Integrating the Healthcare Enterprise

IHE Patient Care Device User Handbook (Also known as "PCD Cookbook")

2018 Edition

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Contents

Executive Summary

Integrating the Healthcare Enterprise (IHE) is an initiative by care providers (including ACCE, HIMSS and RSNA) 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 makes it possible to achieve the level of integration required in the era of the electronic health record. This handbook targets

- Administrators who make purchasing decisions
- Information Systems Analysts
- Clinical Engineers
- Technology evaluators

What is an Integration Profile?

Each IHE integration profile describes a clinical requirement for systems integration and a solution to address it. It defines functional components, called *IHE actors*, by specifying in careful detail the transactions each actor must perform, based on standards such as IEEE 11073, Digital Imaging and Communication in Medicine (DICOM®)[1] and Health Level 7 (HL7®)[2].

How do you get IHE Integration Profiles?

You specify IHE capabilities as requirements on the information systems and medical devices that you are purchasing or upgrading. Simply state in the Request For Proposal (RFP) which IHE actors and integration profiles you want.

What do IHE Integration Profiles cost and what is the return on investment?

In some cases integration profiles cost nothing—they are integral to a product's capabilities. In other cases, vendors may package IHE integration profiles at an added cost with new systems or offer them as upgrades to installed systems. Healthcare providers should insist that any costs for IHE integration profiles be less than the cost of integration services that do not utilize IHE integration profiles. It takes less resources, time, and money to design and implement IHE integration profiles than customized interfaces for both the vendor and the healthcare provider. This should be reflected in the costs.

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 and 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 the pieces fit together.

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

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

What other benefits does IHE provide?

IHE makes it practical for healthcare 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, incomplete and misplaced information, IHE allows the most efficient use of staff time. By providing care providers comprehensive patient information, IHE enables users to make better-informed medical decisions.

Semantic Interoperability

Interoperability messages of IHE Patient Care Device Profiles make use of IEEE 11073 internationally recognized standards for nomenclature in identification of data items and in data item enumerations. Units of measure follow the Unified Code for Units of Measure (UCUM). Such standards are the underpinnings for semantic interoperability across device manufacturers. The same data item is identified by the same identifier. Observations are rationalized for consistency in their units of measure.

What should you do next?

Learn about the IHE integration profiles available for Patient Care Device and other parts of the Enterprise and consider how they meet your organization's goals. Read this IHE User's Handbook to learn how to require these capabilities in an RFP and how to implement them in your setting. These resources and more are available at *www.ihe.net*.

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Reference	Kevin O'Donnell et al, IHE Radiology User's Handbook 2005 edition, June 20, 2005.

How to Use this Handbook

This handbook was assembled by the IHE Patient Care Device (PCD) Planning and Technical committees with input from healthcare professionals who have implemented IHE capabilities at their sites. It is modeled after the IHE Radiology User Handbook, published in 2005. The IHE Patient Care Device User Handbook describes how and why to acquire and implement systems and devices with IHE capabilities for device interaction. IHE capabilities outside of device interactions are not addressed in this Handbook.

IHE was designed to make the complex, intricate and time-consuming tasks involved with integrating healthcare systems easier, faster and more reliable. This handbook describes how you can leverage IHE to improve the integration capabilities of your systems which interact with devices and the medical devices themselves. This handbook illustrates methods to select, specify, purchase and deploy IHE capable devices and systems. The principles outlined can be applied to any systems acquisition and deployment project that involves integration of systems with IHE-defined transactions. The handbook includes advice for those selecting and purchasing new systems and for the technical staff who will handle the installation and configuration of the new system. A series of appendices provide advice and information applicable to each scenario—or any other deployment project linking systems using IHE profiles.

This document includes the following sections:

- Sections 1.1.1 and 1.1.2: Selecting IHE integration profiles by mapping goals and needs to the benefits provided by each profile
- Section 1.1.3: Writing RFPs to obtain the desired profiles (sample text for some recommended profiles is included).
- Sections 1.1.4 and 1.1.5: Identifying and evaluating relevant products
- Section 1.2.1: Workflow changes that maximize the benefit of the IHE profiles
- Section 1.2.2: Installation testing to confirm that IHE capabilities are functioning properly
- Section 1.2.3: Issues to consider when installing and configuring IHE-compliant system
- Section 1.2.4: Identifying and addressing potential problems in order to maximize your benefit despite existing “legacy” systems

This Handbook provides direction on how to make use of the information developed by the IHE initiative to deploy patient care devices and systems that exchange information effectively, using standards-based transactions to meet critical clinical needs. It does not attempt to take account of the many other factors that determine the efficiency and suitability of an application for clinical use. The information provided by IHE is only a part—albeit an essential one—of the full set of resources required to select, purchase, deploy and upgrade systems that support IHE.

Note: This is the third edition of the IHE Patient Care Device User’s Handbook. Future editions will be expanded and enhanced. It is envisioned that this document will be refreshed from time to time on an unscheduled basis to update it for additional and information, corrections, and for

new and updated IHE profiles. The newest edition will always be available at http://ihe.net/Technical_Frameworks.

The Handbook is intended to meet the needs of the healthcare community. Comments and suggestions are welcome. Send them by email to pcdcomments@googlegroups.com or submit them online at http://ihe.net/PCD_Public_Comments.

2018 Changes

1. Added details regarding infusion systems
2. Added field deployment information for the Alert Communication Management (ACM) Profile.
3. Added more information on the Point of care Infusion Verification (PIV) Profile and added the Infusion Pump Event Communication (IPEC) Profile
4. Added recent new IHE PCD profiles in the area of Medical Equipment Management (MEM): the Device Management Communication (DMC) Profile and the Location Services (LS) Profile.

Glossary

Actor [IHE]: A system or application responsible for certain information or tasks—e.g., the Device Observation Consumer Actor. Each actor supports a specific set of IHE transactions to communicate with other actors. A vendor product may support one or more actors.

Admission, Discharge and Transfer (ADT) message [HL7]: Provides for transmitting new or updated demographics and patient visit information. Generally, information will be entered into a Patient Administration system and passed on to nursing, ancillary and financial systems either in the form of an unsolicited update or in response to a record-oriented query.

Clinical Information System (CIS): An umbrella term that has been applied to a broad range of clinical information technology and to various configurations of clinical application components. Additional terms are used to describe information systems that support delivery of health care: electronic medical record system (EMR), health information system (HIS), electronic health record (EHR), clinical data repositories (CDR), clinical decision support systems (CDSs), and computer-based patient record systems (CPRs)are a few. Note: Clinical Information Systems, in common use, typically refer to the departmental systems (critical care information systems, for example). These systems usually manage clinical information locally with respect to a ward or unit. They can be integral to the larger enterprise electronic health record system as a repository of the master ADT and administrative information regarding specific patients.

Connectathon [IHE]: An annual event where participating vendors test their implementations of IHE capabilities with other vendors in a supervised environment. This is IHE profile actor implementation verification testing. It shouldn’t be confused with commercial product certification testing.

Domain [IHE]: A working group in IHE that addresses a particular clinical area—e.g., Patient Care Device, Radiology, Cardiology, Laboratory or IT Infrastructure. Each domain publishes a Technical Framework (TF).

General order message (ORM) [HL7]: The function of this message is to initiate the transmission of information about an order. This includes placing new orders, cancellation of existing orders, discontinuation, holding, etc. ORM messages can originate also with a placer, filler or interested third party.

Health Level 7 (HL7): The established standard for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services.

IEEE 11073: A set of standards for point-of-care device communications.

Integrating the Healthcare Enterprise (IHE): An initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information.

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 and transactions that address that need. Integration profiles reference the fully detailed integration

specifications defined in the IHE TF in a form that is convenient to use 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 a product.

Medical Device Communication (MDC): A general term or acronym used to describe the communication of data from a medical device.

Observation Result (ORU) [HL7]: The function of this message is to provide clinical observations in response to an order.

Patient Care Device (PCD): A medical device used in the process of diagnosing, monitoring, treating, or preventing disease.

Profile [IHE]: See Integration Profile

Registration System: The system used for patient registration under normal workflow; usually the owner/source of patient demographics.

Supplement [IHE]: A proposed addition to the 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 problems and use cases they address, and the actors and transactions involved. It provides detailed implementation instructions for each transaction (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.

