Integrating the Healthcare Enterprise

IHE Patient Care Device (PCD)

Technical Framework
Volume 1
Revision 1.2

Trial Implementation

September 30, 2010

Contents

1 Introduction

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

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

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

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

The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated,

standards-based transactions. It describes this body of transactions in progressively greater depth. Volume 1 provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. Subsequent volumes provide detailed technical descriptions of each IHE transaction.

1.1 Overview of Technical Framework

This document, the IHE Patient Care Device Technical Framework Volume 1 (IHE PCD TF-1), defines specific implementations of established standards to achieve integration goals for the Patient Care Device domain. Such integration promotes appropriate sharing of medical information to support optimal patient care.

The IHE PCD TF will be expanded annually, after a period of public review, and maintained regularly through the identification and correction of errors.

The IHE PCD TF identifies a subset of the functional components of the healthcare enterprise, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. Volume 1 of the Patient Care Device Technical Framework (IHE PCD TF-1) provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. IHE PCD TF-2 provides detailed technical descriptions of each PCD-specific IHE transaction. IHE PCD TF-3 provides detailed specifications for content oriented profiles and includes content from specific device classes.

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

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

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

1.2 Overview of Volume 1

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

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

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

1.3 Audience

The intended audience of this document is:

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

1.4 Relationship to Standards

The IHE Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their interactions in the healthcare enterprise. At its current level of development, it defines a coordinated set of transactions based on the HL7, IEEE, DICOM, W3C and other industry standards. As the scope of the IHE initiative expands, transactions based on other standards will be included as required.

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

IHE is therefore an implementation framework, not a standard. Referencing IHE as a standard is inappropriate. Conformance claims by product must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities shall use an IHE Integration Statement to describe the conformance of their product to the specifications in the IHE Technical Framework. The purpose of an IHE Integration Statement is to communicate in a uniform manner to the users of the corresponding product the IHE capabilities it has been designed to support. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration Statements from different implementations, a user familiar with the IHE concepts of actors and Integration Profiles should be able to determine whether and to what extent communications might be supported between products. See IHE PCD TF-2: Appendix I for the format of such IHE Integration Statements.

IHE encourages implementers to ensure that products implemented in accordance with the IHE Technical Framework also meet the full requirements of the standards underlying IHE, allowing the products to interact, although possibly at a lower level of integration, with products that have

been implemented in conformance with those standards, but not in full accordance with the IHE Technical Framework.

1.5 Relationship to Real-world Architectures

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

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

1.6 Conventions

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

1.6.1 Actor and Transaction Diagrams and Tables

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

The tables of actors and transactions given in subsequent sections indicate which transactions each actor must support.

The transactions shown on the diagrams are identified both by their name and the transaction number as defined in PCD TF-1. The transaction numbers are shown on the diagrams as bracketed number prefixed with the specific Technical Framework domain.

In some cases in IHE, a profile is dependent on a pre-requisite profile in order to function properly and be useful. For example, many PCD profiles depend on Consistent Time. These dependencies are discussed in Section 2.1. An actor must implement all required transactions in the prerequisite profiles in addition to those in the desired profile.

1.6.2 Process Flow Diagrams

The descriptions of Integration Profiles that follow include Process Flow Diagrams that illustrate how the profile functions as a sequence of transactions between relevant actors.

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

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

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

Transactions are shown as arrows oriented according to the flow of the primary information handled by the transaction and not necessarily the initiator.

1.6.3 Normative versus informative contents of the Technical Framework

Most parts of the Technical Framework describe required or optional characteristics of Integration Profiles, actors and transactions: these are normative. For a better understanding of the text, there also exist illustrations (or examples) in the Technical Framework that are informative and non-normative.

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

1.6.4 Technical Framework Cross-references

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

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

<domain designator> is a short designator for the IHE domain (e.g., ITI = IT Infrastructure, RAD = Radiology, CARD = Cardiology, LAB = Laboratory, PCD = Patient Care Device)

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

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

1.6.5 Transaction Referencing

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

<domain designator>-<transaction number>, where:

<domain designator> is a short designator for the IHE domain (e.g., ITI = IT Infrastructure, RAD = Radiology, CARD = Cardiology, LAB = Laboratory, PCD = Patient Care Device)

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

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

1.7 IHE Patient Care Device Current Year Scope

IHE PCD is involved in developing various types of Integration Profiles as well as other documents such as supporting Test Environments, White Papers and User Guides. Currently not all profile types have been addressed; however we envision the provision of:

- Transaction Integration Profiles (focused on Messages)
- Content Integration Profiles (focused on Syntax and Semantics)
- Device Integration Profiles (focused on specific device types)
- Clinical Integration Profiles (focused on specific clinical workflows)
- And potentially other profile types as required

This will be the first IHE PCD Technical Framework released in final text. It includes the following profile(s):

- **[DEC] Device Enterprise Communication** is a Transaction Profile which describes mechanisms to communicate PCD data to enterprise information systems. The typical PCD data includes: periodic physiologic data (heart rate, invasive blood pressure, respiration rate, etc.), aperiodic physiologic data (non-invasive blood pressure, patient weight, cardiac output, etc.), and CLIA waived (or equivalent international waiver) point-of-care laboratory tests (i.e., home blood glucose, etc.). The data may also include contextual information such as the patient ID, caregiver identification, and patient care device configuration information.
- **[SPD] Subscribe to PCD Data** is a Transaction profile which supports limiting the information transmitted from the DEC DOR to the DEC DOC. It is an option to the DEC profile.
- **[PIV] Point-of-care Infusion Verification** is a Transaction Profile which supports communication of a 5-Rights validated medication delivery / infusion order from a BCMA system to an infusion pump or pump management system, thus "closing the loop."

- **[IDCO] Implantable Device Cardiac Observation** is a Transaction Profile which specifies a mechanism for the translation, transmission, and processing of discrete data elements and report attachments associated with cardiac device interrogations (observations).

[RTM] Rosetta Terminology Mapping is a Content Profile which establishes a set of tools (Excel spreadsheets & XML files) that map the proprietary semantics communicated by medical devices today to a standard representation using ISO/IEEE 11073 semantics and UCUM units of measurement.

Additional profiles have been or are being developed but have not yet met the requirements necessary to progress to Final Text. These include:

- **[DPI] Device Point-of-care Integration** is a Transaction Profile which brings focus on device connectivity around a patient-centric point-of-care, including "first link" interfaces between devices or a device manager / supervisor system. This activity includes initial development of a white paper, followed by a number of proposed profiles such as: discovery and association, data reporting, symmetric (bi-directional) communication, and external control.
- **[ACM] Alarm Communication Management** is a Transaction Profile which enables the remote communication of point-of-care medical device alarm conditions ensuring the right alarm with the right priority to the right individuals with the right content (e.g., evidentiary data).
- **[WCM] Waveform Communication Management** is a Content Profile which will extend existing IHE PCD profiles to provide a method for passing near real-time waveform data using HL7 v2 observation messages.

In addition, technical reports and enhancements to existing documents are being developed as part of current year efforts. These include:

- **[SA] Semantic Architecture White Paper** will provide an overview of the sometimes bewildering subject of nomenclature, terminology and information models that are used to enable true semantic interoperability of patient care device information. It will also lay the groundwork for the new terminology development that is required to fill gaps that have been identified, especially during [RTM] "Rosetta" profile development.
- **[MEM] Medical Equipment Management** is a White Paper that investigates the question of how health I.T. might support the activities of clinical engineering / biomedical engineering staff, improving quality and workflow efficiency. Key topics include unique device identification, real-time location tracking, hardware/software configuration and patch management, battery management, and more. PCD anticipates this will develop into a Transaction Profile.
- **PCD User Handbook -** A tool to help implementers understand specific topics in the PCD domain. This first effort is targeted for administrators to show how to specify IHE PCD Profiles in an RFP or RFI. The document will discuss the various profiles and the benefits of specifying and implementing them.

- **Profile Conformance Testing -** IHE and NIST are collaborating to test vendor implementations as defined across the IHE-PCD profiles. This cycle year includes IHE-PCD V2 message verification, both syntactically and semantically. Terminology is constrained to "Harmonized Rosetta" terminology from the ISO/IEEE 11073 standard.

1.8 Comments

The ACCE welcomes comments on this document and the IHE initiative. They should be directed to iheinfo@accenet.org.

1.9 Copyright Permission

1.10 IHE Technical Framework Development and Maintenance Process

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

The first of these principles is that any extensions, clarifications and corrections to the Technical Framework must maintain backward compatibility with previous versions of the framework in order to maintain interoperability with systems that have implemented IHE Actors and Integration Profiles defined there.

