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# IHE Point-of-care Medical Device Tracking (PDMT) Supplement

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## Introduction to this Supplement

The Point-of-Care Medical Device Tracking (PMDT) profile will close the loop on data acquisition at the point-of-care in support of reporting data about implantable medical devices (e.g., pacemaker, titanium plates) and from medical devices (e.g. vital sign monitors, pulse oximeters, blood glucose monitors) during a procedure (e.g., Continuous Pulse Oximetry - 4A19XCZ, Insertion Pacemaker - 0JH607Z, Open Reduction Internal Fixation Elbow - 0PSJ04Z).

* Medical device measurements, settings, status, and alarms are transmitted to patient care system (e.g. ICU flowsheet) using existing standard transaction (e.g. IHE PCD-01 transactions based on HL7 Version 2. 7 ORU\_R01). Sometimes, these transactions include only the device identification without patient identification context and thus device information cannot be assigned correctly by the receiving system to a patient record. This means that the receiving system (implementing Device Observation Consumer – DOC actor) is unable to match the device data with the correct patient. This leads to missing or erroneous data and could further lead to patient safety issues.
* Implantable life-sustaining or life-supporting devices must be tracked to the patient and recorded along with procedure in the EHR to meet Meaningful Use 2015 certifications criteria. This information is necessary to address adverse events and recall notices specify to a device instance (based on device unique device identified using the FDA-specified UDI in the US). Currently we do not have a standard-based mechanism to capture the information consistently across care setting (e.g. hospital Operating Room, cardiology clinic, orthopedic surgery clinic).
* Medical device data may be persisted to the patient’s chart (if “validated/accepted” by clinicians), used for decision support, and exchange with other providers across the continuum of care (e.g. as referrals, transfer, discharge summary documents based on HL7 Consolidated CDA).

Implantable medical devices are essential for the treatment and management of a wide variety of medical conditions. These devices are costly and concerns about illegitimate (i.e., counterfeit, stolen) products being used for patient care has become a global issue. Post-market surveillance of implantable medical devices can be challenging due to the longevity of the patient and the medical device unless there is a reliable implant tracking method. In 2013, the United States Food and Drug Administration (FDA) issued a unique device identifier (UDI) system designed to identify and track implantable medical devices throughout their distribution and use in the United States. The EU will be developing and adopting similar legislation. The desire is to combine data from premarket approval with post-market settings to help address issues of cost and concerns about illegitimate products and to gain understanding of performance and clinical outcomes of implantable medical devices.

The manufacturer supplies a unique computer-readable identifier on the label of implantable medical devices to enable traceability of where the implantable medical device has been distributed. Unfortunately, it does not enable standardized data exchange from healthcare organizations inventory management systems (IMS) to an EHR and then to a national registry, where activities occur such as infection prevention or guideline development to protect patients from hospital acquired infections (HAIs). The inability to track a medical device from premarket through post-market surveillance systems for adverse event reporting, recalls, corrections, removals/revisions, continued evaluation on safety, effectiveness and reliability of device for intended use, due to the lack of standards available to electronically share the UDI data, makes post-market surveillance of implantable medical devices challenging.

Currently, healthcare organizations collect data on healthcare-associated infections (HAI) caused by certain medical devices (i.e., central venous catheters). Implantable medical device data is collected in a variety of ways, manually entered or partial look up in the electronic health record (EHR), manually entered in an EHR tab that doesn’t become part of the patients EHR, or manually on a study or registry log that is aggregated by a healthcare organization’s Quality Department or special study coordinator that is sent to the national registry. Inoperability of electronic data, manual data entry, and data manipulation lends itself to human error and inaccurate data capture leading to healthcare inefficiencies and patient safety errors.

Implantable medical devices enter healthcare organizations through a variety of methods. No matter the method used to requisition the implantable medical device, once it arrives at the healthcare organization supply chain, inventory control personnel scan the implantable medical device which adds it into the healthcare organization’s inventory and master item file. The UDI, which is embedded in one of the barcodes on the package, is not accepted by the IMS system. The IMS typically only accepts the global trade identification number (GTIN) from the scanned barcode. At the point of use the clinician scans the barcode on the implantable medical device package, if the healthcare organization has an automated identification and data capture (AIDC) technology. Or the clinician manually enters the UDI data into the EHR.

If the clinician has a scanner and finds the correctly formatted barcode, the scanner accepts the UDI. The barcode scanner and EHR system exchange the UDI data and the data becomes part of the patient’s EHR. The EHRs UDI data cannot be exchanged with the IMS for the healthcare organizations business processes because different data standards are being used on the device packaging that can’t be used by the IMS. By transforming the information that is stored in the different barcode formats into a standardized format, healthcare organization’s IMS and EHRs can become interoperable and standardized submission of that data can be exchanged with a national registry or payer organizations.