Table of Acronyms

Acronym	Definition
ACM	Alert Communication Management
ADT	Admission, Discharge, and Transfer
BPOC	Barcode-enabled Point of Care (often used interchangeably with BCMA)
BCMA	Barcode computer assisted medication administration (often used interchangeably with BPOC)
CDR	Clinical Data Repository
CDSS	Clinical Decision Support System
CE	Clinical Engineer
CIS	Clinical Information System
CMMS	Computerized Maintenance Management System
CPOE	Computerized Physician Order Entry
DEC	Device Enterprise Communication
DICOM	Digital Imaging and Communications in Medicine
DMC	Device Management Communication
EC	Event Communication
eMAR	Electronic Medication Administration Record system
EHR	Electronic Health Record

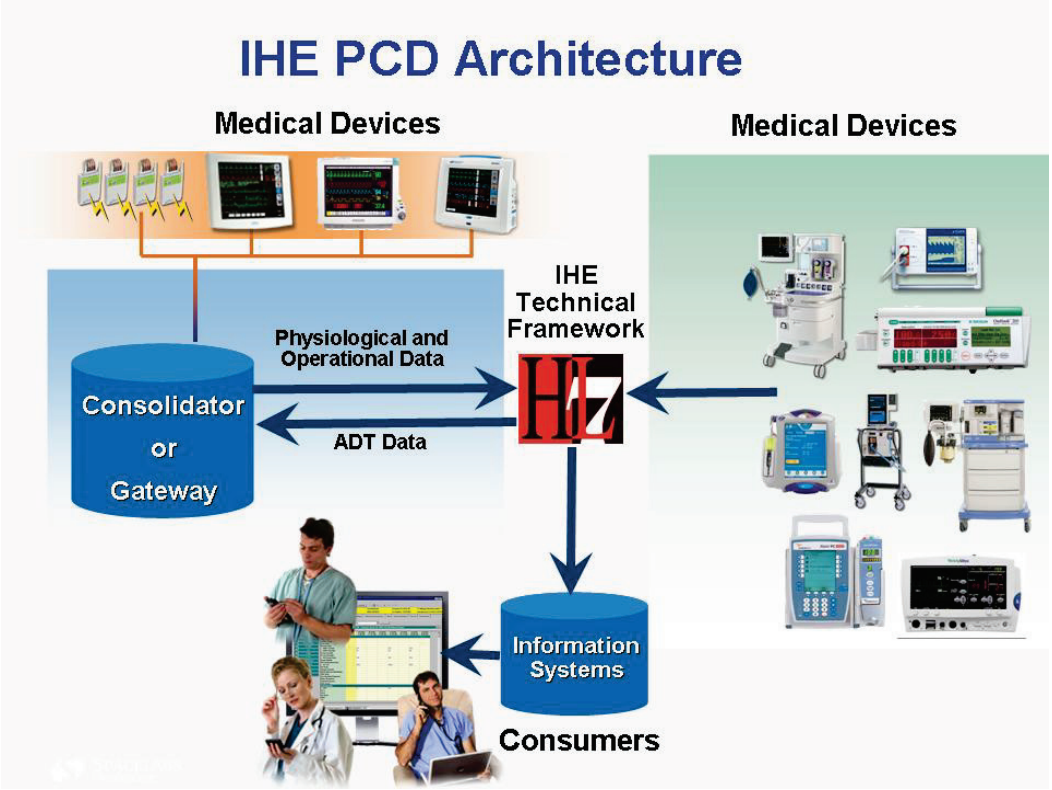
Acronym	Definition
EMR	Electronic Medical Record
HIS	Hospital Information system
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating the Healthcare Enterprise
IPEC	Infusion Pump Event Communication
LS	Location Services
MDC	Medical Device Communication
MEM	Medical Equipment Management
PACS	Picture Archiving and Communication Systems
PCA	Patient Controlled Anesthesia
PCD	Patient Care Device
PIV	Point of Care Infusion Verification
RFID	Radio Frequency Identification
RTLS	Real-Time Location Services
TF	Technical Framework, as in PCD TF
UCUM	Unified Code for Units of Measure
VSM	Vital Signs Monitor
WG	Working Group

1 Scenario: Integrating Medical Devices into a CIS

When considering integrating medical devices to a CIS there are many considerations. Implementing a device or CIS with IHE integration capabilities can provide many benefits over using vendor-proprietary interfaces. Integrating medical devices to a CIS can help ease staff shortages and transcription accuracy and consistency issues with documenting vital signs, medications and responding to alerts. There are a number of medical devices that are capable of transmitting information to a CIS.

The Patient Care Device domain’s goals are to:

- Improve patient safety and clinical efficacy
- Reduce healthcare delivery cost by improving efficiency, reliability, and operational flexibility for healthcare providers
- Enable innovative patient care capabilities



1.1 The Planning and Purchasing Process

Intended for administrators who make purchasing decisions, this section lists organizational goals to consider when specifying requirements for a device, how to select the IHE integration profile that will address those goals, how to clearly state IHE requirements in a Request For Proposal (RFP) and how to interpret vendor responses.

1.1.1 Selecting IHE Integration Profiles and Actors

Specifying integration requirements for the system or devices 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 functionality differences which you may decide to select. The integration profiles relevant to the purchase of a patient care device and the functionality each provides are given below.

Device Enterprise Communication (DEC) transfers patient care device (PCD) data to Enterprise applications (CIS, CDR, CDS, EHR, EMR, etc.). It addresses the need for consistent communication of PCD data to the enterprise that supports efficient patient care and better patient safety by reducing manual data entry (e.g., patient demographics) and populating data from medical devices into enterprise systems automatically.

Point-of-Care Infusion Verification (PIV) brings infusion systems into the electronic medication administration process. The workflow provides for the electronic transmission of infusion information from a barcode-enabled medication administration system (BCMA) to an infusion pump as part of the medication administration process. This reduces the need for manual programming of the pump, and leverages the use of the pump’s onboard drug library to reduce medication errors.

Infusion Pump Event Communication (IPEC) defines the communication of events associated with infusion sequences to management systems.

Alert Communication Management (ACM) defines the communication of alerts (physiologic and technical alarms and advisories) from alert source systems to alert management systems and from alert management systems to alarm communication systems. This profile provides for alert dissemination between alert source devices and systems, from the connector to and within the communication services to the required abstract semantics, in a manner that, if complied with, enables multi-vendor multi-device interoperation, in particular with phones, pagers, and other portable and desktop devices. ACM is for the purpose of alert communication to communication devices associated with people (pagers, PBX phones, smartphones, tablets, personal computers, etc.). Event communication is considered to be system or device to system or device communication.

Medical Equipment Management Device Management Communication (MEMDMC) defines the communication of devices to Computerized Maintenance Management Systems (CMMS).

Medical Equipment Management Location Services (MEMLS) defines the communication of location monitoring systems and additional information from location monitoring tags (environmental, operator input, accelerometers, etc.).

1.1.2 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 in acquiring a new device or system and the contributions that each relevant integration profile may make in supporting these goals.

Reduce Errors and Enhance Patient Care

Device Enterprise Communication (DEC) on medical device:

- Prevents or reduces manual data entry errors at the device by retrieving patient demographics information from master ADT systems via an HL7 interface and binding the demographics to the device
- Prevents stale demographic data by updating current information to the device
- Prevents or reduces manual data entry errors to the CIS by transmitting information electronically from the device
- Reduces delays in patient care by transmitting patient device data electronically, reducing the number of manual steps and allowing the data to be viewed across the enterprise
- Mitigates the risk of loss of data

Point-of-Care Infusion Verification (PIV) on medical device:

- Reduces or eliminates errors in data entry during infuser programming
- Improves patient safety by providing correct medication orders to the right patient at the right time
- Mitigates the risk of errors that may be introduced by the manual administration of medications at the point of care
- Applies the "five rights" of medication administration electronically (right patient, right route, right dose, right time, right drug)

Alert Communication Management (ACM) on medical device:

- Allows centralization of alerts (physiological and technical alarms) and advisory notifications
- Improves alert notification delivery time to the caregiver
- Reduces alert confusion
- Reduces noise levels in care environment
- Allows alert active status and histories to be reviewed and managed
- Improves safety by delivering alert notifications to the appropriate personnel

Improve Throughput

Device Enterprise Communication (DEC):

- Saves manual data entry time at the device by enabling communication with master ADT systems.
- Improves data collection efficiency and homogeneity by sending directly and regularly to CIS
- Reduces delays in the review/reporting process—device sends complete data or data in progress to the CIS, allowing faster initial and final diagnosis

- Reduces staff administrative time by electronically recording data instead of manual entry

Point-of-Care Infusion Verification (PIV) on medical device:

- Improves caregiver efficiency by integrating the infusion pump into the electronic medication administration process
- Reduces staff time by electronically programming the infusion pump dosing and delivery data

Alert Communication Management (ACM) on medical device:

- Improves alert quality and response time
- Allows different alert priorities to be managed efficiently and effectively

Reduce Costs

Device Enterprise Communication (DEC):

- Reduces extra steps in the workflow by utilizing automatic communication between the device and CIS
- Prevents lost data by electronically transmitting to CIS
- Improves billing accuracy
- Promotes automated validation for more complete electronic charting
- Reduces delays in the review/reporting process—device specifically sends complete data or data in progress to the CIS, allowing faster initial and final diagnosis
- Reduces staff administrative time by electronically recording data instead of manual entry