The IHE PCD Technical Framework is developed and re-published annually following a three-step process:

1. The PCD Technical Committee develops supplements to the current stable version of the Technical Framework to support new functionality identified by the IHE Strategic and Planning Committees and issues them for public comment.

2. The Committee addresses all comments received during the public comment period and publishes an updated version of the Technical Framework for "Trial Implementation." This version contains both the stable body of the Technical Framework from the preceding cycle and the newly developed supplements. It is the version of the Technical Framework used by vendors in developing trial implementation software for Connectathons.

3. The Committee regularly considers change proposals to the Trial Implementation version of the Technical Framework, including those from implementers who participate in the Connectathon. After resolution of all change proposals received within 60 days of the Connectathon, the Technical Framework version is published as "Final Text".

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

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

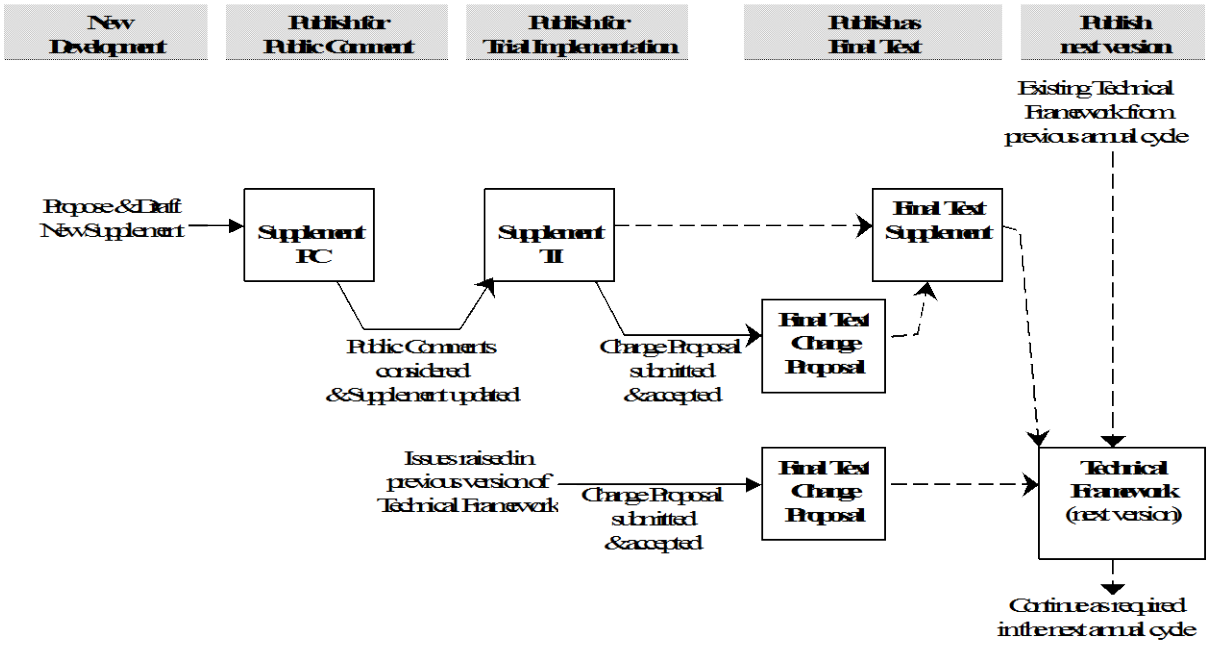


Figure 1.10-1 IHE Development Process

Figure 1.10-1 IHE Development Process shows the process of developing and maintaining the Technical Framework during an annual cycle. Dashed arrows indicate the assembly (merging) of text.

1.10.1 New Development – Extending the Existing Technical Framework

Each year, new functionality to be developed is identified by the IHE Patient Care Device Planning Committee. Individuals or organizations wishing to submit recommendations for new development are encouraged to join and participate in the PCD Planning Committee. The Technical Committee performs the necessary analysis and design work and generates new text for the Technical Framework. Generally, new functionality is published in the form of a Supplement. The scope of a Supplement is to make one of the following additions to the Technical Framework:

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

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

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

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

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

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

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

1.10.2 Maintenance of existing Technical Framework content

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

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

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

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

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

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

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

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

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

1.10.3 Use of Technical Framework

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

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

- Product Implementations
  Products implemented based on Trial Implementation text are expected to review the subsequent Final Text and update their products as necessary. Further, it is expected that vendors will monitor Final Text Change Proposals and make any corrections relevant to their product in a timely fashion.
- Connectathon Implementations
  Testing at the Connectathon will be based on the current version of the Technical Framework for the appropriate IHE Domain, plus any relevant Supplements for Trial Implementation and Final Text Change Proposals.

1.10.4 Product Verification and Validation Implications

The IHE process is geared around additional activities designed to assist in assuring interoperability of implementations, and correctness of the specification. Each year Connectathons are held where solution suppliers test their implementation of IHE profiles with other suppliers, typically as pairs of information suppliers and consumers. These activities not only test the implementations of the profiles, but also serve to test the completeness and quality of the Supplements which will find their way into the Final Text documents. In fact, a Supplement cannot become Final Text until the Profile has been vetted during a Connectathon.

The IHE testing activities can have some relationship to the product verification and validation activities that product vendors must engage in, in order to release their products. Indeed, involvement in the IHE process ideally would be complementary to the product development process with the goal of reducing the overall development effort.

The testing activities during the Connectathon can be referred to as Product Verification activities by the solution suppliers and the results can be included as part of a regulatory submission package. However it is up to each organization to decide whether this is appropriate according to their internal development policies.

While the IHE process is also built around Use Cases, it may also be tempting to consider that the IHE testing is also a form of product validation. This is probably not appropriate since the Intended Use of specific devices is not considered during the IHE testing activities.

2 PCD Integration Profiles

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

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

2.1 Dependencies between Integration Profiles

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

Table 2.1-1 Patient Care Device Integration Profiles and Dependencies defines the required dependencies between the Integration Profiles in a tabular form.

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

Table 2.1-1 Patient Care Device Integration Profiles and Dependencies

Integration Profile	Depends on	Dependency Type	Purpose
Device Enterprise Communication (DEC)	Consistent Time	Each actor implementing DEC shall be grouped with the Time Client Actor	Required for consistent time-stamping of PCD data.
Point-of-Care Infusion Verification (PIV)	Consistent Time	Each actor implementing PIV shall be grouped with the Time Client Actor	Required for consistent time-stamping of messages and data
Implantable Device - Cardiac – Observation (IDCO)	None	N/A	N/A

Vendor products support an Integration Profile by implementing the appropriate actor-transactions as outlined in the Integration Profile in Section 4. A product may implement more than one actor and more than one Integration Profile.

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

Actors (see Section 3.1) are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise.

Transactions (see Section 3.2) are interactions between actors that transfer the required information through standards-based messages.

2.2 Integration Profiles Overview

In PCD TF-1, each Integration Profile may be defined by:

- The IHE actors involved
- The specific set of IHE transactions required for each IHE actor

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

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

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

In a recent HIMSS survey of requirements for Patient Care Device (PCD) the respondents identified Enterprise Sharing of PCD data as their highest priority. Goals include shortening decision time, increasing productivity, minimizing transcription errors, and obtaining increased contextual information regarding the data.

PCD data includes:

- periodic physiologic data (heart rate, invasive blood pressure, respiration rate, etc.)
- aperiodic physiologic data (non-invasive blood pressure, patient weight, cardiac output, etc.)
- alarm and alert information
- device settings and the ability to manipulate those settings
- CLIA waived (or equivalent international waiver) point-of-care laboratory tests (i.e., home blood glucose, etc.)

PCD data may also include contextual data such as the patient ID, caregiver identification, and physical location of the device.

2.2.1 Device Enterprise Communication (DEC)

The Device Enterprise Communication (DEC) profile addresses the need for consistent communication of PCD data to the enterprise. Enterprise recipients of PCD data include, but are not limited to, Clinical Decision Support applications, Clinical Data Repositories (CDRs), Electronic Medical Record applications (EMRs), and Electronic Health Records (EHRs).

The current profile does not address issues of privacy, security, and confidentiality associated with cross-enterprise communication of PCD data. The assumption is made that the DEC profile is implemented in a single enterprise on a secure network. These aspects are on the IHE PCD roadmap for subsequent years.

The current profile does not address use cases and transactions associated with either open loop or closed loop control of patient care devices. Real-time data such as alarms and alerts, waveforms (ECG, EEG, etc.) is currently not addressed.