Implantable medical device failures, infections, or complications cost healthcare organizations and payer associations thousands of dollars. The benefits of this profile will improve patient safety, remove clinicians from manual data entry, foster accurate data capture, and provide an approach for implantable medical device collection to a national registry. This profile will produce the technical specifications for the exchange of implantable medical device data from the various healthcare information systems using the UDI barcode data to exchange with a national registry to track implantable medical device safety, effectiveness, and rates of infection.

### Open Issues and Questions

The following issues are outstanding:

##### *Actor Options*

Do we need [options](#BKM_C0E96CED_3629_4E07_8E78_05057EA75CE2) specific to a device type or will this profile be sufficient to address point-of-tracking for:

* implantable
* monitoring
* cardiology ?

##### *Device Resource*

The Device resource is missing data elements to support:

* date/time the resource was created at the point-of-care indicating when a device was associated with a patient. In the absence of this data element, the [Procedure.performed](http://build.fhir.org/procedure-definitions.html#Procedure.performed_x_) ([dateTime](http://build.fhir.org/datatypes.html#dateTime)).
* "Device Identifier" portion of the parsed Universal Device Identifier

Our team will discuss these issues with the HL7 Patient Care WG which manages this resource:

http://build.fhir.org/device.html

### Closed Issues

The following issues have been discussed and resolved:

#### Relationship to IHE Patient Care Devices (PCD) Technical Framework

*This profile is intended to augment Device Manager systems that implement IHE PCD Technical Framework but it is focused on FHIR adoption at this time.*

When associating the device with the patient using HL7 V2 transactions implementers have the option to use, PAM (Patient Administration Management) or PCIM (Point-of-Care Identity Management) specification currently under development. This profile provides a FHIR-bases approach to creating individual device and procedure records as well querying those data sets.

#### Secure Transport

FHIR resource security issues are addressed by the IHE IT Intrastruute specification referenced across the IHE PCC Technical Framework (e.g. Transport-level security) - see [1.5 Security Consideration](#BKM_A29B6068_2442_43B7_A493_17B4E842F84E).

#### Condition associated with a Procedure

One of the requirements communicated by the IHE CARD domain was to be able to "search for a device based on the procedure and associated diagnosis". The issue is two-fold:

* The [Procedure](http://build.fhir.org/procedure.html) resource specifies a "related condition" as [Procedure.reasonReference](http://build.fhir.org/procedure-definitions.html#Procedure.reasonReference) (a reference to a Condition) or [Procedure.reasonCodeableConcept](http://build.fhir.org/procedure-definitions.html#Procedure.reasonCodeableConcept) (a reference to SNOMED-CT or ICD-10 concept code).

## General Introduction

This supplement is providing a FHIR-based approach to acquiring medical device information at the point-of-care such that it can be retrieved and reused at a later time.

Implantable medical devices are essential for the treatment and management of a wide variety of medical conditions. These devices are costly and concerns about illegitimate (i.e., counterfeit, stolen) products being used for patient care has become a global issue. Post-market surveillance of implantable medical devices can be challenging due to the longevity of the patient and the medical device unless there is a reliable implant tracking method. In 2013, the United States Food and Drug Administration (FDA) issued a unique device identifier (UDI) system designed to identify and track implantable medical devices throughout their distribution and use in the United States. The EU will be developing and adopting similar legislation. The desire is to combine data from premarket approval with post-market settings to help address issues of cost and concerns about illegitimate products and to gain understanding of performance and clinical outcomes of implantable medical devices.

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Currently, healthcare organizations collect data on healthcare-associated infections (HAI) caused by certain medical devices (i.e., central venous catheters). Implantable medical device data is collected in a variety of ways, manually entered or partial look up in the electronic health record (EHR), manually entered in an EHR tab that doesn’t become part of the patients EHR, or manually on a study or registry log that is aggregated by a healthcare organization’s Quality Department or special study coordinator that is sent to the national registry. Inoperability of electronic data, manual data entry, and data manipulation lends itself to human error and inaccurate data capture leading to healthcare inefficiencies and patient safety errors.

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This supplement supports a combination requirements dealing with managing medical devices at the point-of-care:

* “Implantable Medical Device Registry Workflow Definition (IMDR-WD)” submitted by Denise Downing Informatics Nurse Specialist, Perioperative, AORN Syntegrity®
* “Point-of-care Medical Device Manager to improve patient safety, documentation clarity, and decision support”, submitted by Ioana Singureanu, BSEE, MSCS, FHL7, Standards Architect, Veterans Health Administration (VHA)

Both sets of requirements relied on correctly recording the identifier of medical devices, most likely automatically (e.g. scanning), at the point of care, using its Unique Device Identifier (UDI) specified by manufacturers using of standard-based [supported formats](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm/oUDIformats).