Point-of-Care Infusion Verification (PIV) on medical device:

- Reduces extra steps in the workflow by utilizing automatic communication between the device and CIS
- Mitigates the possibility of introducing medication errors
- Promotes more complete medication administration records
- Improves billing accuracy for medications and consumables

Alert Communication Management (ACM) on CIS:

- Improves alert quality and response time
- Allows different alert priorities to be managed efficiently and effectively

Reduce Deployment Costs/Time

All IHE profiles on the device:

- Eliminates the need to create custom interface specifications for the medical device, saving the hospital time and expense

- Reduces interface compliance testing, time, and expense—IHE TF provides a detailed specification for a powerful interface, supported and tested by many vendors
- Reduces intersystem testing time and expense—many combinations of systems have already been directly tested together at IHE Connectathons
- Reduces custom interface maintenance time and expense by mainlining a single IHE interface instead of multiple custom interfaces

Improve Device Management

Medical Equipment Management – Device Management Communication (MEMDMC):

- Communicates device status information to Computerized Maintenance Management System (CMMS)
- Awareness of devices on infrastructure reduces rogues
- Through communication with devices that support consuming MEMDMC observations can add information to DEC observations, IPEC observations, and ACM alerts

Medical Equipment Management – Location Services (MEMLS):

- Communicates equipment and people location information (movement, boundary crossings)
- Communicates information provided by location tags for environmental information (temperature, humidity, pressure, gasses)
- Communicates tag interaction information (buttons, pulls, falls)
- Through communication with devices that support consuming MEMLS observations can add information to DEC observations, IPEC observations, and ACM alerts

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 device 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 device, 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 G.

1.1.3 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 the profiles and actors for a medical device:

1. *"The device shall support the IHE **Device Enterprise Communication (DEC)** Integration Profile as the **Device Observation Reporter (DOR)** Actor."*

2. *"The device shall support the IHE **Device Enterprise Communication (DEC)** Integration Profile as the **Device Observation Filter (DOF)** Actor."*
3. *"The pump shall support the IHE **Point-of-Care Infusion Verification (PIV)** Integration Profile as the **Infusion Order Consumer (IOC)** Actor."*
4. *"The device shall support the IHE **Alert Communication Management (ACM)** Integration Profile as the **Alert Reporter (AR)** Actor."*

The following are sample statements to specify profiles and actors for a CIS:

1. *"The CIS shall support the Device Enterprise Communication (DEC) Profile as the Device Observation Consumer (DOC) Actor using the MLLP Option."*
2. *"The CIS shall support the Point Of Care Infusion Verification (PIV) Profile as the Infusion Order Provider (IOP) Actor."*
3. *"The CIS shall support the Alert Communication Management (ACM) Profile as the Alert Manager (AM) Actor."*

For products that do not currently support IHE integration profiles, it may be possible to include contract language that binds the vendor to agree to support IHE over time. Some vendors may also be actively developing compliant products that will soon be on the market, this should be addressed during the RFP process.

Appendix H also explains how to map clinical requirements to particular specification language.

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

1.1.4 Identifying Suitable Products

While you may choose to proceed directly to sending your RFP to a broad group of potential vendors, 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.

1.1.5 Reading Integration Statements from Vendors

An Integration Statements is a direct statement of which IHE profiles, actors and options are supported by a particular product from a particular vendor. For the contents of an Integration Statement, see Appendix D.

Vendors may respond to your RFP by providing an IHE Integration Statement document. IHE Integration Statements are also available for many products at the IHE Product Registry

http://ihe.net/IHE_Product_Registry

The existence of an Integration Statement is a statement of conformance by the vendor and should not presume that the vendor implementation of the IHE profiles, actors, and options has undergone IHE Connectathon verification testing.

1.2 The Design, Configuration, and Implementation Process

The following sections are intended for the design and implementation team. They cover important clinical and IT considerations when planning to deploy a device or CIS with IHE

capabilities, including dealing with "legacy" issues when connecting a device or CIS to systems that do not support IHE profiles.

1.2.1 Considering Changes to Your Workflow

IHE Patient Care Device profiles are designed to transmit data or alerts in a streamlined clinical workflow. For instance, they eliminate the need to enter patient information at the device, and transcribing information into the electronic chart. They also allow device data 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. A current state assessment should be performed, then a future state assessment and a gap analysis will help to identify significant changes that would be required. For example a nurse may no longer need to manually record vital signs in a patient's chart but there may be additional tasks within the charting application that must be performed to properly document them. One common task may be to confirm or accept the data that is provided.

1.2.2 Confirming That It's Working

The following section provides guidance on how to confirm that the device is operating according to the IHE profile implemented. This section provides elements for testing an individual profile as it relates to the device. Often, there are other ways than the ones described to confirm the data and the transactions—see Appendix F.

1.2.2.1. Device Enterprise Communication (DEC)

1.2.2.1.1 Device

For devices, it is important that patient demographics be available to the device through a CIS. Verify that the critical information is available for reviewing on the device and that information sent from device to the CIS is correct. Confirm that the correct information is maintained by checking information associated with the orders. The following is an example of the high-level list of tests that may need to be run on a new device with DEC:

a. Confirming the scenario: Verify that the patient demographics including location information on the device match the CIS. Compare the physiological parameters displayed on the device matches the data shown in the CIS. Verify that data are being sent as programmed. Verify that data are not lost when a break in communications occurs.

   For each of these areas, detailed test sets need to be developed with the appropriate data sets. For example, when a device sends physiological data to the CIS, the following types of items must be taken into account:

   a. What type of data can the device gather?

   b. What types of data can the device send?

   c. What types of data can the CIS receive?

   d. How much data can be buffered in the event of a loss of connectivity?

Develop tests that ask for the relevant fields (e.g., check all parameters for accuracy)

b. Verifying information: Verify the information that this device can display and send.

Develop tests to review all of the data and verify each of the DEC fields returned and displayed on the device (patient name, patient ID, etc.). Develop tests to review all of the resulting information, which was generated from the device and used in the resulting HL7 messages out to the CIS. For example check that the physiological parameters such as SPO2, heart rate, blood pressures that are displayed in the CIS match those on the devices (with special attention to units of measure and nomenclature).

1.2.2.1.2 CIS

It is important that the patient demographics and order information sent from the CIS are recorded correctly by the medical device. This information, along with additional patient demographics and order and procedural information, must be correctly forwarded to the medical device so that the proper care is performed and reported on. Likewise, the data returned to the CIS from the medical device is critical in providing the enterprise with appropriate information.

Confirming the CIS interoperability requires checks at several points in the process. Confirm that the patient demographics have been received by the medical device. Confirm the information sent from the medical device is available and accurate in the CIS.

The following are examples of the high-level list of tests that may need to be run on a new CIS with DEC. Some or all may be relevant to a specific enterprise. These test scenarios are based on the use cases identified in Section 3.3 of Vol. 1 of the IHE PCD 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.

Communicate patient data to CIS

1. Associate a patient to the medical device and begin sending both periodic (e.g., heart rate) and aperiodic data (e.g., NIBP) to the CIS.

   Confirming the scenario: Verify that the information displayed on the medical device matches the information displayed in the CIS with particular attention to value and units of measure. Verify that these match. Verify that the timestamps in the medical device and the CIS are the same. Review the transactions at the message level for conformance to the IHE TF specification.

Communicate validated periodic data to CIS

1. Associate a patient to the medical device and send a set of validated periodic data from the medical device to the CIS. Note: Some CIS systems or medical devices do not support validated versus unvalidated data, in which case this test should be skipped.

   Confirming the scenario: Verify that the information displayed on the medical device matches the information displayed in the CIS and that the data is represented as being verified. Verify that the timestamps in the medical device and the CIS are the same. Review the transactions at the message level for conformance to the IHE TF specification.

Subscribe to PCD data for patients from a specific location

1. Associate a patient to the medical device and send a subscription request from the CIS to the medical device to retrieve the information for a specific location in the enterprise.

Confirming the scenario: Verify that the information displayed on the medical device matches the information displayed in the CIS. Verify that the timestamps in the medical device and the CIS are the same. Verify that only parameters from the requested subset of patients are sent. Review the transactions at the message level for conformance to the IHE TF specification.

1.2.2.2. Alert Communication Management (ACM)

1.2.2.2.1 Alert Reporter (AR) Actor

If a device supports the ACM Profile as an AM Actor and it has been configured to send Report Alert messages to an Alert Manager (AM) Actor then when an alert occurs in the device the device will output a Report Alert message to the AM Actor.