2.2.1.1 Subscribe to PCD Data (SPD)

Consuming all of the data from a collection of patient connected medical devices at the rates at which meaningful parametric data can be produced has been described as “drinking from a fire hose”. The Device Enterprise Communication profile provides an optional publish/subscribe mechanism for applications to negotiate which PCD messages are communicated to a given application based on negotiated predicates. This optional mechanism is termed Subscribe to Patient Data (SPD).

“Publish and subscribe” refers to the ability of one system, the “Publisher”, to offer a data stream that can be sent to recipient systems upon subscription.[1] The right of the Subscriber to subscribe is decided at interface setup time. At runtime, the Subscriber controls the data rules under which the Publisher sends messages.

This option to the DEC profile describes a mechanism by which an optional Device Observation Filter (DOF) actor agrees to select a subset of a Device Observation message stream based on query-like data constraints. The right of the Device Observation Consumer (DOC) to subscribe is decided at interface setup time. At runtime, the DOC controls the data rules under which DOF sends messages.

2.2.1.2 Note on Patient Identification

Patient Identification is perhaps the most essential infrastructural component of any interoperability and communication process, particularly when PCD data is exported to the

[1] In one sense, the entire HL7 unsolicited update paradigm, in which the sender sends out a stream of messages to recipients, is a kind of publish and subscribe mechanism. Subscriptions to unsolicited updates are established at interface set-up time when analysts on both sides agree to start sending a stream of data.

enterprise. It is the key element in medical device, communication, data analysis, reporting and record keeping. Automation of the entry of patient identification to Patient Care Devices has the potential for improving throughput, reducing errors, increasing safety and device and drug effectiveness, and efficiency. It is strongly recommended that implementations use IHE compliant transactions for acquisition of Patient Identification credentials. These transactions include: ITI-21, ITI-30 and ITI-31. Other mechanisms such as bar code or RFID are also perfectly valid alternatives or complements.

2.2.2 Point-of-Care Infusion Verification (PIV)

The goal of the proposed integration is to bring infusion systems into the electronic medication administration process. The following primary steps comprise this process:

- Order medication
- Verify order for inclusion in the eMAR
- Prepare and dispense medication
- Administer medication

While medication errors can occur at each point in this process, this proposal is concerned with the "Administer medication" step, where half of the errors made by clinicians involve infusions. These errors usually involve a breach of one of the 5 Rights of Medication Administration:

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

It is the caregiver's responsibility to ensure that these rights are reviewed prior to administering each drug or starting each infusion.

Because manual programming of the pump may still result in administration errors, this profile was developed to support automated programming of the pump, thereby closing the loop between the clinician who uses a BCMA system to verify the 5 Rights and the actual programming of the pump.

The Point-of-Care Infusion Verification profile supports the electronic transfer of infusion parameters from a Bedside Computer assisted Medication Administration (BCMA) system to an infusion pump. This capability will reduce errors by eliminating keystroke errors and by increasing the use of automatic dosage checking facilitated by the onboard drug libraries in "smart pump" systems. In addition to the reduction of medication administration errors, this integration may also increase caregiver productivity and provide more contextual information regarding infusion data.

Electronic transfer of infusion status information from an infusion pump to a clinical information system can be accomplished using the PCD-01 (Communicate PCD Data) or PCD-02 (Subscribe to PCD Data) transactions of the IHE-PCD Device Enterprise Communication profile.

The use case addressed in this profile includes the following steps (note that the workflow supported by the BCMA application may not necessarily occur in the order specified):

- Clinician uses BCMA to administer an IV
- Clinician identifies self, medication, patient, pump
- Clinician confirms or edits infusion parameters for an IV medication order using the BCMA
- Infusion parameters are transmitted to pump
- Clinician confirms settings directly on pump and starts infusion

2.2.3 Implantable Device – Cardiac - Observation (IDCO)

The Implantable Device – Cardiac – Observation Integration Profile defines a mechanism for the translation, transmission, and processing of discrete data elements and report attachments associated with cardiac device interrogations (observations). It supports the uses cases for in-clinic and remote implanted cardiac device follow-ups by standardizing the messages from clinical reviewer to the medical record system.

2.2.4 Rosetta Terminology Mapping (RTM)

The primary purpose of the Rosetta Terminology Mapping (RTM) profile is to *harmonize the use of existing ISO/IEEE 11073-10101 nomenclature terms* by systems compliant with IHE PCD profiles. The RTM profile also specifies the *units-of-measure* and *enumerated values* permitted for each numeric parameter to facilitate safe and interoperable communication between devices and systems.

The Rosetta Table also is designed to serve as a temporary repository that can be used to define *new nomenclature terms* that are currently not present in the ISO/IEEE 11073-10101 nomenclature. Based on our experience to date, well over 100 new terms will be required, principally in the area of ventilator and ventilator settings. could the RTM will also serve as a framework for capturing new terms to support the IEEE 11073 ‘Personal Health Devices’ (PHD) initiative.

3 Overview of Actors and Transactions

3.1 Actor Descriptions

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

New actors

Device Observation Reporter – The Device Observation Reporter (DOR) actor receives data from PCDs, including those based on proprietary formats, and maps the received data to transactions providing consistent syntax and semantics.

Device Observation Filter – The Device Observation Filter (DOF) actor is responsible for providing PCD data filtering services based on publish/subscribe predicates negotiated with client applications implementing the Device Observation Consumer.

Device Observation Consumer – The actor responsible for receiving PCD data from the Device Observation Reporter, the Device Observation Filter, or both.

Infusion Order Programmer – The Infusion Order Programmer (IOP) actor sends the information comprising an order to the Infusion Order Consumer (IOC). The mechanism by which the IOP obtains the order information is outside the scope of this profile.

Infusion Order Consumer – The Infusion Order Consumer (IOC) actor receives the order information from the IOP actor and in turn programs the pump. The mechanism by which the IOC programs the pump with the received information is outside the scope of this profile.

Implantable Device Cardiac Reporter – This actor reports data from systems which communicate with Cardiac Implantable Devices.

Implantable Device Cardiac Consumer – This actor receives data from Implantable Device Cardiac Reporters.

Existing actors

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

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

Table 3.1-1 Integration Profile Actors

Integration Profile / Actor	DEC	PIV	IDCO
Device Observation Reporter	X		

Integration Profile / Actor	DEC	PIV	IDCO
Device Observation Consumer	X		
Device Observation Filter	X		
Infusion Order Consumer		X	
Infusion Order Programmer		X	
Time Client	X	X	
Implantable Device – Cardiac – Reporter			X
Implantable Device – Cardiac – Consumer			X

3.2 Transaction Descriptions

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

Communicate PCD Data – Transmit PCD data to enterprise clients from a Device Observation Reporter and Receive PCD data by a Device Observation Consumer.

Subscribe to PCD Data – Informs Device Observation Reporter when or how often to send data and what subset to send.

Communicate Infusion Order – This transaction contains the information from the Infusion Order Programmer, such as caregiver, patient, and pump identification, medication, volume, and rate for the infusion being programmed.

Communicate IDC Observations – This transaction contains the observations, measurements or reports from the IDCO Reporter.

Maintain Time – This transaction contains the current time.

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

Table 3.2-1 Integration Profile Transactions

Integration Profile / Transaction	DEC	PIV	IDCO
Communicate PCD Data [PCD-01]	X		
Subscribe to PCD Data [PCD-02]	X		
Communicate Infusion Order [PCD-03]		X	
Maintain Time [ITI-01]	X	X	
Communicate IDC Observations [PCD-09]			X

3.3 Product Implementations

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

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

Implementers should provide a statement describing which IHE actors, IHE Integration Profiles, optional transactions and optional features are incorporated in a given product. The recommended form for such a statement is defined in IHE PCD-TF2 Appendix H.

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

- {None at this time}

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

4 Device Enterprise Communication (DEC)

The Device Enterprise Communication Integration Profile supports communication of vendor independent, multi-modality Patient Care Device data to Enterprise Applications using consistent semantics. It accomplishes this by mapping PCD data from proprietary syntax and semantics into a single syntactic and semantic representation for communication to the enterprise. The PCD data is time stamped with a consistent enterprise time. Options are provided to allow applications to filter particular PCD data of interest.

4.1 Actors/Transactions

The following figure diagrams the actors involved with this profile and the transactions between actors.