UDIs on implantable medical device labels and packages and in certain cases, directly on the devices, will improve the quality of information for medical device adverse event reporting, to identity product quality issues more quickly, target recalls, and ultimately improve patient safety. These are not only US based concerns, but also international concerns as identified in the International Consortium for Orthopedic Registry (ICOR). ICOR is a US FDA sponsored initiative that represents 14 nations (i.e., England/Wales, Denmark, Portugal, New Zealand) to evaluate implant safety and effectiveness. This international consortium nor U.S. healthcare organizations collect surveillance data for implantable medical devices. When data has to be manipulated by an individual data quality becomes a factor. Manually transcribing data because it uses one standard and its source uses another it prone to human error. Incorrect data formatting or missing data can cause rejection of a registry submission or rework may need to occur. Patient safety can be jeopardized if incorrect data is transcribed and decisions made off of incorrect data.

### 

### Scope

This supplement supports a combination requirements dealing with managing medical devices at the point-of-care:

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### Standards

* [Harmonization Pattern for UDI](http://wiki.hl7.org/images/2/24/Harmonization_Pattern_for_Unique_Device_Identifiers_20141113.pdf) (referenced by the [ONC Standards Advisory for 2017 (Draft)](https://www.healthit.gov/standards-advisory/draft-2017)
* [UDI Formats by FDA-Accredited issuing agency](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm): GS1, Health Industry Business Communications Council (HIBCC), ICCBBA – the details of the format are explained in the [UDI formats by FDA-Accredited Issuing Agency Version 1.2](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396595.doc): March 9, 2016.
* Clinical terminology consistent with Meaningful Use 2015 (LOINC, SNOMED CT, RxNorm) based on the type of data to be represented. For PCD transactions, we will use the LOINC concepts provided by Regenstrief to represent IEEE 11073-10101 concepts.

### Technical Approach

The approach outlined here relies on the use of FHIR resources (i.e. RESTful services) to record information acquired at the point-of-care and add it to the set of data maintained by enterprise information system (e.g. EHR systems, IMS systems, flow sheets).

Unlike previous approaches that put the emphasis and responsibility on the enterprise to manage the point-of-care and ancillary systems, this integration profile adds new capabilities to the point-of-care systems (e.g. device managers) to enhance patient safety and effectiveness.

## Appendix A - Actor Summary Definitions

*<Add any actor definitions for new actors defined specifically for this profile. These will be added to the IHE TF General Introduction list of Actors namespace.>*

NOTE: this section be added after finalizing Volume 1.

## Appendix B - Transaction Summary Definitions

*<Add any transaction definitions for new transactions defined specifically for this profile. These will be added to the IHE TF General Introduction list of Transactions namespace.>*

NOTE: this section be added after finalizing Volume 1.

## Glossary

*Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:*

### Implantable Device

Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:1) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life- control of conception; disinfections of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body and: 2) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means. (Reference: GHT)

### UDI

Unique Device Identifier - An identifier of an entity, such as persistent document, that has been generated by an algorithm guaranteeing its global uniqueness. [http://wiki.ihe.net/index.php/IHE\_Glossary#M](http://wiki.ihe.net/index.php/ihe_glossary#m)

The U.S. Food and Drug Admnistration (FDA) specifies that:

A UDI is a unique numeric or alphanumeric code that consists of two parts: **a device identifier (DI**), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and a **production identifier (PI**), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:

* the lot or batch number within which a device was manufactured;
* the serial number of a specific device;
* the expiration date of a specific device;
* the date a specific device was manufactured;
* the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. ([FDA UDI Basics](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIBasics/default.htm))

## Volume I - Profiles

This supplement is intended to enable the industry to create standard-based Point-of-care Medical Device Managers and Medical Device Registries.

### 1. PMDT profile

The Point-of-Care Medical Device Tracking (PMDT) Integration Profile actors and transactions intended to support several business use cases detailed in [this document:](#BKM_09E050EC_D05B_4A0F_B8C2_7DFA040E3090)

* [Implantable Medical Registration](#BKM_DF3BF2A8_D89E_404D_81D5_C61C2A3CD03A) to a enterprise [Device Registry](#BKM_F04A1DF8_A267_47B3_A0BC_7F4A91AFCF3C);
* [Tracking Implantable Devices](#BKM_2C0AECCF_07C8_4B81_9E85_BBCE043D22CC) at the point of care, during a procedure;
* [Vital Signs Monitoring and Charting](#BKM_CA8A279F_BFE0_469F_ADC3_B0CC9FC33D4A) using device and patient identity acquired at the point-of-care;
* [Cardiology - Implanted Stent](#BKM_C3F4BE69_7F0E_40B0_93FB_EC9DC7040079)
* [Cardiology - Pacemaker](#BKM_AC936C7C_D64F_429C_8C0C_5A9982279914)