1.2.2.2.2 Alert Manager (AM) Actor

The AM Actor will receive the alert and map it to a destination endpoint communication device associated with an Alert Communicator (AC) Actor. The AM will then send the alert notification text message to the AC Actor for disseminate by the AC Actor. The AM Actor will likely expect to receive signaling from the AC Actor for delivery confirmation, read receipt, and endpoint communication device operator responses, minimally accept and reject. The AM Actor uses such signaling to implement escalation of alert notifications to alternate alert notification destinations. While the ACM Profile recognizes that an internally implemented escalation mechanism is best implemented within the AM Actor the manner in which such escalations are processed is left up to the AM Actor implementing vendor.

1.2.2.2.3 Alert Consumer (ACon) Actor

While the AM Actor has responsibility for mapping alerts to assigned endpoint communication devices and disseminating the alert notification to the associated AC there is often a need to maintain the alert status for active alerts. The display of such information can be considered an active alerts dashboard. The Alert Consumer (ACon) Actor was added to the ACM Profile to fill this role. The ACon Actor has no further obligation than to receive alerts from AR Actors.

1.2.2.2.4 Alert Communicator (AC) Actor

The AC Actor will receive the alert notification text message and dispatch it to the destination endpoint communication device. Depending upon whether or not the endpoint communication device supports one-way or two-way notifications the operator of the endpoint communication device can send responses back to the AC Actor which can then send them back to the AM Actor, and if supported then the AM Actor can close the loop and send the status of the disseminated alert back to the AR Actor.

1.2.2.2.5 Endpoint Communication Protocol

In order for the AM Actor to remain endpoint communication device type agnostic the protocol between the AM and AC Actors is defined in the ACM Profile to be the Wireless Communication Transfer Protocol (WCTP). In order to support existing deployments of endpoint communication devices most commercially available AM Actor systems will support additional endpoint communication device proprietary protocols. While this would not be conformant to the ACM Profile it is recognized as a deployment reality. The deployed AM – AC Actors interface would hopefully support the ACM Profile defined advantageous signaling for delivery confirmation, read receipt, and endpoint communication device operator responses, minimally accept and reject. Absent such signaling the AM Actor would be hard pressed to internally implement certain forms of alert notification escalation to alternate destinations.

1.2.2.3. Medical Equipment Management Device Management Communication (MEMDMC)

1.2.2.3.1 Device Management Information Reporter (DMIR) Actor

If a device sends equipment status or configuration information to a CMMS independent of observations relating to a possibly associated patient then that device is a candidate for use of the MEMDMC Profile. If a device is conformant to the profile as a DMIR Actor then when device events are triggered observations are send to the DMIC Actor. Such messages can be any of the following

- Power on, or change of power source, identifying current power source (mains, battery)
- Battery charging status
- Device self-test status
- Device requires maintenance (cleaning, calibration, other)

1.2.2.3.2 Device Management Information Consumer (DMIC) Actor

The DMIC Actor can use the reports from the DMIR Actor to identify devices not already in the CMMS inventory. This helps the Clinical Engineering (CE) team maintain device inventory information.

If a device is no longer visible on the network after identifying that it has gone on battery sourced power then it is likely that its battery is exhausted. If there is a patient associated with the device when the battery goes low it is expected that this would result in an alert notification under the ACM Profile as immediate clinical assistance is required.

1.2.2.4 Medical Equipment Management Location Services (MEMLS)

1.2.2.4.1 Location Observation Reporter (LOR) Actor

If a device or a person has been outfitted with a location reporting capability then it is the function of the LOR Actor to receive the information and communicate it to the LO Actor. This allows the LOR Actor to maintain abstraction to the technology utilized in identifying the

location. Multiple LOR Actor implementations can utilize different technologies and standard or proprietary technologies and communication the information in a standards based uniform manner to the LOC Actor.

The reported observations are not constrained to only reporting location. Contemporary reporting systems can also report environmental information (temperature, pressure, gasses, etc.) and operator interaction information (button presses, tampers, pulls, falls, etc.).

If an observation exceeds a boundary or limit or requires immediate response (panic button, falls) then it is better sent to an AM Actor as an alert notification.

1.2.2.4.2 Location Observation Consumer (LOC) Actor

The LOC Actor receives the location observations and can utilize that information for many purposes, including active mapping of reported locations, dashboards of environmental status, etc.

Another way in which vendor systems utilize consumed location information is to include that information in messages associated with other IHE PCD profiles, such as DEC, ACM, or IPEC. The location observation can be consumed, filtered to only cache location for specific devices (brand/type) and then to include that information when communicating DEC, ACM, or IPEC observational messages.

1.2.3 Considering Installation Issues

Even with IHE, installation is not entirely “plug & play”(yet!)—the systems are not self-configuring. Required information such as HL7 interface IP address and ports must be coordinated between the medical device and the CIS. There should be a pre-coordination of the parameters to be exchanged and the frequency of transactions. The nomenclature and units of measure will also have to be coordinated and verified between the CIS and medical devices in conjunction with the Rosetta Terminology Mapping tables. Furthermore, this step should be coordinated with clinical leadership and points of contact to ensure that flow sheets contain required and desired information for use in various enterprise clinical environments (e.g.: specific parameters required for review during rounding in ICUs, Medical/Surgical wards, etc.).

There are some compatibility issues that are outside the scope of the IHE TF that must be evaluated to ensure the proper workflow is safely maintained. Some bar code medication administration (BCMA) systems will verify the patient once while all activities for that encounter occur, while some require that the patient be bar-coded again for each interaction. Some BCMA systems will assume functionality at the pump such as those implemented in typical "smart pumps." To maintain a safe workflow implementers must understand the IHE TF and be able to recognize workflows that are outside the framework specification. Functional testing of all feasible scenarios is critical.

1.2.4 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 (for example, HL7), 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.

1.2.4.1 Connecting the IHE Device to a Non-IHE CIS

Interoperability between the CIS and a medical device enables the electronic flow of device physiological and operational parameters from the bedside to the medical record. The same interoperability may still be available when connecting the IHE device to a non-IHE CIS based on the capabilities of the CIS. The organization should request a current HL7 interface specification from your CIS vendor to determine how to integrate the IHE device with a non-IHE CIS (See Appendices F and G). The following section provides brief guidelines to be followed when verifying IHE device and non-IHE CIS interoperability.

1.2.4.1.1 Device Enterprise Communication (DEC)

In the DEC Profile, the device outputs HL7 messages in a specific format with constraints beyond the normal HL7 specification (refer the TF). The following standards are utilized by the IHE PCD DEC transactions.

- HL7 - Health Level 7 Version 2.6 Ch5 Query and CH7 Observation Reporting
- ISO/IEEE 11073-10201 Domain Information Model
- ISO/IEEE 11073-10101 Nomenclature

If your CIS also supports these standards the next step is to confirm that critical attributes provided in the messages by the device are acted on in the CIS. A summary of the key identifying attributes defined by IHE to ensure information consistency throughout the acquisition workflow is found in the technical framework. These attributes should also be reviewed with clinical and IT leadership within the enterprise to ensure clinical requirements are met. For a complete mapping of the key attributes, see the Patient Care Device TF, Vol. 2, Appendix B and Appendix C. If your CIS does not act on any of these key attributes, your vendor may have an option or upgrade to provide proper support for these attributes.

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, while the flexibility this affords may facilitate a more completely integrated medical device and information technology environment, challenges will still exist. Usually however, a complete or nearly complete suite of partially integrated information systems 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.

Systematic use of the IHE integration profiles will ease the burden of device integration, but will not eliminate all challenges. A careful review of these profiles together with clinical engineering and care providers will be necessary during planning, implementation and rollout to establish the best approach suited for a particular healthcare environment. The IHE integration profiles and detailed use cases can greatly facilitate this and can serve as boilerplate for such discussions.

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 a hospital (which demonstrates that incremental benefits are possible), consider the following:

Assume that at the start, the situation in the hospital is such that there are some medical devices connected to proprietary networks. What IHE brings you in this situation is the vision, blueprint and strategy for the quest toward the IHE.

The first simple and pragmatic step could be to have a few medical devices sending data to a clinical information system (CIS). IHE has a profile available for this step, the DEC Profile, which ensures the proper flow of physiological data to the CIS. Clinical workflow is paramount here.

The second step could be to introduce an electronic medication administration process. IHE has a profile available for this step, the PIV Profile, which integrates the administration of I.V. medications using infusion pumps into systems that support the 5 Rights of Medication Administration.

- Right Patient
- Right Drug
- Right Dose
- Right Route
- Right Time

In summary, with the IHE approach to enterprise integration, one may expect a reduction of the hospital’s integration costs, which represent a significant portion of the hospital’s 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. 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 hospitals. The roadmap covers new clinical domains, such as Cardiology 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 and device 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 Integration Statements describing specific IHE capabilities of a product.

A.1 Integration Approaches in IT Environments with Legacy Systems

Interoperability between systems in 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 IEEE 11073, HL7 v2.x interfaces. This should ease integration efforts because defined messages with a limited variability need to be adapted.