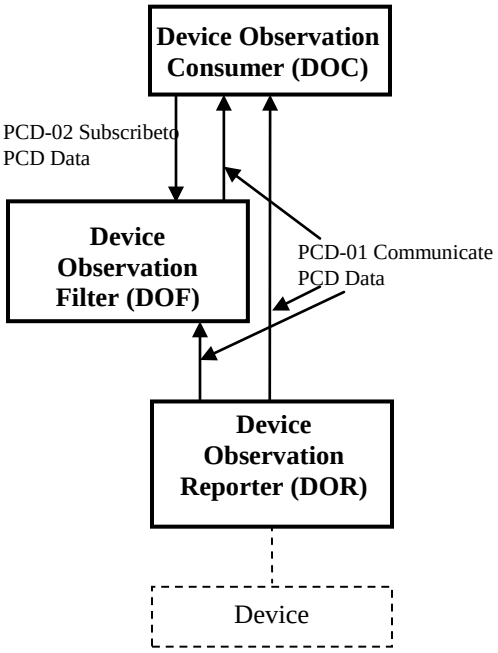


Figure 4.1-1 DEC Integration Profile with SPD: Actors and Transactions

Table 4.1-1 DEC - Actors and Transactions lists the transactions for each actor directly involved in the DEC Integration Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options defined by this Integration Profile that implementations may choose to support is listed in Section 3.2.

Table 4.1-1 DEC - Actors and Transactions

Actors	Transactions	Optionality	Section in Volume 2
Device Observation Consumer	Communicate PCD Data [PCD-01]	R	Section 3.1
	Subscribe to PCD Data [PCD-02]	O	Section 3.2
	Maintain Time	R	ITI TF 2:3-1
Device Observation Filter	Communicate PCD Data [PCD-01] (Outbound only)	R	Section 3.1
	Communicate PCD Data [PCD-01] (Inbound only)	R	Section 3.1
	Subscribe to PCD Data [PCD-02]	R	Section 3.2
Device Observation Reporter	Communicate PCD Data [PCD-01]	R	Section 3.1
	Maintain Time	R	ITI TF 2:3-1

Refer to Table 2.1-1 Patient Care Device Integration Profiles and Dependencies for other profiles that may be pre-requisites for this profile.

4.1.1 Patient Demographics – Recommended Transactions

While not required, it is recommended that IHE transactions be employed for acquisition of Patient Demographics from other systems. The recommended transactions include:

Patient Demographics Query – This transaction contains the Patient Demographics information in response to a specific query on a specific patient. [ITI-21]

Patient Identity Feed - This transaction is broadcast from the Patient Demographics supplier when changes to the patient demographics occur. [ITI-30]

Patient Encounter Management - The Patient Encounter Source registers or updates an encounter (inpatient, outpatient, pre-admit, etc.) and forwards the information to other systems implementing the Patient Encounter Consumer Actor. This information will include the patient's location and care providers for a particular (usually current) encounter. [ITI-31]

4.2 Integration Profile Options

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

Table 4.2-1 DEC - Actors and Options

Actor	Option Name	Section in Volume 2
Device Observation Reporter	*MLLP Transport*	Appendix I
	WS- Transport*	Appendix J

Actor	Option Name	Section in Volume 2
Device Observation Consumer	*Subscribe PCD Data*	3.2
	MLLP Transport	Appendix I
	WS- Transport*	Appendix J
Device Observation Filter	*MLLP Transport*	Appendix I
	WS- Transport*	Appendix J

NOTE: For all actors in Table 4-2.1, either the MLLP and/or WS-* transport option(s) must be implemented and specified.

4.3 Process Flow Diagram

This Section describes the specific use cases and interactions defined for the DEC Workflow Profile. There are both standard Use Cases as well as optional Use Cases.

4.3.1 Standard Use Cases

4.3.1.1 Case DEC-1: Communicate patient identified DEC data to EMR/EHR

Data from all of the patient care devices associated with a particular patient is communicated by a Gateway, Device or Clinical Information System (CIS) implementing the DOR actor to an EMR/EHR, implementing the DOC actor. Examples include data from bedside monitors, ventilators, and infusion pumps. Discrete parameters representing both periodic and aperiodic data are typically communicated at an interval of no less than once per minute. The data is time stamped with a consistent time across the data from the respective patient care devices.

The primary intent is communication of structured data, however provisions are made for inclusion of unstructured data. The application provides facilities to bind an authoritative enterprise patient identifier required for inclusion of the PCD data in the patient record. The workflow for associating the authoritative enterprise patient identifier to the PCD data is outside the scope of the current PCD TF.

4.3.1.2 Case DEC-2: Communicate validated periodic DEC data to EMR/EHR

This Use Case builds on Case C1 by communicating only data which has been validated by a caregiver by identifying the caregiver in the PCD data. The workflow implementing validation is outside the scope of the current PCD TF.

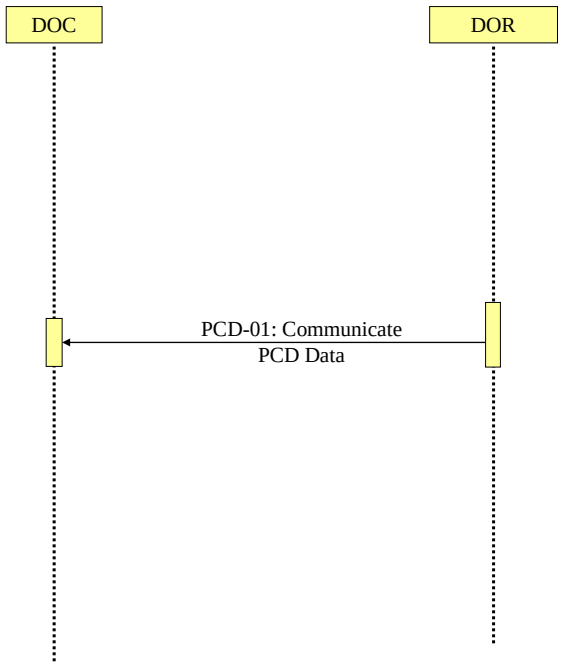


Figure 4.3.1.2-1 DEC Process Flow (No filtering)

4.3.2 Optional Use Cases for Subscribe to PCD Data

4.3.2.1 Case DEC-DOF-1: Subscribe To PCD Data at specific periodic interval

An EHR does not require data at the frequency that the Device Observation Reporter uses for default reporting. To receive data at an acceptable interval the EHR application makes a request of the Device Observation Filter for a subscription specifying the frequency or range of allowable frequencies at which PCD data should be sent to the EHR application. (This Use Case is currently supported in part, since update rate is restricted by the capabilities of the DOR).

4.3.2.2 Case DEC-DOF-2: Subscribe To PCD Data for specific patients

A clinical research application is being evaluated for clinical decision support on a specific population of patients, for example. The application requests a subscription for PCD data for a known group of patients appropriate to the study being conducted.

4.3.2.3 Case DEC-DOF-3: Subscribe To PCD Data for patients from a specific location

A clinical application only wants to be informed of PCD data for patients in a specific hospital unit, for example. The application requests a subscription for PCD data for the hospital unit of interest.

4.3.2.4 Case DEC-DOF-4: Subscribe To PCD Data for a specific device or class of devices

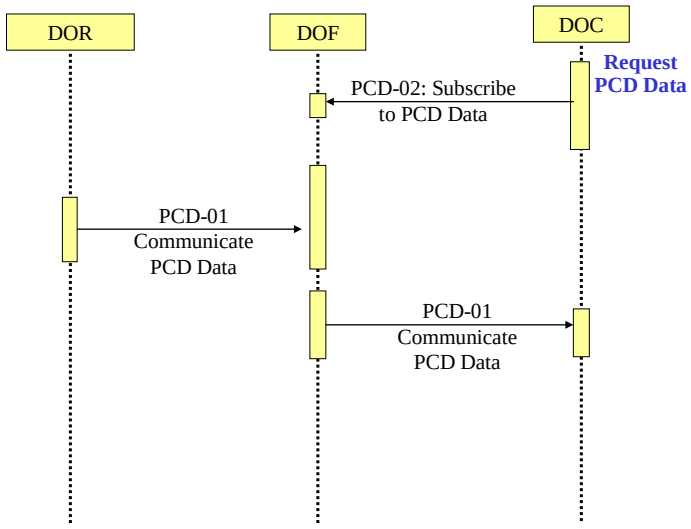
A respiratory clinical decision support application only requires data from ventilators, for example. The application requests a subscription for PCD data for ventilators.

4.3.2.5 Case DEC-DOF-5: Subscribe To PCD Data for specific parameters or class of parameters

A clinical decision support application is based upon correlation of a selected set of monitored PCD data. The application requests a subscription for only the PCD data of interest.

4.3.2.6 Case DEC-DOF-6: Request a snapshot of current or most recent PCD Data

An EHR or other application requests a 'snapshot' of the current or most recent data for the patient. After the data is sent the connection is left open until closed by the DOC.



Note: An implementation may combine the DOF and DOR into a single system, in which case the PCD-01 transaction shown on the right need not be externally available outside the combined system.