These business use cases require the implementation of to main FHIR STU3 resources:

* [Device](http://build.fhir.org/device.html)
* [Procedure](http://build.fhir.org/procedure.html)

and references to

* [Patient](http://build.fhir.org/patient.html)

Analysis of the business requirements identified several interoperability requirements necessary to exchange information from the pont-of-care to enterprise systems to:

* [Register Medical Device](#BKM_3E99AADD_148D_46E8_98FE_74CC8A2FD69D)
* [Register Implantable Device](#BKM_38ADD49B_F109_4A8E_9B77_8DEA93DD504C)
* [Start Procedure](#BKM_F2CFD98C_F10A_4639_90BA_138A867E3578) part of [Manage Point-of-care Procedure](#BKM_49646E78_2B68_45CD_B473_D9EE884D53A3)
* [Complete Procedure](#BKM_DA44E8E8_005A_4F53_947D_74E75A4647EB) part of [Manage Point-of-care Procedure](#BKM_49646E78_2B68_45CD_B473_D9EE884D53A3)
* [Complete Post-Procedure](#BKM_8835C6BF_013E_4710_B40A_EF037C587C28) part of [Manage Point-of-care Procedure](#BKM_49646E78_2B68_45CD_B473_D9EE884D53A3)
* [Search Medical Device](#BKM_9ECEE198_2D4A_455E_9D2C_60F946776094) and the specialization [Search Implantable Device by Patient](#BKM_3F13ECF9_137C_4730_8000_00ED3BB76A67) and variations for [Search Implantable Device by UDI](#BKM_01751BC1_EE8B_4615_91F7_6245B4F66E7D)
* [Search Point-of-Care Procedure](#BKM_60507CE1_C383_426A_9518_9FB77B63E6C6) using a variety of criteria.

These requirements are organized into two use case analyzed as [Use Case #1: Manage and Search Device information](#BKM_111002FF_8A3D_457C_92AC_F5E29EDDC902) and [Use Case #2: Manage and Serach Point-of-care Procedures](#BKM_BDB8079F_8211_432C_A5AA_307ED839EDE8).

#### 1.1 PMDT Actors, Transaction, and Content Modules

This section identifies the system behavior ("actors") and the FHIR resource operations as transactions initiated at the point-of-care.

##### *1.1.1 Actor Descriptions and Actor Profile Requirements*

This section describes the Actors defined by this Profile and the transaction supported by each:

Table X.1-1 lists the transactions for each actor directly involved in the PMDT P Profile. To claim compliance with this Profile, an actor shall support all required transactions (labeled “R”) and may support the optional transactions (labeled “O”).



Table 1.1.1-1 PDMT Profile - Actors and Transactions

The following diagram shows the device-management related actors and transactions:



Figure 2: PMDT Actors: Device Server, Reporter, Consumer

The following diagram shows the procedure-management related actors and transactions:



Figure 3: PMDT Actors: Procedure Server, Reporter, Consumer

The following diagram identifies the actors and the information FHIR resources implemented to complete each transaction/operation.



Figure 4: Actors

Device Data Reporter

This actor is implemented as a FHIR Device resource client that creates Device resource instances. The Device resource will reference the patient who received the implant. If the device is used to monitor a patient, the Device resource does not require a reference to the Patient. The Device resource includes the UDI of the device as human readable text representation of the scanned bar code.

| **Transaction** | **Notes** | **Parameters** |
| --- | --- | --- |
| **send register Device()** | The actor initiates an new device registration ( [register Device(Device, Patient)](#BKM_27551DF6_A046_42E4_82CE_136974DC802B) ) that associates a device a patient based on information acquired at the point-of-care. This transaction creates a new instance of a Device. | Device ] device  Patient ] referencedPatient |

Device Server

This actor processes the request to create and search Device resources. This actor could be implemented by Medical Device Registries for implantable devices.The type of queries (aka search operations) may be more extensive than the example shown in this proposal (i.e. “search by patient Id”).

| **Transaction** | **Notes** | **Parameters** |
| --- | --- | --- |
| **register Device()** | The device server processes the request (to "create" a Device instance) . It creates a new Device record based on the data provide by the client/reporter at the point-of-care. | Device ] device  Patient ] referencedPatient |
| **search Devices()** Device | The device server responds queries for device records that match specific criteria (e.g. device UDI, patient identifier). | Patient.identifier ] patientId  Device.udiCarrier ] deviceId |

