are given below as a starting point. Select metrics that reflect your priorities and your process. Refer to the sources mentioned later in this section for more academic information.

Department Operational Metrics: patients per year, patients per day per piece of equipment, procedures per year, steps per procedure, film media costs per year, film processing and disposal costs per year, film storage and handling costs per year, report turnaround time, repeated exams per year, "reconciliation events" per year, time spent per reconciliation event and manual demographic data entry error rate

Patient Experience Metrics: patient "turnaround time" from arrival to departure and patient waiting time in for tests to occur

Project Implementation Metrics: time to specify systems and interfaces, time to test integration and time/money spent on custom interfaces

One approach to metrics is to record for each exam the time stamps at certain key milestones/progress points in your process.

Outpatient exam: exam scheduled (optional), patient arrival, order written, prior studies available (optional), procedure protocol selected (optional), patient consent obtained (optional), patient in procedure room, scan started, scan completed, patient out of procedure room and patient dispatched

Image handling: exam transferred to PACS, current exam matched with prior exam, current exam interpreted, current exam placed in active file, exam moved to less active files and exam purged

Reporting: preliminary report called, report dictated, report transcribed, report edited, report signed, report distributed and report archived

Reimbursement: patient demographics collected

With raw time stamps, many time-related metrics can be calculated. Specific milestones will depend on your institution's workflow. The order of time stamps will likely vary at some institutions, and some may vary between exams. Some flexibility will be required.

Another source is your peers: Ask about their goals and what they measure.

I.2 SAMPLE MEASUREMENT RESULTS

This section discusses measurements considered useful by some sites and what values they recorded. This is a quick sample of some of the available information. More can be found by referring to the sources listed above. Many sites have focused on the time until availability of the report as the performance metric of most significance to the customers of an Eye Care operation. Different studies start the timer at different points: some from when the study is ordered, others from when the patient arrives for the exam, others from when the images are available for review. Having clear definitions of your selected metrics is a key point to making them comparable and useable as references to other sites.
Many institutions have documented improvements in some of these turnaround types. In one institution, the time between study performance and interpretation averaged approximately 20 minutes (down from 8–24 hours), and between interpretation and transcription (and made immediately available for reading with the PACS) from 1–2 days down to 2 hours (available immediately after being read by phoning the digital dictation system).[5] Other reports of decreases in turnaround times are similarly impressive.

[4] Mehta A, Dreyer K, Boland G, et al. Does PACS improve report turnaround time? Journal of Digital Imaging 2000;13:105–107.
[5] Mattern CW, King BF Jr, Hangiandreou NJ, et al. Electronic imaging impact on image and report turnaround times. Mayo Medical Center, Rochester, MN 55905.

GLOSSARY

Actor [IHE]: A software process responsible for a specific workflow requirement (e.g., the Order Placer Actor which permits the distribution of the order throughout the connected system including the practice management system, ophthalmic devices, and the electronic health record). Each single vendor product may include one or more Actors.

Admission, Discharge and Transfer (ADT) message [HL7]: Enables transmission of new or updated demographics and patient visit information. Generally, information will be entered into a practice management system and passed on to the electronic health record system either in the form of an unsolicited update or in response to a record-oriented query without requiring manual re-entry.[1]

Acquisition Modality Importer (AMI): An instrument or application support actor used to integrate acquisition modalities that do not natively support a required DICOM SOP Class defined for that instrument internally in a product. This can be helpful in legacy devices. Messages to and/or from the system are translated by the AMI, which meets the required specification.

Connectathon [IHE]: An annual event where participating vendors test their implementations of IHE actors and capabilities with other vendors in a supervised environment.

Digital Imaging and Communication in Medicine (DICOM): An established standard for the

[1] Definition taken from HL7 Version 2.3.1

exchange of digital information between medical imaging equipment and other systems. Most devices used in radiology utilize a DICOM standard.

DICOM Service: See *Service Class*.

General order message (ORM) [HL7]: The function of this message is to initiate the transmission of information about an order. This includes any action taking on an order including placing new orders, cancelling existing orders, discontinuing, or holding orders. ORM messages can originate with a placer, filler or interested third party.

Health Level 7 (HL7): A well-established standard used in the United States and worldwide for the exchange, management and integration of data to support clinical patient care and the management, delivery and evaluation of healthcare services.

Integrating the Healthcare Enterprise (IHE): An initiative of the **Healthcare Information and Management Systems Society (HIMSS)** and the Radiological Society of North America (RSNA) that brings together healthcare professionals and healthcare systems vendors to improve the way computer systems in healthcare enable information sharing. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical information needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively. (www.ihe.net). The American Academy of Ophthalmology (AAO) is the sponsoring organization for IHE Eye Care.

Integration Profile [IHE]: A precise description of how standards are to be implemented to address a specific clinical integration need. Each Integration Profile includes definitions of the clinical use case, the clinical information and workflow involved and the set of actors, messages, documents and transactions that address that need. Integration profiles implement the fully detailed integration specifications defined in the IHE TF in a form that is convenient to reference in requests for proposals (RFPs) and product descriptions.

Integration Statement [IHE]: A document prepared and published by a vendor to describe the IHE Integration Profiles, Actors and options supported by a specific version of that supplier's product.

Registration System: The system used for patient registration under normal workflow; usually the software application source of patient demographics. In Eye Care, this may be a Practice Management System (PMS) or ADT system in a hospital information system.

Service Class [DICOM]: A function, such as storage or printing, specified by DICOM and implemented by an instrument or actor, which provides (SCP) or uses (SCU) the service.

Service Class Provider (SCP) [DICOM]: A system or application that provides a DICOM Service (often viewed as the "server" of a service).

Service Class User (SCU) [DICOM]: A system or application that uses a DICOM Service (often viewed as the "client" of a service).

Supplement [IHE]: A proposed addition to the Technical Framework (TF). After public comment, review, trial implementation and testing, it is generally merged into the TF.

Technical Framework (TF) [IHE]: The document that defines Integration Profiles, the use cases they address, and the Actors and Transactions involved. It provides detailed

implementation instructions for each transaction. It is primarily used as a guide for vendors.

Transaction [IHE]: An exchange of information between Actors. For each Transaction, the TF describes how to use an established standard (such as HL7, DICOM or W3C) to exchange information.

Worklist: A list of work items, such as image acquisitions, to be performed. Generally, it is retrieved electronically and contains details about the task, such as patient name and identification (ID) number, Accession Number, and relevant input data. A worklist may or may not dictate a specific schedule or piece of equipment.

Additional Abbreviations

AE Title = Application-Entity Title
AN = Accession Number
DCS = DICOM Conformance Statement
EHR = Electronic Health Record System
HIS= Hospital Information System
MPPS = Instrument Performed Procedure Step
MWL = Worklist
PACS = picture archiving and communication system
PIR = Patient Information Reconciliation
PMS = Practice Management System
PPS = Performed Procedure Step
RFI = request for information
RFP = request for proposals
B-EYECARE = Basic Eye Care Workflow (such as within an eye care clinic)
A-EYECARE = Basic Eye Care Workflow with added features