Figure 4.3.2.6.-1 DEC Interactions (With filtering)

4.3.3 Optional Use Cases for Automatic Patient Demographics Acquisition

The following examples describe which actors typical systems might be expected to support. This is not intended to define requirements, but rather to provide illustrative examples.

- A general purpose observation reporting gateway which combines the Device Observation Reporter and patient demographics.
- A patient care device which bundles the Device Observation Reporter and patient demographics.

Patient Demographic Data that can be used in identifying the patient includes the following:

- Partial or complete patient name (printed on the patient record or wrist band, or related by the patient)
- Patient ID (from printed barcode, bedside chart, RFID, scan, etc.)
- Date of Birth / age range

Note: Bed ID is not accepted by the Joint Commission as a means of patient identity verification.

Patient Identification Binding Use Cases: The caregiver connects the patient to a patient care device. The patient is physically identified by the caregiver, using some institutionally unique protocol for identification such as verification of information contained on a wristband. The caregiver uses the information from the physical patient identification to authorize an electronic identification, made by the device or an independent device or system, binding the patient's electronic identity to all data communicated from the patient care device. The verification may involve direct entry of data to the device being bound, a gateway, or an actor residing in a separate system. It may be based on direct physical identification of the patient by the caregiver, or on confirmation by the caregiver of an electronic identification made by the device in concert with other devices or systems. The verification may also include fully automated binding when a unique logical authentication can be made. The end result is that data communicated from the patient care device contains an authoritative institutionally unique electronic identifier.

4.3.3.1 Case DEC-ID-1: Patient ID known in ADT, locally available

Note: The following are Use Cases in support of automatic acquisition of patient demographics. They do not map into any specific PCD profiles or transactions.

A patient is connected to a bedside monitor of a cardiac monitoring system (e.g., central station with continuous ADT feed via PAM broadcasts that includes a number of bedside monitors. The patient may or may not be able to provide positive ID information. Demographic information used to identify a patient includes: partial or complete patient name (printed on the patient record or told by the patient); Patient MRN (this may be obtained from printed barcode, a bed-side chart, etc.); Partial ID entry or scan; Date of birth / age range. *Note: Bed ID is not permitted as an identifier in accord with Joint Commission standards.)* Caregiver selects the patient from a pick list on the system console, in response to prompts by caregiver. System information

includes showing the Medical Record Number (MRN), full name, age, sex, room/bed, and admit date. The central station binds the patient identity information with the device data.

4.3.3.2 Case DEC-ID-2: Patient ID known in ADT, not locally available

In the event that the patient above is not registered in the cardiac monitoring system, due to ADT lag or other situations, caregiver can execute a PDQ query of the patient registry to receive a pick list of patients and enter the patient ID into the system

4.3.3.3 Case DEC-ID-3 Patient ID not known in ADT, locally available

This is the John/Jane Doe patient, for whom the system has set up a Proxy Identification. The Proxy Identification is determined by either method, in accord with institutional policy and later linked with the true patient ID via ITI-PAM.

4.3.3.4 Case DEC-ID-4: Patient ID not known in ADT, not locally available.

This is the case of a patient presenting in the ER who is not registered in the system, where care must continue and identification may follow. When the patient demographics are unknown, time and device MAC address can be sent automatically, providing unique identification to the data. This last approach can also be used to create an audit trail as a complement to the other binding mechanisms.

4.3.3.5 Other Clinical Examples

DEC-ID-A: A patient is connected to an infusion device. The infusion device is connected to the network but is not managed by an infusion or drug administration management application. Caregiver scans barcode of the patient and the device. Caregiver is presented with a display of patient IDs from ADT and device ID from an authoritative database. Caregiver confirms.

DEC-ID-B: A patient is connected to an infusion device. The infusion device is connected to the network but is not managed by an infusion or drug administration management application. No ADT feed is available to confirm the ID. Caregiver confirms patient's wristband identity through interactive communication with patient. The Patient ID wristband is scanned (barcode, RFID, etc.) and bound to the PCD.

DEC-ID-C: A patient is connected to a ventilator. The ventilator is connected to the network but is not managed by a system. Ventilator and patient have RFID tags. Proximity of the tags implies binding of patient's ADT identification and device's ID from an authoritative database. Verification of an existing Order for a Ventilator for the identified patient is required. If verified, Patient Id is bound to PCD.

5 Point-of-Care Infusion Verification (PIV)

The Point-of-Care Infusion Verification profile supports the electronic transfer of infusion parameters from a Bedside Computer assisted Medication Administration (BCMA) system to a general-purpose infusion pump. This capability will reduce errors by eliminating keystroke errors and by increasing the use of automatic dosage checking facilitated by the onboard drug libraries in "smart pump" systems. In addition to the reduction of medication administration errors, this integration may also increase caregiver productivity and provide more contextual information regarding infusion data.

Electronic transfer of infusion status information from a pump to a clinical information system can be accomplished using the PCD-01 (Communicate PCD Data), possibly with PCD-02 (Subscribe to PCD Data) transactions of the IHE-PCD Device Enterprise Communication profile.

The goal of the proposed integration is to bring infusion systems into the electronic medication delivery process.

5.1 Actors/Transactions

Figure 5.1-1 shows the actors involved in the Point-of-Care Infusion Verification Integration Profile and the relevant transactions between them.

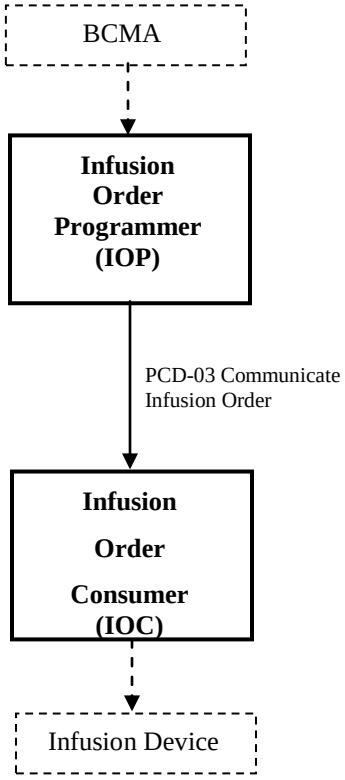


Figure 5.1-1 Point-of-Care Infusion Verification Actor Diagram

930 Table 5.1-1 lists the transactions for each actor directly involved in the Point-of-Care Infusion Verification Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" involve optional actors. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed in Volume I, Section 3.3.

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Table 5.1-1 Point-of-Care Infusion Verification Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Infusion Order Programmer	Communicate Infusion Order	R	3.3
Infusion Order Programmer	Maintain Time	R	ITI TF 2:3-1
Infusion Order Consumer	Communicate Infusion Order	R	3.3
Infusion Order Consumer	Maintain Time	R	ITI TF 2:3-1

5.2 Integration Profile Options

Options that may be selected for this Integration Profile are listed in the table 5.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 5.2-1 Evidence Documents - Actors and Options

Actor	Options	Section in Volume 2
Infusion Order Programmer	*No options defined*	- -
Infusion Order Consumer	*No options defined*	- -

5.3 Integration Profile Process Flow

Figure 5.3-1 shows the sequence diagram for this profile. The use case is described in section 2.2.2 above.

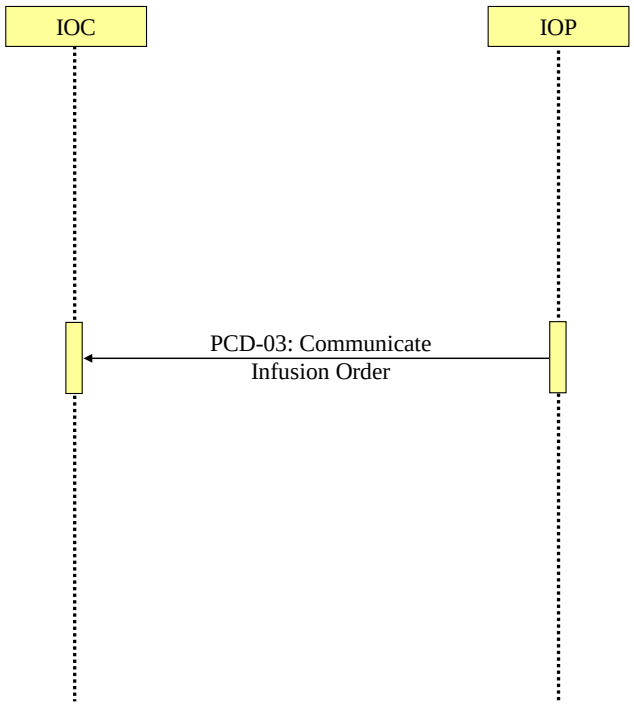

Figure 5.3-1 Basic Process Flow in Point-of-Care Infusion Verification Profile

5.4 Integration Profile Safety and Security Considerations

This profile relies on the BCMA system to verify the clinician and patient, as well as the correct medication and infusion parameters, prior to initiating the Communicate Infusion Order transaction.