Device Data Requester

Implemented as a FHIR Device resource client that implements the “search” operation and uses the parameters supported by the FHIR specification. This actor could be implemented by systems that compile an Implantable Device list for a patient consistent with the Meaningful Use 2015 EHR system certification requirements.

| **Transaction** | **Notes** | **Parameters** |
| --- | --- | --- |
| **send search Device()** Device | The requester initiates queries for device records that match specific criteria (e.g. device UDI, patient identifier). | Patient.identifier ] patientId  Device.udiCarrier ] deviceId |

Procedure Data Reporter

This actor is responsible for sending procedure code, status, and related information to consumer(s) in the enterprise and is implemented as FHIR Procedure resource client. Initiates the creation and update of a procedure for a vital sign monitoring session. It is used to identify the type procedure that implants a life-supporting or life-sustaining medical device or uses the device (e.g. pulse oximetry, vital sign monitoring, IV drug administration). The reporter is implemented by a point-of-care system (e.g. Medical Device Manager).

| **Transaction** | **Notes** | **Parameters** |
| --- | --- | --- |
| **send start Procedure()** | The reporter creates a **new** Procedure resource with status "in-progress" to indicate a new point-of-care procedure was initiated. | Procedure ] procedure  Patient ] patient  Device ] device |
| **send complete Procedure()** | The reporter **updates** theProcedure resource with status "completed" to indicate a new point-of-care procedure was completed. In addition to the status, the "performedPeriod.end" is set to the date/time when the procedure was completed. | Procedure ] procedure  Patient ] patient  Device ] device |

Procedure Server

Thiis actor processes the requests and maintains the Procedure resources across the enterprise. It stores a record of the procedure used to implant a device or a procedure that uses a medical device (e.g. vital sign monitoring). The procedure will provide unambiguous documentation of procedures that use a medical device or equipment at the point-of-care.

| **Transaction** | **Notes** | **Parameters** |
| --- | --- | --- |
| **start Procedure()** | The receives and validate a **new** Procedure resource initiated at the point-of-care procedure. The status of this Procedure is "in-progress". | Procedure ] procedure  Patient ] patient  Device ] device |
| **complete Procedure()** | The server processes **update** and revises the status ( "completed") and the "performedPeriod.end" to indicate a new point-of-care procedure was completed. | Procedure ] procedure  Patient ] patient  Device ] device |
| **search Procedure()** Procedure | This server returns the Procedure resources that match the criteria specified by the requester (i.e. procedure code, patient identifier, or focal device). | Procedure.code ] procedureCode  Patient.identifier ] patientId  Procedure.focalDevice.udiCarrier ] deviceId |

Procedure Data Requester

This actor queries the Procedure Server for the information related to point-of-care procedures.

| **Transaction** | **Notes** | **Parameters** |
| --- | --- | --- |
| **search()** Procedure | This transaction allows the requester to search/queries procedures of a specific type, for a certain patient, procedure code, or focal device. | Procedure.code ] procedureCode  Patient.identifier ] patientId  Procedure.focalDevice.udiCarrier ] deviceId |

#### 1.2 Actor Options

See [Open Issues and Questions](#BKM_E94030AB_95CA_41DA_87AE_6310E34A2862) - [Actor Options](#BKM_387E1B76_C99A_461E_A871_EEE4C9885684)

#### 1.3 Required Actor Groupings

The actors describe in this profiles organized around the Device and Procedure resources. Based on the high-level  [Business Use Cases](#BKM_5289EADE_7006_470F_AD4E_23174A6D703B) we have identified the need to capture patient identity, device identity, and point-of-care procedure information right at the point-of-care.

The following diagram summarizes the types of systems that will implement the actors specified in this profile including [Device Manager](#BKM_8C20B368_EC49_4E81_999D_C42552D0F828)  used at the point-of-care and an enterprise-wide [Medical Device Registry](#BKM_F04A1DF8_A267_47B3_A0BC_7F4A91AFCF3C) system.

A fully functional system must implement more than one actor to support meaningful queries from other enterprise systems.



Figure 5: Required Actor Groupings for Point-of-care

##### *1.3.1 Example Systems*

Systems that implement the proposed actors would be deployed at the pont-of-care and record information about the devices and procedures initiated by clinicians.

Device Manager

This system is used at the point-of-care to record procedure (including patient context) and device information.

The following are possible capabilities that may also be provided by this type of system at the point-of-care:

Medical Device Registry

This enterprise system implements [Procedure Server](#BKM_FA4CE1CB_6A00_462D_9F6A_50FD8B14B0CB) and [Device Server](#BKM_E6114844_61CE_44FF_BE15_0F7360BCCA1C) actors.

#### 

#### 1.4 PDMT Overview

The use case analysis in this section provides informative background information and requirements for both Volumes 1 and 2 of this profile.