The 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. 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 “custom” solution can only be recommended for peripheral systems with specific usage in a limited organizational scope—e.g., to realize data collection for research.
2. Medical devices connect to a translator gateway: In this case the gateway will translate the data coming from medical devices into HL7 messages. Where such gateways exist, medical device vendors should be consulted to supply user documentation to assist with the implementation of outbound and inbound messaging.
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, a patient monitor may get ADT data via the interface engine from a registration system.

Implementing any of the above alternative approaches is subject to the costs / benefits to the organization and must be determined by the stakeholders with the help of medical device

vendors. A “one size fits all” approach usually does not work. Therefore, those implementing such systems should educate themselves as completely as possible in the capabilities of their existing medical devices relative to interoperability and integration to determine what the true cost will be to the enterprise in achieving the intended goal.

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.

Detailed descriptions of each profile are contained in Volume 1 of the IHE TF, which contains a chapter dedicated to each profile outlining the problem solved, the actors involved in the solution, and the associated transactions they use to interact. If you wish to dig deeper, explore the IHE TF documents. Refer to the section below on reading the IHE TF.

B.2 Reading the IHE Technical Framework

The complete IHE Technical Framework (TF) of each domain is available for download at http://ihe.net/Technical_Frameworks. Each IHE domain publishes a separate TF; however, they are 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.

When new profiles are first published their documentation status is Trial Implementation (TI). They are considered as Technical Framework Supplement documents. Profiles whose documentation is at TI status may make use of interim nomenclature not yet normalized in a standard. This is to permit demonstration and verification testing. Once a profile has been verification tested in multiple vendor implementations it would seek to have nomenclature normalized in a version of a released standard.

Once a profile has been judged stable and sufficiently verified to achieve Final Text (FT) documentation status, the profile supplement document is merged into the next release of the appropriate TF document.

A TF is structured 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. 2 is split into a Vol 2a, 2b, etc. (or a Vol. 3). 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.

B.3 Rosetta Terminology Mapping

The Patient Care Device Domain is working towards complete semantic interoperability of medical devices. This means not only allowing devices to be able to speak to each other, but

allowing them to understand each other. This is also of benefit for retrospective analysis to examine and evaluate recorded information long after the point in time at which it was recorded. The primary purpose of the Rosetta Terminology Mapping (RTM) Working Group within PCD is to harmonize the use of existing nomenclature terms defined by the ISO/IEEE 11073-10101 nomenclature standard. The RTM work also specifies the appropriate units-of-measure and enumeration values for each communicated data item to facilitate safe and interoperable communication between devices and systems. This vendor-neutral specification makes implementing and verifying PCD profiles quicker, safer, cheaper and more efficient by eliminating the process of custom mapping each device interface’s terms and units of measure.

The RTM WG effort has amassed a great many identifiers, enumerations, and units of measure. To automate the management of these values the National Institutes of Standards and Technology (NIST), a unit of the US Department of Commerce, has established and maintains a freely accessible Internet based online system to maintain and to lookup the identifier, enumeration, and units of measure information. It is the RTM Management Service or RTMMS located at https://rtmms.nist.gov.

B.4 Content Profiles

The Patient Care Device Domain of IHE is further advancing the interoperability of medical devices by creating Content profiles within the Technical Framework. Many use cases within the PCD domain can be accomplished by leveraging the existing actors and transactions of the DEC Profile. The difference in most cases is the content within the messages and not the structure or behavior of the message itself. For example, the content of an infusion pump’s communication to an EMR will look much different that the content of a physiological monitor. These Content profiles will further constrain existing actors and transactions to facilitate interoperability.

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 actor within a particular profile, and IHE provides several hundred pages documenting what the vendor needs to do to claim conformance to that requirement. Referencing an actor within 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 Patient Care Device Technical Framework and include a link to *http://ihe.net/Technical_Frameworks/#pcd* 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 a prospective vendor provide an integration statement for applicable products either before or in response to the RFI/RFP. The format of the integration statement should follow the template of an IHE integration Statement which can be found at https://wiki.ihe.net/index.php/Statements.

The existence of a vendor provided integration statement formatted per the IHE integration Statement template is not an assertion by IHE regarding the verification of the product to the indicated IHE profile and actor. It is an assertion by the vendor that the product they are offering to you can be verified as conformant to the actor role of the indicated profile.

The next step in verification that the prospect product is conformant to an indicated IHE profile and actor is that the vendor profile actor implementation has successfully passed a recent IHE Connectathon. The successful participation by the vendor implementation in a Connectathon can be verified independent of the vendor at the IHE Connectathon Results site at https://connectathon-results.ihe.net.

RFI versus an RFP

An RFI asks a vendor to describe their technology and how it would solve the requesting enterprise's integration and workflow challenges. An RFP is a proposal of what the enterprise intends to accomplish and includes a project schedule, budget, and statement of need. This Appendix describes an RFI. To make this RFI into an RFP, the enterprise's timetable and budget should 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 standards such as 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 an electronic Medication Administration Record. (eMAR):

Table C-1: Evaluation of Integration Features Example

Integration Profile	Problem	Internal Rating	Vendor Capability	Rank*
Device Enterprise Communication (DEC)	Integrating vendor independent, multi-modality patient care device data to enterprise applications using consistent semantics.	5	4	20
Point of Care Infusion Verification (PIV)	Electronic transmission of medication orders from a bedside medication administration system to a pump and documenting the administration parameters to the eMAR.	5	3	15
Infusion Pump Event Communication (IPEC)		4	3	12
Alert Communication Management (ACM)	Communicating alerts (alarms, both physiological and technical, and advisories) from source systems to management systems and from management systems to communication systems.	4	3	12
Medical Equipment Management Device Management Communication (MEMDMC)	Communicating medical device equipment management information to the Computerized Maintenance and Management System (CMMS)	1	1	1
Medical Equipment Management Location Services (MEMLS)	Communicating equipment and people location and tag related information to systems that need it	3	1	3
Total				**73**

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.

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. Please also see Appendix H for further information on mapping clinical requirements into specific purchasing specification language.

"The device shall support the IHE Device Enterprise Communication (DEC) Integration Profile as the Device Observation Reporter (DOR) Actor."

"The gateway shall support the IHE Device Enterprise Communication (DEC) Integration Profile as the Device Observation Filter (DOF) Actor."

“The pump shall support the IHE Point-of-Care Infusion Verification (PIV) Integration Profile as the Infusion Order Consumer (IOC) Actor.”

“The pump shall support the IHE Infusion Pump Event Communication (IPEC) Integration Profile as the Device Observation Reporter (DOR) Actor.”

“The device shall support the IHE Alert Communication Management (ACM) Integration Profile as the Alarm Reporter (AR) Actor.”

“The Barcode Medication Administration system shall support the IHE Point-of-Care Infusion Verification (PIV) Integration Profile as the Infusion Order Provider (IOP) Actor.”

“The CIS shall support the IHE Device Enterprise Communication (DEC) Integration Profile as the Device Observation Consumer (DOC) Actor.”

For your Like-to-haves and especially for newer integration profiles (MEMDMC, MEMLS), 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. You are putting unrealistic expectations on a vendor to deliver functionality if it is not incorporated in the contract.

“The device shall support the IHE Medical Equipment Management Device Management Communication (MEMDMC) Integration Profile as a Device Management Information Reporter (DMIR) Actor.”

“The CMMS shall support the IHE Medical Equipment Management Device Management Communication (MEMDMC) Integration Profile as a Device Management Information Consumer (DMIC) Actor.”

“The Location Services System (LS/RTLS) shall support the IHE Medical Equipment Management Location Services (MEMLS) Integration Profile as a Location Observation Reporter (LOR) Actor.”

Or if the location monitoring technology is embedded in a medical device then

“The device shall report location information by supporting the IHE Medical Equipment Management Location Services (MEMLS) Integration Profile as a Location Observation Reporter (LOR) Actor.”

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 fromhttps://connectathon-results.ihe.net/. The PCD domain utilizes NIST test tools during the Connectathon for more rigorous testing of interface messages. 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., HIMSS, RSNA, ACCE) and Connectathon Monitors, who are technically knowledgeable individuals hired by IHE, who manage the test execution and examine and log the testing results. They report to domain specific project managers. Success generally means a vendor successfully tests their product with products from at least three other vendors. Profile options are currently not listed on the Connectathon results web site. However, the vendors do have the opportunity to test profile options at Connectathons. If you require functionality that is specified in a profile option then ask the vendor if they tested that option at the Connectathon.

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 IHE Integration Statements. 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 D for details on interpreting the contents of an Integration Statement.