Although the profile provides infusion settings for an infusion pump, the infusion is not started automatically. The clinician must always verify all settings and start the infusion directly on the pump.

6 Implantable Device – Cardiac – Observation (IDCO)

Cardiac physicians follow patients with implantable cardiac devices from multiple vendors. These devices are categorized as implantable pacemakers, cardioverter defibrillators, cardiac resynchronization therapy devices, and cardiac monitor devices. As part of patient follow-up an interrogation of an implanted cardiac device is performed (either in-clinic or remotely from a patient's residence). These interrogations (solicited or unsolicited) are performed by vendor proprietary equipment. Information is collected regarding the implanted device (attributes, settings and status), the patient (demographics and observations) and therapy (delivery and results).

To improve workflow efficiencies cardiology and electrophysiology practices require the management of "key" information in a central system such as an EHR or a device clinic management system.

To address this requirement, the Implantable Device – Cardiac – Observation (IDCO) Profile defines a standards based translation and transfer of summary device interrogation information from the interrogation system to the information management system.

The IDCO profile specifies a mechanism for the translation, transmission, processing, and storage of discrete data elements and report attachments associated with cardiac device interrogations (observations).

6.1 Actors/ Transactions

Figure 6.1-1 shows the actors directly involved in the IDCO Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in other related profiles are not necessarily shown.

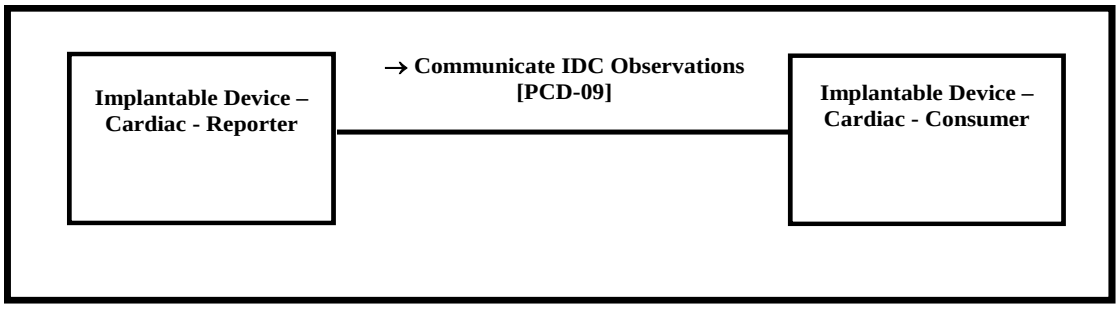

Figure 6.1-1 IDCO Actor Diagram

See section 6.5 Patient Identification for details concerning how patient identity is managed.

Table 6.1-1 lists the transactions for each actor directly involved in the IDCO Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled "R"). Transactions labeled "O" are optional. A complete list of options

defined by this Integration Profile and that implementations may choose to support is listed in Volume I, Section 6.2.

Table 6.1-1 IDCO Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Volume 2
Implantable Device – Cardiac – Reporter	Communicate IDC Observation [PCD-09]	R	3.9
Implantable Device – Cardiac – Consumer	Communicate IDC Observation [PCD-09]	R	3.9

6.2 IDCO Integration Profile Options

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

Table 6.2-1 IDCO - Actors and Options

Actor	Options	Section in Volume 2
Implantable Device – Cardiac – Reporter	PV1 – Patient Visit	3.9.4.1.2.3
	OBX – Encapsulated PDF or Reference Pointer	3.9.4.1.2.7
Implantable Device – Cardiac – Consumer	PV1 – Patient Visit	3.9.4.1.2.3
	OBX – Encapsulated PDF or Reference Pointer	3.9.4.1.2.7

6.3 IDCO Use Cases

6.3.1 Use Case IDCO-1: Implantable Cardiac Device In-Clinic Follow-up

Clinical Context:

Alex Everyman presents at the implantable cardiac device follow-up clinic for his appointment. Alex will present for follow-up 7-10 days after implant and every 3-6 months thereafter, depending on the therapy protocol.

Dr. Tom Electrode, a cardiac physician, and Nicci Nightingale, a registered nurse (R.N.), work in the implantable cardiac device follow-up clinic.

Nicci interrogates the device using a cardiac device programmer. The programmer extracts the device data (e.g., settings, status, events) from the device. Nicci reviews and verifies the device data and initiates a transfer of the data from the programmer to a translator system. A necessary subset of the data that represents a summary is converted by the translator system from a

proprietary data format to a standard HL7 format. The data is then transmitted using HL7 messaging to the EHR or device clinic management system.

This summary data is sent as an unsolicited observation message.

Notes:

- In the area of Electrophysiology, a "programmer" is a commonly used term to describe a specialized computer that is capable of communicating with an implanted device. Programmers are used to interrogate implanted devices (as are “interrogators”) and "program", or make changes to the cardiac device settings.
- In this use case the translator system is a clinical information computer system that can receive proprietary structured data from the programmer and perform the necessary transformation and communication protocols to communicate effectively with the EMR.
- Electrocardiograms are not currently addressed in the HL7 standards. They can be sent as a PDF attachment to the HL7 message.

IHE Context:

In the use case the translator system equates to the Implantable Device – Cardiac – Reporter actor and the EHR or device clinic management system equates to the Implantable Device – Cardiac – Consumer actor. The HL7 formatted cardiac device message is the [PCD-09] transaction.

6.3.2 Use Case IDCO2: Implantable Cardiac Device In-Clinic Followup with Networked Programmer that Translates Information

Clinical Context:

Same as in-clinic use case above with the following change. The programmer communicates directly with an EHR or device clinic management system, acting as a translator system.

IHE Context:

Same as in-clinic use case above with the following change. The programmer assumes the role the actor Implantable Device – Cardiac – Reporter.

6.3.3 Use Case IDCO-3: Implantable Cardiac Device Remote Followup

Clinical Context:

Portions of the previous use case also apply to Alex Everyman having his device followed remotely. Alex will present to an interrogation device located outside of the clinic (e.g., in Alex’s residence) which will capture the state of his implanted device and will transmit the information to a translator system. The translator system converts the data into an HL7 message and communicates the summary data to the clinic's EHR.

IHE Context:

Same as in-clinic use case 6.3.1 above. It is recommended that the Implantable Device – Cardiac – Reporter actor be grouped with the Secure Node actor of the ATNA Profile to secure communications for remote follow-ups if data is sent across an un-trusted network.

6.3.4 Use Case IDCO-4: Remote Monitoring of Implanted Cardiac Devices

Clinical Context:

The translator system described in use case IDCO-3 may be implemented as a service, e.g., the device manufacturer or a monitoring service. This system may collect data provided on a periodic basis to enable early detection of trends and problems, or provide other event information. This system may also provide various types of value-added services, such as data aggregation and analysis, trending, statistical reports, and the ability to review and verify data before sending to the EMR. Depending on user selectable settings in the translator system, detailed information concerning the current status of the patient and reports may be sent to the recipient system.

IHE Context:

The same as the Remote Follow-up use case above. The additional data aggregation or rendering can be sent as a PDF attachment to the HL7 message.

These types of value-added services are likely to be provided by a party that will send the results over the Internet. It is recommended that the Implantable Device – Cardiac – Reporter actor be grouped with the Secure Node actor of the ATNA Profile to secure communications for remote follow-ups if data is sent across an un-trusted network.