##### *1.4.1 Concepts*

*Not applicable.*

##### *1.4.2 Use Cases*

The following use case analysis includes both business and technical use cases

###### 1.4.2.1 Business Use Cases

The following scenarios were analyzed to create the use cases identified in this section:



Figure 6: Business Use Cases

Implantable Medical Registration

Mr. Smith is a 65-year-old male who lives in Colorado and is very active, but his right knee arthritis has finally put a stop to his ability to hike. Mr. Smith goes to his primary care physician who refers him to Dr. Denver, an orthopedic surgeon. Dr. Denver performs an exam, sends Mr. Smith for some diagnostic studies, and determines a right total knee replacement is necessary. Mr. Smith is scheduled for a right total knee replacement, at St Castles Medical Center, using XYZ manufacturer’s knee replacement systems. Dr. Denver’s office schedules Mr. Smith’s total knee replacement with the operating room scheduling system.

St. Castles’ operating room has an Orthopedic/Spine Coordinator who reviews the surgical schedule to make sure the correct implantable medical devices are available for the scheduled procedures. XYZ manufacturer has a contract with St Castles Medical Center, but they do not stock the system that is needed for Mr. Smith. The Orthopedic Coordinator notifies the operating room (OR) materials manager (MM) to purchase the total knee components needed for Mr. Smith. The MM creates a purchase order (PO) using the medical center’s enterprise revenue program (ERP). The ERP system interfaces with the medical centers ORs materials (inventory) management information system (ORMMIS) for development of the ORs item master. The ORMMIS doesn’t exchange data within the medical center’s EHRs to capture specialty medical supplies and implantable medical devices used for patient care. If the UDI data was exchanged, the circulator nurse could then validate she has the correct implant for the patient by scanning and validating the barcode that came for the ORMMIS to the one she scanned on the package(s) - similar to identifying correct meds being administered.

Mr. Smith has his scheduled procedure and has XYZ implantable medical device implanted. The OR circulating nurse, using the medical centers’ EHR, manually documents the XYZ UDI barcode numbers on the packing because the scanner will not scan the barcodes on the medical device packaging used for Mr. Smith’s right total knee replacement procedure. Dr. Denver is part of a national orthopedic registry that is collecting data on total knee procedures. The Quality Department is given a list of all orthopedic procedures that Dr. Denver performed during the week and they begin to review each patient’s medical record for data elements that should be sent to the national registry.

Tracking Implantable Devices

* SSgt. Sam Share, a **veteran**, receives a **consult** from Dr. Lister at a VA facility to treat his combat-related **condition**. It requires an implantable device to improve Sam’s health status.
* Dr. Lister, **VA physician**, prescribes an **implantable device or tissue** based on device type and other criteria (e.g. clinical size) and **orders** the **device** (based on device identifier (DI portion of UDI) the **procedure** (HCPCS)
  + The VA physician Looks up a suitable device using **prosthetic** list based on the FDA Global Unique Device Identifier Database (GUDID) or uses the pre-loaded “gold” Master Device Identifier file which is a local subset of device identifier records including SNOME CT device taxonomy codes. This local list allows enterprise application to look up devices based on: type, model, version, vendor, clinical size
* Ms. Martin, a **VA clerk** reviews the order before forwarding the information from the VA-approved distributor and obtains the device required for SSgt. Sam. Once the implantable medical device arrives at the medical center, its id is scanned and cross-referenced with the GUDID to ensure device legitimacy and recalls.
* A **procedure** is **scheduled** for SSgt. Sam, the device is implanted by Dr. Wilson and the UDI is scanned by the designated nurse into VistA. The UDI is associated with the patient and available to community providers in the “Patient Device List” of a CCD. If a recall is initiated, the manufacturer notifies VA to inform Sam and other patients using the same type of device in the affected production.

Vital Signs Monitoring and Charting

* SSgt. Sam Share (ret.) is admitted at the VA medical center and requires **continuous monitoring** of vital signs including oximetry. Dr. Lister orders monitoring for the next **24 hours**.
* Nurse Nightingale starts the monitoring session by **assigning** a standard-based vital sign monitor to Sam by **scanning the device label** and Sam’s **wrist band** (UDIßàPID) and her badge (PIDßàEID). She uses the vendor-provided medical device manager or a VA-provided device gateway to record the devices associated with this procedure and patient.
* Once the patient-to-device association is completed any measurements, status information, reference ranges, etc. acquired by the device is exchanged with the flowchart system that persists the measurement in the VistA database using a common device integration adapter. **LOINC, SNOMED, UCUM** used to convey the measurements.
* Throughout the monitoring session, Ms. Nightingale validates the data entered by the integrated device into VistA. The validated results become part of Sam’s legal health record
* The CCD includes relevant/pertinent vital signs along with other treatment information