D.3 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	Alarms-A-Lot Central Station	V2.0	17 Oct. 2009

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
Device Enterprise Communication	Device Observation Reporter Device Observation Filter	MLLP WS*
Alert Communication Management	Alert Reporter	none

Web address for vendor's IHE information: *www.integratedmedicalsystems.com/ihe*

Links to Standards Conformance Statements for Implementation	
HL7	www.integratedmedicalsystem.com/devices/HL7
IHE at Integrated Medical Systems	www.integratedmedicalsystem.com/IHE

Links to general IHE information

In North America: *www.ihe.net*
In Europe: *www.ihe-europe.org*

The first part of the statement indicates that it applies to version 2.0 of the Alarms-A-Lot Central Station from a vendor called Integrated Medical Systems, and it was published on 17 Oct. 2009. The middle part of the statement indicates that this Central Station supports the IHE Device Enterprise Communication Profile as the Device Observation Reporter Actor and it supports the MLLP Transport Option as well as the Device Observation Filter Actor. It also supports the Patient Demographics Query Profile as a Patient Demographics Consumer Actor.

Integration statements from a growing number of companies are included in the IHE Product Registry at http://product-registry.ihe.net/.

D.4 Verifying Integration Statements

A vendor can claim conformance to IHE specifications without ever testing or verifying their product. This is why it is important to leverage the Integration Statement only as an introduction to discussing specific interoperability requirements. For example you should first check the Connectathon results to see if the vendor has successfully completed testing at this venue. If they have then you should also ask the vendor:

1. What years did the vendor pass their Connectathons?
2. What version of software was tested at the Connectathon?
3. What version of the domain specific Technical Frameworks does the product conform to?
4. Was the commercially available product version that will be delivered tested at a Connectathon?

Appendix E: Obtaining and Reading HL7 Interface Specifications

Purchasers should 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.

The IHE TF serves as a basis to constrain the options and HL7 message structure. In the Patient Care Device domain the TF makes use of the ISO/IEEE 11073-10201 Domain Information Model standard and the ISO/IEEE 11073-10101 Nomenclature standard. These standards provide a framework for modeling the communication between medical device applications.

Appendix F: 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 and HL7 specifications), 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?
- Which tests should be executed?
- What data are required to perform the testing?
- How will the operation of the test be verified, and which tools must be acquired to support verification testing?
- What are the goals of each test?
- Has sufficient time been allocated to develop these specifications?

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 network interruptions, many Device Observation Reporters sending data to one Device Observation Consumer, multiple Device Observation Reports sending data to many Device Observation Reports.

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 “simulated results,” using device emulators that output the same values repeatedly. An array of medical devices 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, the use of the medical device to display results, or alternatively the use of an EMR to verify that the information within EMR contains the same data displayed on the medical device. The following are classes of tools that may be used to verify results:

- HL7 Parsers: Parse out the fields of HL7 messages and present the components in a more human-readable way.
- NIST Test Tools:
  - ICSGenerator - tests implementations against the ISO/IEEE 11073 set of standards,
  - ValidatePDU - validates the basic syntax and structure of messages,
- HL7 v2 IHE-PCD Pre-Connectathon Test Tool – available at the NIST HL7 version 2 tools portal (http://hl7v2tools.nist.gov/portal/#/tools) – Supports vendor IHE-PCD Pre-Connectathon static HL7 V2 message verification according to the HL7 Standard, IHE-PCD Technical Framework and Supplement documents, Harmonized Rosetta Terminology Mappings (hRTM), and test cases.
- 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 Radiology 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 http://ihedoc.wustl.edu/mesasoftware/)

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 G: 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 a hospital 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.

G.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 the chosen target, sometimes using unexpected strategies that make undesirable sacrifices. 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.

Departmental Operational Metrics: time to document physiological data

Patient Experience Metrics: code team response times

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.

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. To find “best in class” hospitals, consider winners of the annual HIMSS Davies Award of Excellence in healthcare IT.

Appendix H: Mapping Clinical Requirements to Purchasing Requirements

Introduction

The purpose of this guidance document is to provide "drop-in" requirements that facilities can use to request conformance to IHE's standardized information transfer profiles in their purchasing documents such request for proposal (RFP) documents. These requirements ask suppliers to spell out conformance to IHE PCD profiles, actors, transactions, and nomenclature. By including these requirements in an RFP, a facility can assess how well a new device or information system under consideration will support a standards-based approach to information transfer. This document is a living document and will be updated with additional device types and additional clinical requirements as time permits.

Structure and Nomenclature

There are two main components to standards-based integration: sending the right information in the right order (structure) and sending a message using terminology that both the sender and receiver can understand (nomenclature). Both structure and nomenclature are addressed by this document.

Structure is specified by supporting an IHE transaction, which means that all the information deemed required/mandatory in the message according to the IHE profile is populated (by the sending system) and used/persisted (by the receiving system). This document includes tables and diagrams of clinical requirements, organized by device type (e.g., infusion pump, vital signs monitor), and will be added to as time permits. The diagrams show the relationship between clinical workflow and IHE profiles when possible and also outline additional requirements that may be required such as terminology and nomenclature stipulations. The tables map clinical requirements to specific RFP requirements based on IHE profiles. Ideally, the diagrams and tables will allow a purchaser to use the right IHE profiles to meet their required clinical objective. For more information on specific IHE profiles, please refer to the IHE PCD Technical Framework.

Structure only solves one part of integration: a vendor could support an IHE profile (i.e., information is present and in the right order) but use terms that connected systems can't understand, requiring either the supplier or the facility to perform the translation. To identify cases in which a system under consideration does not support standardized nomenclature and terminologies, purchasers must ask suppliers to specify their level of terminology and nomenclature support when responding to an RFP.

To do this, purchasers should copy the Technology and Nomenclature support levels in Table H-1 into their RFP introductory materials and then require this level to be stated on all RFP responses related to integration (e.g., "*Compliant/ Noncompliant. If Compliant, state Technology and Nomenclature Support Level (T0-T3) as defined in xx*").

Table H-1: Terminology and Nomenclature Support Levels for RFP Use

Terminology and Nomenclature support levels:

- ○ **T0: No support for standardized terms (e.g., ad-hoc value sets configured at each client site)**
- ○ **T1: Vendor-specific codes and value sets, consistent across all clients and sites**
- ○ **T2: A mix of vendor-specific and standard codes**
  Specify the code systems:_____
- ○ **T3: Standard codes only from the following standards:**
  Specify the standard code systems:_____
- ○ **T4: IHE PCD Rosetta Terminology Mapping (RTM) specified nomenclature and terminologies**

Use Case 1: Infusion Pumps Selection Criteria

Interoperability specifications like the IHE PCD Technical Framework support the automation of clinical tasks. Therefore the need for interoperability can be linked directly to a PCD profile. Consider a facility with the following clinical need:

> *To automate the clinical task of entering the drug information into an infusion pump, we need the medication order details (drug, dose, volume, etc.) to be sent from our Bedside Point of Care (BPOC) system to the pump sever that manages that pump.*

Figure H-1 illustrates that orders that travel from a Point-of-Care Medication System (BPOC) or to a pump server use an Order request represented by the PCD-03 message. Row #3 of Table H-2 provides specific RFP language for both the BPOC system and the pump server to meet this clinical requirement.