6.4 IDCO Process Flow

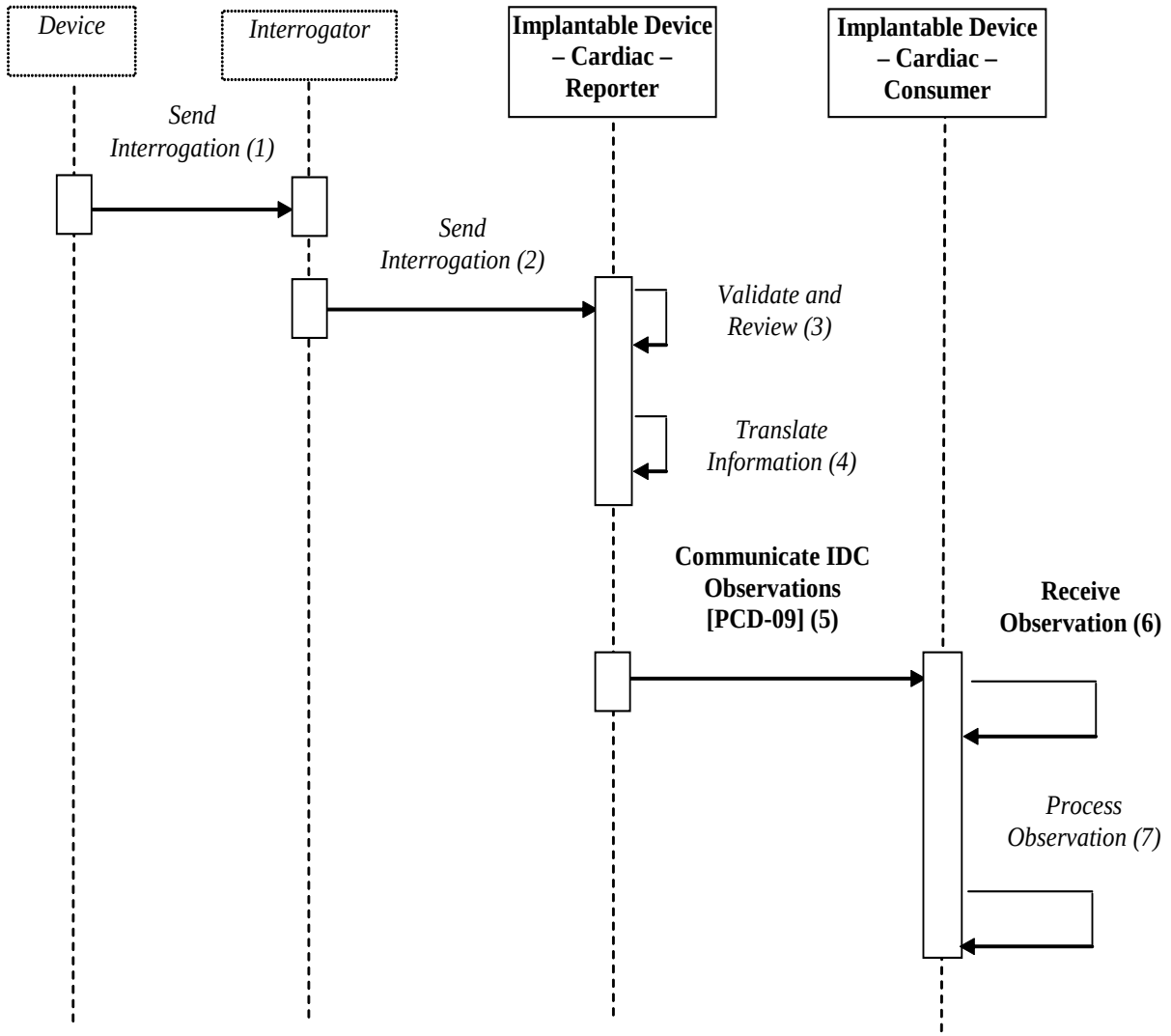

Figure 6.4-1 Basic Process Flow in IDCO Profile

Process Flow Steps for Figure 6.4-1

Note: Device, Interrogator, and steps 1 thru 4, 6 and 7 are informative and are not formal actors or transactions of the IDCO profile.

1. Send Interrogation – The Device sends information in a manufacturer-proprietary manner to the Interrogator.
2. Send Interrogation – The Interrogator sends information in a manufacturer-proprietary manner to the Implantable Device – Cardiac – Reporter.

3. Validate and Review – The Implantable Device – Cardiac – Reporter validates the information. This may include the clinician reviewing and approving the information.
4. Translate Information – The Implantable Device – Cardiac – Reporter translates/maps/transforms the information into the proper HL7 format.
5. Send Observation – The Implantable Device – Cardiac – Reporter sends the device information to the Observation Consumer using the [PCD-09] transaction.
6. Receive Observation – The Implantable Device – Cardiac – Consumer receives the observation message.
7. Process Observation – The Implantable Device – Cardiac – Consumer further processes the observation message for inclusion within derivative products, such as clinical reports, databases, or trans-coded / reformatted results.

6.5 IDCO Patient Identification Considerations

This profile assumes a pre-coordinated association of identifiers across the two Patient Identifier Domains: the device vendor systems providing the observations and the clinics receiving the observations.

Depending on local regulations each implantable cardiac device vendor may be obligated to maintain a registry that maps a unique device identifier with the patient in which it is implanted. In some locales this mapping is the strict responsibility of the implanting or other organization. Specific patient identification information is typically not stored in the device but is made available in the registry or by other means. Consequently the Implantable Device – Cardiac – Reporter is only required to send this identifier which represents the patient to device relationship for an implanted device as part of the [PCD-09] transaction. This identifier by normative convention is the concatenation of a unique industry wide manufacturer id, unique manufacturer model number, and unique manufacturer serial number.

This profile specifies one actor, the Implantable Device – Cardiac – Consumer, as the endpoint for observation messages. The Implantable Device – Cardiac – Consumer will have pre-coordinated a cross-reference of patient identifiers across the two Patient Identifier Domains. This will be done by storing the unique device identifier within the patient's record. This will typically be the patient's unique identity but could be the patient's location in emergency situations.

In some cases the Implantable Device – Cardiac – Reporter will have detailed patient identification information like name, address, etc. In these cases the Implantable Device – Cardiac – Reporter can send this information as part of the [PCD-09] transaction.

6.6 IDCO Security Considerations

This profile does not require the use of ATNA. There are several implementation models for this profile that do not require transmission of data over public networks including intra-institutional, VPN, etc. However, when public networks are used, ATNA is one option for secure transport over those networks. It is recommended that the Implantable Device – Cardiac – Reporter actor be grouped with the Secure Node actor of the ATNA Profile to secure communications for remote follow-ups if data is sent across an un-trusted network.

7 Rosetta Terminology Mapping (RTM)

7.1 Problem Statement

The majority of PCD devices use vendor-specific or proprietary nomenclatures and terminologies. As a result, even though information may be exchanged using standards-based transactions such as Device Enterprise Communication (DEC), semantic interoperability requires that the content be mapped to a standard nomenclature as well. This mapping is often inconsistent and subject to loss of semantic precision when mapping from a specific term to a more generic term.

This profile identifies the core set of semantics appropriate for medical devices typically used in acute care settings (e.g., physiological monitors, ventilators, infusion pumps, etc.) and mapping them to a standard terminology. The RTM mapping effort initially focused on numeric parameters and their associated units of measurement and enumerated values. The RTM mapping effort currently is focused on numeric parameters and associated units of measure and enumerated values, and will likely be expanded to include aspects of the observation hierarchy expressed in OBR-4 and event content models in the future.

The RTM information is represented in a uniform manner e.g., in a machine readable form that is easily adaptable by industry, as a set of Excel worksheets and a set of XML files for publication and distribution. This will facilitate use by production systems, but more importantly, facilitate comparison between vendors that have (or will) implement the nomenclature standards in their systems, with the following goals:

- identify terms that are missing from the standard nomenclature
- ensure correct and consistent use if multiple representations are possible
- ensure correct and consistent use of units-of-measure
- ensure correct and consistent use of enumerated values
- ensure correct and consistent identification of ‘containment hierarchy’

During the development of the RTM and later, gaps in the standardized medical device terminology will be identified. In these cases, proposals will be made for adding the semantics to the appropriate terminologies. Although the immediate focus of the RTM profile will be to standardize the content in transaction profiles such as DEC, which are typically between a device data gateway and enterprise level applications, the standardized terms should also support direct device communication, enabling semantic interoperability literally from the sensor to the EHR.

The availability of the RTM information will also facilitate development of tools that can more rigorously validate messages, such as enforcing the use of the correct units-of-measure and correct enumerated values associated with specific numeric values. For example, ST segment deviation will be expressed in "uV" or "mV", rather than the traditional "mm". This will promote greater interoperability, clarity and correctness which will in turn benefit patient safety.

The consistent and correct use of standard nomenclatures such as ISO/IEEE 11073-10101 and UCUM for medical device and system data exchange will facilitate further development of real-time clinical decision support, smart alarms, safety interlocks, clinical algorithms, and data mining and other clinical research. This work can also be expanded at a future date to support events and alarms, waveforms, device settings and other critical monitoring information.

7.2 Actors/Transactions

No new actors are created by this Content Profile. Contents of the RTM tables will affect most, if not all, IHE PCD Transaction Profiles.

7.3 Integration Profile Options

No options have been defined by this Content Profile.

7.4 Integration Profile Process Flow

There is no process flow for this Content Profile.