Cardiology - Implanted Stent

SSgt. Sam was having some chest pain so he goes to see his primary care physician who orders some diagnostic tests and refers him to Dr. Heart, a cardiologist. Dr. Heart sees SSgt. Sam and determines he has a blocked cardiac artery and needs a cardiac stent inserted. Dr. Heart orders the cardiac stent procedure with the Cardiac Catheterization Laboratory. On the request Dr. Heart has identified which implantable cardiac stent he would like to implant into SSgt. Sam. Prior to the procedure, the requested cardiac stent’s UDI is verified with the FDA’s GUDID to ensure there has not been a recall or any other adverse events. During the stent placement procedure Dr. Heart determines a different cardiac stent is needed for SSgt. Sam. The cardiac nurse obtains the requested implantable medical devices, scans it for verification against the FDA GUDID, and the stent is inserted without complications. The **scanned** UDI data from the cardiac stent’s label **is transmitted automatically to** SSgt. Sam medical record. SSgt. Sam is transferred to the Cardiac Care Unit for post-procedure care.

Cardiology - Pacemaker

SSgt. Sam was having some chest pain so he goes to see his primary care physician who orders some diagnostic tests and refers him to Dr. Heart, a cardiologist. Dr. Heart sees SSgt. Sam and determines he needs a cardiac pacemaker inserted. Dr. Heart orders an insertion of pacemaker (ICD10 code - 0JH605Z) with the Cardiac Catheterization Laboratory (or this can be in the OR – it depends on the HCO where these are performed). On the request Dr. Heart identifies which pacemaker and leads he would like to implant into SSgt. Sam. Prior to the procedure, the pacemaker and leads UDI are verified with the FDA GUDID to ensure there has not been a recall or any other adverse events for the requested implantable medical devices. During the pacemaker insertion procedure, Dr. Heart drops a lead. The cardiac nurse obtains another lead, scans it to verify it against the GUDID, aseptically gives it to Dr. Heart and the pacemaker and lead are inserted without complications. The cardiac nurse ensures the UDI data on each implantable medical device label inserted into SSgt. Sam **is automatically transmitted** to in his medical **record using a point-of-care system to avoid data entry errors**. Prior to being transferred to the Cardiac Intensive Care Unit for post-procedure care, SSgt Sam has an external pacemaker medical device attached to him per the cardiac surgery protocol.

###### 1.4.2.2 Use Case Analysis

The main use case is to provide a standard-based approach to accomplish Patient-Device and Device-Operator Associations and Management using FHIR Procedure, FHIR Device using the UDI of physical device. These use cases informed the transactions specified per actor and are further developed in [Volume 2](#BKM_2317B51E_FB0B_43AB_8CA2_CC89E48511A0).

The main scenario uses FHIR Procedure and Device to associate a patient to one or more device(s) and operator/nurse/physician who configured or implanted the device. The device will be identified using the UDI scanned at the point of care along the patient id wristband, and the provider's badge.

* Create a FHIR Procedure specifying the patient, the device or devices involved, and the operator (i.e. perioperative nurse, respiratory therapist, etc.) or provider who configured the device, validated its configuration and initiated the procedure.
* If the device is implanted, a FHIR Device resource will associate the patient with the implanted device. The Patient Device List will be created by querying the EHR using a Device.search (by patient) operation.
* If the device is used monitor the patient or administer medication the procedure indicates duration, the associated medication order.

The scenario involves the use of system referred to as “Point-of-care Device Manager”. This system is HL7 FHIR client intended to track implantable devices, associate a patient to their monitoring devices, or help validate medication administration at the point of care using an infusion pump. This type of system uses FHIR resources to:

* start and end a session using a device (e.g. monitoring) as a [Procedure](http://hl7-fhir.github.io/procedure.html) "in-progress" and updates the procedure at the end of the monitoring session (and set the status to "complete")

create a [Device](http://hl7-fhir.github.io/device.html) resource corresponding to each device implanted during a surgical procedure and creates [Procedure](http://hl7-fhir.github.io/procedure.html) to document it.

Use Case #1: Manage and Search Device information

The following is a description of the interoperability use case required to support the [business requirements](#BKM_5289EADE_7006_470F_AD4E_23174A6D703B) section related to managing and searching device records:

The following is an overview of the requirements subsumed in managing a device including UDI:



Figure 7: Use Cases: Medical Device Registry

Register Medical Device

The device information is sent from the point-of-care to an enterprise Device Server that plays the role of "Medical Device Registry".