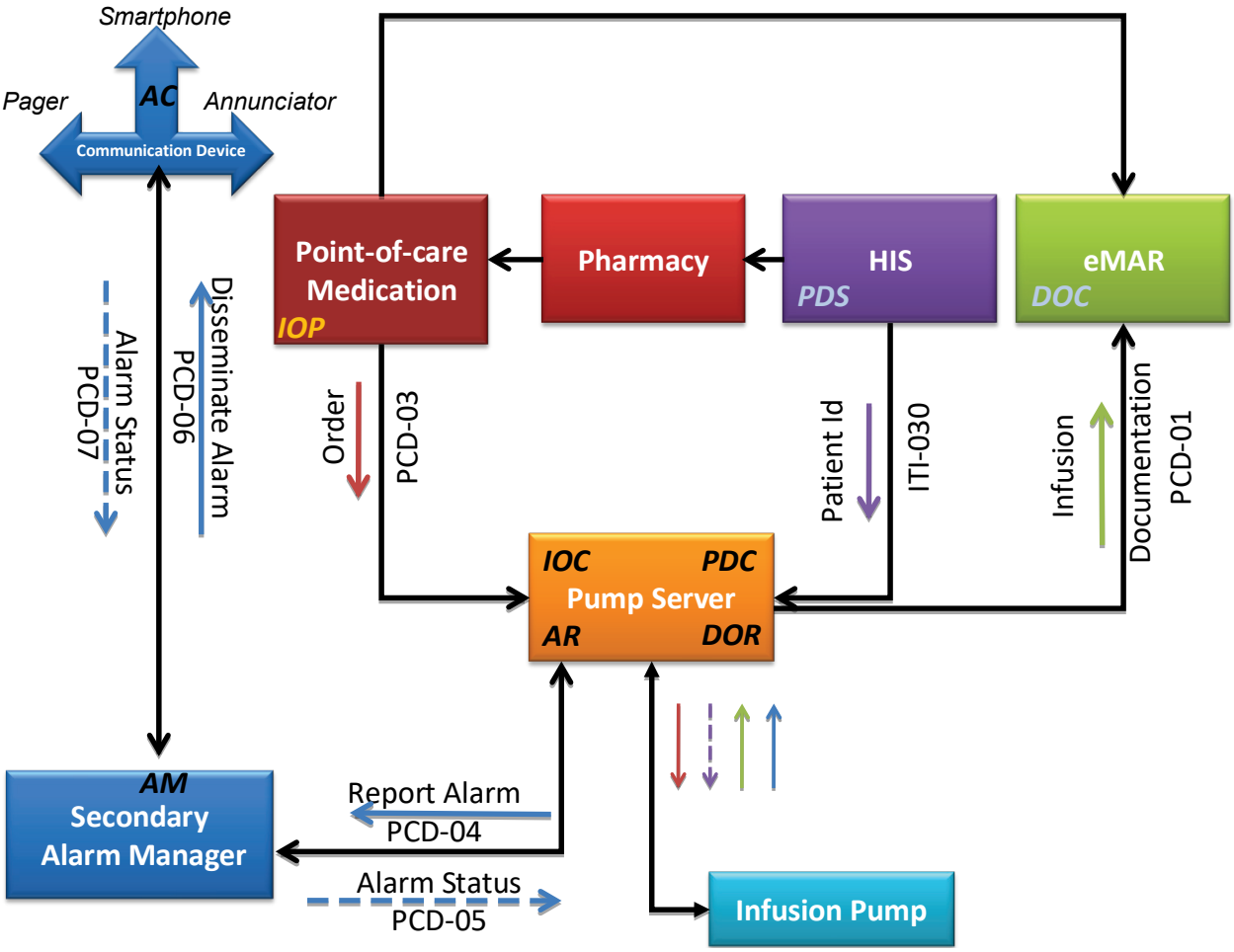


Figure H-1: Infusion Pump Information Flow

1195 **Table H-2: Infusion Pump RFP Language**

	I want this vendor system (Sender)	To send this information (Requirements)	To another vendor system (Receiver)	What is my RFP language for the sending system?	What is my RFP language for the receiving system?	What is the related transaction?
1.	For All Systems below	Maintain consistent time based with the other systems on the LAN		Shall Support the CT as the TC	N/A	ITI-1 Maintain Time
2.	Pump Server	*Drug information*	Pump	N/A	N/A	None, may be PCD-03 or proprietary
3.	Pump	*Results and status*	Pump Server	N/A	N/A	None, may be PCD-01 or proprietary
4.	Pump Server	*Drug delivery results recorded electronically*	eMAR	Shall support DEC as the DOR	Shall support DEC as the DOC	PCD-01
5.	Point-of-care Medication (BPOC) or Pharmacy	*Here are programming parameters for drug, dose, etc. for the patient on this pump*	Pump server	Shall Support PIV as the IOP	Shall Support PIV as the IOC	PCD-03
6.	Point-of-care Medication (BPOC)	*Here is the patient ID and pump ID and drug ID that was scanned at the bedside*	Pump server	Shall Support the PIV as the IOP	Shall Support PIV as the IOC	PCD-03
7.	CPOE, BPOC or Pharmacy	*An order was entered to start an infusion with these parameters*	eMAR	Shall Support the PIV as the IOP	Shall Support PIV as the IOC	PCD-03
8.	Pump server	*An infusion with these parameters was started for this patient*	eMAR	Shall support DEC as the DOR	Shall support DEC as the DOC	PCD-01
9.	Pump server	*Alarm notification- e.g., "something's wrong with this pump"*	Secondary alarm manager	Shall Support ACM as the AR	Shall Support ACM as the AM	PCD-04
10.	Secondary alarm manager	*Alarm status update- e.g., "nurse has cleared the alert"*	Pump server	Shall Support ACM as the AM with the Report Alarm Status Option	Shall Support ACM as the AR with the Report Alarm Status Option	PCD-05

	I want this vendor system (Sender)	To send this information (Requirements)	To another vendor system (Receiver)	What is my RFP language for the sending system?	What is my RFP language for the receiving system?	What is the related transaction?
11.	Secondary alarm manager	*Alarm condition sent to a clinician's phone or pager*	Communication Device (e.g., phone, pager, monitor, annunciator)	Shall Support ACM as the AM	Shall Support ACM as the AC	PCD-06
12.	Communication Device (e.g., phone, pager, monitor, annunciator)	*Alarm status update- e.g., "nurse has cleared the alert"*	Secondary alarm manager	Shall Support ACM as the AC	Shall Support ACM as the AM	PCD-07
13.	HIS (if no bar code reader on the pump)	*Patient identification (e.g., name, medical record number)*	Pump Server	Shall Support ITI-030 as the PDS	Shall Support ITI-030 as the PDC	ITI-030
14.	Bar Code Reader on pump	*Patient ID is scanned directly into the pump*				N/A

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Use Case 2: Vital Signs Monitor (VSM) Interoperability Criteria

Interoperability specifications like the IHE PCD Technical Framework support the automation of clinical tasks. Therefore the need for interoperability can be linked directly to a PCD profile. Consider a facility with the following clinical need:

To automate the clinical task of entering patient vital signs into our electronic medical record, we need to send patient vital sign results from the vital signs server to the EHR SYSTEM.

Figure H-2 illustrates that vital signs that travel from a vital signs monitor server to an electronic health record system use the PCD-01 message, and Row #2 of Table H-3 provides specific RFP language for both the EHR SYSTEM and the vital signs server to meet this clinical requirement. Of course, if the vital signs monitors itself is capable of transmitting information directly to an EHR SYSTEM, the RFP language of Row 2 can be used for the monitor itself. This same diagram and table can be substituted for nearly any medical device such as anesthesia systems, ventilators, beds, or bedside physiological monitors.