7.5 Key Use Case

A patient is monitored at home. A potentially life-threatening cardiac event is detected and reported to a remote monitoring service that confirms and forwards the event to his caregiver. The patient is subsequently admitted to the ER complaining about chest pain. A diagnostic 12-lead is taken followed by continuous vital signs monitoring or telemetry for further observation. Following a series of premonitory episodes of ST segment deviation, the patient exhibits short runs of ventricular ectopy that rapidly devolve into ventricular tachycardia and then fibrillation, all along triggering alarms from the monitor. The patient is cardioverted in the ER and scheduled for CABG surgery. During surgery, the patient is connected to well over a dozen medical devices (e.g., multiparameter patient monitor, anesthesia machine, multiple infusion pumps, bypass machine, etc.) and the data from these devices and systems is displayed in a unified and comprehensible manner and automatically charted. After successful surgery, the patient is monitored in the ICU. The patient is discharged a week later to continue his recovery at home, where, among other things, he uses a spirometer with a low-cost wireless interface to facilitate recovery. He also exercises while walking around in and outside the house attached to a wireless sensor that records and transmits his ECG via his cell phone to a remote monitoring service. The patient also has follow-up visits to cardiac rehab, where his ECG and glucose measurements are taken before and after exercise, with all the data also electronically recorded. This information is ultimately stored in the patient's personal health record and made available for a follow-up clinical research study regarding the cardiac medications he was taking.

The key point of this comprehensive but realistic use case is that the patient's data is "touched" by well over three dozen medical devices and systems designed and manufactured by nearly an equal number of different vendors. An essential first step towards achieving interoperability across all these devices and systems is that they use a shared and common semantic foundation.

Glossary

ACC: American College of Cardiology. http://www.acc.org/

ACCE: American College of Clinical Engineering. http://www.accenet.org/

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

ACM: Alarm Communication Management is an IHE PCD Profile for communication of clinical alarms and technical alerts from patient care devices to Alarm Managers and from Alarm Managers to Alarm Consumers which annunciate the alarm.

ADT: Admit, Discharge & Transfer.

Alarm: A clinical alarm is an indication from a system or device, that when activated, indicates a condition requiring urgent clinical assessment and possible intervention.

Alert: A clinical alert is an indication from a system or device that a condition exists requiring clinical assessment and possible attention.

Aperiodic: PCD data which occurs at irregular intervals such as a Cardiac Output measurement.

Authoritative: Acknowledged to be reliable.

Bedside: The point of care, typically in an acute care environment.

BCMA: Bedside Computer assisted Medication Administration system, aka Barcode Medication Administration system.

Binding: Process of associating two related elements of information. In the PCD context this typically means the association of a Patient with a device or set of devices.

Biometric: Measurable, physical characteristic or personal behavioral trait used to recognize the identity, or verify the claimed identity.

Cardiac Device Programmer: A device used to noninvasively interrogate, monitor, and alter the operating parameters of an implantable pacemaker, defibrillator, or cardiac resynchronization device.

CDR: Clinical Data Repository.

CIS: Clinical Information System.

CLIA: Clinical Laboratory Improvement Amendments. http://www.cms.hhs.gov/clia/

Connectathon: IHE testing process - a weeklong interoperability testing event where participating companies test their implementation of IHE capabilities with corresponding systems from industry peers.

CT: Consistent Time Integration Profile.

DEC: Device Enterprise Communication**.**

DICOM: Digital Imaging and Communications in Medicine. http://medical.nema.org/

DOB: Date of Birth.

DOC: Device Observation Client: Actor responsible for receipt of PCD data.

DOF: Device Observation Filter: Actor responsible for filtering of PCD transactions based on negotiated predicate.

DOR: Device Observation Reporter: Actor responsible for mapping legacy and standards based PCD data to the IHE PCD message profile(s). Based upon the ISO/IEEE 11073.

ECG: Electrocardiogram**.**

EEG: Electroencephalogram.

EHR: Electronic Health Record.

eMAR: Electronic Medication Administration Record.

eMPI: Enterprise Master Patient Index.

EMR: Electronic Medical Record.

FDA: The United States Food and Drug Administration.

General Purpose Infusion Pump: a pump used to infuse fluids intravenously in a wide variety of clinical settings. Differentiated from specialty infusion pumps, which are used for a specific purpose or in a specific setting, such as PCA (patient-controlled analgesia) or syringe pumps.

Grouping: Associating Actors together in one system such that information transferred between the actors is accomplished through direct application program interfaces, being out of scope to the IHE.

HIMSS: Healthcare Information and Management Systems Society.

HIS: Hospital Information System.

HL7: Health Level 7. http://www.hl7.org/

IHE: Integrating the Healthcare Enterprise. http://www.ihe.net

IEEE: Institute of Electrical and Electronics Engineers. http://www.ieee.org

IETF: Internet Engineering Task Force. http://www.ietf.org/

Implantable Cardiac Resynchronization Therapy (CRT) Device: An electronic device implanted beneath the skin used to reestablish ventricular synchrony in an effort to improve left ventricular efficiency.

Implantable Defibrillator: – An electronic device implanted beneath the skin used to counteract fibrillation of the heart muscle and restore normal heartbeat by applying an electric shock.

Implantable Pacemaker: An electronic device implanted beneath the skin for providing a normal heartbeat by electrical stimulation of the heart muscle, used in certain heart conditions.

MPI: Master Patient Index – see eMPI.

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

IT: Information Technology.

MAC: Media Access Control – A unique identification/serial number associated with every device used in network communications.

MPI: Master Patient Index.

MRN: Medicare Record Number (US) or Medical Record Number.

NEMA: National Electrical Manufacturers Association.

NTP: Network Time Protocol. This is the standard Internet protocol for synchronizing computer clocks. The web site http://www.ntp.org provides extensive background documentation at the introductory and expert level on how to synchronize computers.

PAM: Patient Administration Management, an IHE-ITI implementation profile.

PDQ: Patient Demographics Query, an IHE-ITI implementation profile.

PES: Patient Encounter Source, a system responsible for adding, updating and maintaining encounter information about a patient. It supplies new and updated information to the Patient Encounter Consumer.

PEC: Patient Encounter Consumer, a system that uses patient encounter information provided by the Patient Encounter Source about a patient.

Physiological Alarm: an alarm reflecting the physiological state of the patient (such as a heart rate above or below a caregiver-specified safe range for the patient).

Primary Alarm System: the patient care device itself provides visual and aural indications of alarms that can be seen and heard in the immediate patient vicinity, and that are the authoritative primary indicators of alarms resulting from monitoring the patient. It is understood that caregivers shall be in a position to take immediate action based on these primary alarm indications and shall not rely exclusively on secondary alarm systems for alarm notifications.

PCD: Patient care device.

PIV: Pump Infusion Verification profile for communicating orders from Medication Administration Systems to infusion devices.

PnP: Plug and Play.

Point of Care: Physical area in close proximity to the patient under clinical care. Usually the vicinity around the patient bedside and may include adjacent areas (glucose, blood gas).

Physiologic: Mechanical, physical, and biochemical functions of living organisms.

RFC: Request for comment. http://www.rfc-editor.org/

RFID: Radio frequency identification.

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

RSNA: Radiological Society of North America. http://www.rsna.org/

RTM: Rosetta Terminology Management Profile

Safety Infusion System (Smart Pump System): infusion devices designed to reduce the error rates associated with infusions through the use of one or more of the following “smart” features:

- Ability to check programmed doses against pre-configured limits in an onboard drug library.

- Ability to read infusion parameters from RFID tags or bar codes.
- Ability to send and receive infusion parameters via a wired or wireless network.
- Ability to communicate through a server or gateway.

Scope: A brief description of the transaction.

Secondary alarm system: A system intended to give "best effort" notification of alarms at additional locations, to additional persons, or for additional purposes such as archiving, but not intended to take the place of a primary alarm system as the authoritative primary indicator of alarms resulting from monitoring the patient.

SNTP: Simple Network Time Protocol. This is a reduced accuracy version of NTP. The protocol fields are the same, but the data values and algorithms used have greatly reduced accuracy so that it can be implemented on limited capacity systems.

Subscribe: Make a request that only messages satisfying specific predicates be sent to the subscriber.

Technical alarm: An alarm reflecting the state of the patient care device themselves that may require action from caregivers (such as ECG leads off the patient).

The Joint Commission – Formerly The Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

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

UID: Unique Identifier.

Unbinding: Disassociation of a patient from a device.

Unsolicited: Within the context of HL7 when the transfer of information is initiated by the application system that deals with the triggering event, the transaction is termed an unsolicited update.

Universal ID: Unique identifier over time within the UID type. Each UID must belong to one of specifically enumerated species. Universal ID must follow syntactic rules of its scheme.

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

UTC: Universal Coordinated Time. This is the replacement for GMT. It defines a reference time base that is internationally recognized and supported.

Validated: PCD data which has been marked as correct by a caregiver.

W3C: World Wide Web Consortium. http://www.w3.org/