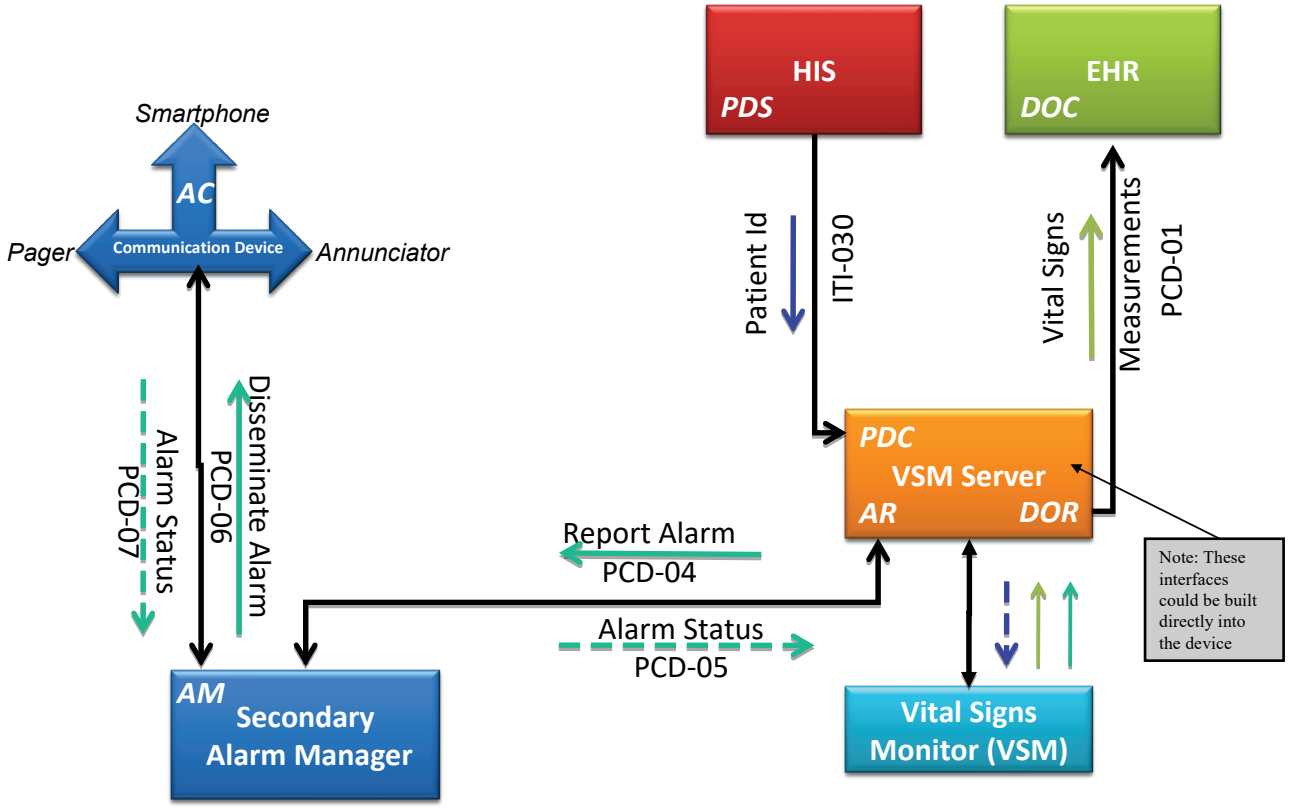

Figure H-2: Vital Signs Information Flow

Table H-3: Vital Signs Monitor RFP Language

	I want this vendor system (Sender)	To send this information (Requirements)	To another vendor system (Receiver)	What is my RFP language for the sending system?	What is my RFP language for the receiving system?	What is the related transaction?
1.	For All Systems below	Maintain consistent time based with the other systems on the LAN		Shall Support the CT as the TC	N/A	ITI-1 Maintain Time
2.	Vital Signs Monitor (VSM)	*Patient vital sign results and status information*	VSM Server			None, may be PCD-01 or proprietary
3.	VSM server	*Vital Signs Results*	EHR System	Shall Support PCD-01 as the DOR	Shall Support PCD-01 as the DOC	PCD-01
4.	VSM server	*Alarm notification- e.g., "something's wrong with this monitor"*	Secondary alarm manager	Shall Support PCD-04 as the ACM AR	Shall Support PCD-04 as the ACM AM	PCD-04
5.	Secondary alarm manager	*Alarm status update- e.g., "nurse has cleared the alert"*	VSM Server	Shall Support PCD-05 as the ACM AM with the Report Alarm Status Option	Shall Support PCD-05 as the ACM AR with the Report Alarm Status Option	PCD-05
6.	Secondary alarm manager	*Alarm condition sent to a clinician's phone or pager*	Communication Device (e.g., phone, pager, monitor, annunciator)	Shall Support ACM as the AM	Shall Support ACM as the AC	PCD-06
7.	Communication Device (e.g., phone, pager, monitor, annunciator)	*Alarm status update- e.g., "nurse has cleared the alert"*	Secondary alarm manager	Shall Support ACM as the AC	Shall Support ACM as the AM	PCD-07
8.	HIS	*Patient Identity traits including Patient ID*	VSM Server	Shall Support ITI-030 as the PDS	Shall Support ITI-030 as the PDC	ITI-030
9.	VSM Server	*Patient ID (e.g., from HIS)*	VSM	Shall Support ITI-030 as the PDS	Shall Support ITI-030 as the PDC	ITI-030

Appendix I: Deployment of Alert Communication Management solutions

Introduction

Vendors that implement Alert Communication Management (ACM) Profile actors create a solution for the communication of alerts (physiologic alarms, technical alarms, and advisories) from medical devices and systems to the ever growing variety of communication devices associated with people.

Common Solution for a Common Need

Communication of alerts from devices and systems to people is a common need that is alerting device type and specific alert agnostic. In healthcare institutions alert notification goes way beyond medical device physiologic alarms. It extends beyond even device alerts to systems workflow advisory notifications and reminder notifications. To avoid needing to deal with the delivery specific types of alerts to different types or instances of devices having to be carried by the same person a common solution needs to respond to common issues.

- To which recipients (people or devices) is a specific alert to be sent?
- What is the alert text to contain based upon correlated information from all available sources?
- Who are those recipients at this particular moment in time or shift (staff assignments)?
- To which communication device is this alert to be sent at this time (in office, on floor)?
- What is the priority of the alert (immediately actionable or respond when less occupied)?
- What is the phase of the alert (start, continuing, escalated, end)?
- What is the status of the alerting device or system (audibly indicating)?
- What if that person doesn't receive the notification, can't currently respond, or is occupied?
- How is that response signaled such that escalation of the notification can take place?
- What is the communication protocol for the specific destination communication device?

Solution Best Suited for Each Role

Which ACM Profile actor in their role is best suited to have access to the information to best answer each of these questions? It is readily apparent that the source device currently in an alarming condition is not the one best suited to answer all of these questions. The Alert Reporter Actor is best positioned to know the current state of the alert, its phase, and status. However, it simply doesn't have access to sufficient information and the information it does have when initially configured may not be kept current in an automated fashion. This makes the alert reporter not a good fit for maintaining the information needed to deal with staff assignments and escalations. While a middleware alert management is best positioned and best suited to answer a

great many of these questions it is not the best role to answer all of them. A few are best answered by an actor in a role that knows far more about the alert notification communication devices themselves. This is the justification for the Alert Communication Management Profile being comprised of three actors, the alert reporter, the alert manager, and the alert communicator, each with specific role responsibilities.

The alert reporter is the actor that is the source of alerts, and of knowing their current signaling status and the status of the alerting device or system. The alert reporter may be the alerting (alarming) device itself or it may be a gateway system that maps the potentially proprietary alarm signal into the HL7 version 2.6 based common format used by the alert reporter to signal alerts to the alert manager. The presumption is that in a hospital there may be many thousands of Alert Reporter Actors. It is unrealistic to expect to keep this vast population of alert reporters current as to who is to receive what alerts on what communication devices from what sources at what times of the day and days of the week. The alert reporter may not have access to care unit wide or hospital wide actively updated information which needs to be correlated and potentially included into the alert notification message. It is also unrealistic for alert reporters to understand how to directly communicate with the ever growing variety of alert notification communication destination devices that exist today. And it is also unrealistic for the Alert Reporter Actor to be configured to deal with all the details of assignment shifts and organizational hierarchies to execute alert notification escalations. By moving all these action decisions to the Alert Manager and Alert Communicator Actors it offloads this burden from the configuration as well as the design of the alert reporter.

The alert manager is the alert notification communication middleware. Being in the middle it is best suited to identify the recipients that are to get what alerts at what times. The alert manager is likely to be tapped into multiple actively updated information flows (the ADT feed being just one of them, active directory staff assignments and definitions might be another) that provide alert instance correlated information useful to include in the alert notification message. The alert manager may also be statically configured to provide information not available from the alert reporter. Being in the middle it has the opportunity to harmonize alert notification messages across vendors and device types or it can provide alert notification message information unique to a care unit. Having access to all these information sources the alert manager is also well positioned to deal with alert escalation should the alert notification be undeliverable, not read, not responded to, or rejected (if the recipient person is currently occupied). However, the alert manager is likely not the best actor to understand all the remote device communication protocols and alert notification communication device user interface behavioral nuances needed to provide the common signaling for the indications of delivered to recipient or not, message read or not, and the various ways to accept or reject the received alert notification. Therefore a message common signaling protocol is used between the alert manager and the alert communicator. That protocol is Wireless Communication Transfer Protocol (WCTP). While historically associated with paging it is the most complete and contemporary protocol currently available for this purpose. It utilizes hypertext transport protocol (HTTP), Extensible Markup Language (XML) for message data items, and the protocol supports authentication and encryption in requests and responses. WTCP also already supports all the required signaling mechanisms for delivery confirmation, read receipt, and user interface label to communicated response for operator signals such as accept and reject. There are other protocols that utilize HTTP, XML, and are securable, such as XMPP. However, they lack the signaling in a standardized form.

The alert communicator abstracts from the alert manager the ever growing variety of endpoint communication device protocols and signaling mechanisms (secured SMS, Jabber/Extensible Messaging and Presence Protocol or XMPP, proprietary protocols, legacy device protocols, paging protocols, secured e-mail, etc.) supporting the ever growing variety of endpoint communication device types (personal computers, PBX phones, proprietary Wi-Fi phones, public wireless smartphones, tablets, communication apps, smart watches, and legacy one-way pagers, etc.).

The WCTP based common communication and signaling between the alert manager and the alert communicator provides an endpoint device type and protocol agnostic mechanism for sending messages, and for signaling delivery conformation, read receipt, and endpoint communication device operator responses, such as accept and reject.

As the Alert Communication Management Profile matured it was realized that an additional actor was needed, that of the Alert Consumer or ACon Actor. This actor receives carbon copies of alert reports from the alert reporter community. However the ACon has no responsibility for mapping people or communication device assignments, communication to devices or people, or notification escalations. It is limited in its access to the complete picture of an alert and so is best suited to provide a dashboard of active alerts. It receives the original alert report. It receives phase updates on the alert. It receives the indication when the alert has ended.

Alert Retrospective Traceability

The Alert Communication Management set of actors provide in the messaging sufficient information to implement end to end history of alerts from origination to completion and all the phases and signals in between. The time of day in the messages is synchronized for all actors using the IHE Information Technology Infrastructure (ITI) domain’s Consistent Time (CT) Profile. In the logs of the actors an alert can be followed from the alert reporter, to the alert manager, to the alert communicator with bridging identifiers and timestamps all along the way. This information may be used in fatigue or workflow optimization analysis to assure that alerts are handled in a safe and efficient manner.