Register Implantable Device

The device information is sent from the point-of-care to an enterprise Device Server that plays the role of "Medical Device Registry". This use case is a specialization of [Register Medical Device](#BKM_3E99AADD_148D_46E8_98FE_74CC8A2FD69D)

Use Case #2: Manage and Search Point-of-care Procedures

The following is a description of the interoperability use case required to support the [business requirements](#BKM_5289EADE_7006_470F_AD4E_23174A6D703B) section related to managing and searching device records:

The following is an overview of the requirement subsumed by managing procedure information at the point-of-care:



Figure 8: Use Cases: Point-of-Care Procedure

Manage Point-of-care Procedure

This use case includes:

* [Start Procedure](#BKM_F2CFD98C_F10A_4639_90BA_138A867E3578) use case
* [Complete Procedure](#BKM_DA44E8E8_005A_4F53_947D_74E75A4647EB) use case
* [Complete Post-Procedure](#BKM_8835C6BF_013E_4710_B40A_EF037C587C28) use case

Start Procedure

This use case includes the activities required to identify the start of a point-of-care procedure.

Complete Procedure

The event information associated with the completion of the procedure. It updates the point-of-care procedure information and updates the status of the procedure object (to "completed").

If the procedure does not have significant time duration, the start of the procedure may be omitted and only the completion event may be recorded - see [Interactions : Implantable Device Registration](#BKM_5510C0CB_E461_4BBF_83DC_F7954960C3DD)  .

Complete Post-Procedure

The activities in this use case are triggered by a clinician. The business trigger could be that clinician is signing off on the documentation acquired during the procedure. From a clinical point-of-view this use refers to the completion of a specific treatment or procedure (in FHIR standards terms would be documented as an [Encounter](http://build.fhir.org/encounter.html) - which may part of a larger [EpisodeOfCare](http://build.fhir.org/episodeofcare.html)).

The business trigger may be that after nurse document the procedure and physician signs off on the documentation. Previously the procedure start and/or completion may be documented in predecessor use cases:

* [Start Procedure](#BKM_F2CFD98C_F10A_4639_90BA_138A867E3578)
* [Complete Procedure](#BKM_DA44E8E8_005A_4F53_947D_74E75A4647EB)

Search Point-of-Care Procedure

The consumer searches the Procedure Server for a point-of-care Procedure that matches specific criteria (e.g. subject patient identifier, procedure code, focal device identifier)

Use Case Actors

The following systems/actors have been identified by analyzing the business use cases detailed in the [business requirements](#BKM_5289EADE_7006_470F_AD4E_23174A6D703B) section:

PDC

Procedure Data Consumer is a system that queries the Procedure Server for specific procedures.

DS

This system support the FHIR Device resource required to manage the device identity at the point-of-care. This system is implements [Device Server](#BKM_E6114844_61CE_44FF_BE15_0F7360BCCA1C) actor.

DDR

Device data reporter is a system available at the pont of care to record the device UDI and other contextual information. This system implements the [Device Data Reporter](#BKM_EA1D1B3A_CEA4_48A2_B7F7_1BEA867AFA4A) actor.

DDC

The system that requires/queries information from the device server that serve as the registry system. This system implements the [Device Data Consumer](#BKM_DDD0C8DA_7C92_4CD0_BBF4_44584418AA36) actor.

PDR

This system acquires information about a procedure involving a focal device. This system implements the [Procedure Data Reporter](#BKM_9B8CE0D7_5711_4A16_9A8F_8D9BDD349592) to share this information with systems in the enterprise.

PS

This system implements the Procedure resource and provides other systems in the enterprise the ability to create/update and search these resources. This system implements the [Procedure Server](#BKM_FA4CE1CB_6A00_462D_9F6A_50FD8B14B0CB) actor.

###### 1.4.2.3 PDMT Interactions

The following sequence diagrams illustrate the system interactions including the related PCD transactions that are needed to support the [Use Case #1: Manage and Search Device information](#BKM_111002FF_8A3D_457C_92AC_F5E29EDDC902) and [Use Case #2: Manage and Serach Point-of-care Procedures](#BKM_BDB8079F_8211_432C_A5AA_307ED839EDE8). These interaction show how the use cases are implemented by related systems to accomplish a specific goal:

The following diagram describes the interactions required to support patient-to-device association for vital signs monitoring using information acquired at the point-of-care focusing strictly on the actor defined in this profile (see [1.1.1 Actor Descriptions and Actor Profile Requirements](#BKM_AC41EDA6_7099_4BAB_AC5D_3FE95F9FB9CD) ):



Figure 9: Point-of-Care Monitoring - Actors Only

The following diagram describes the interactions required to support device tracking and registration based on information recorded at the point-of-care. This diagram ignores the business triggers and focuses exclusively on the actors defined in this profile (see [1.1.1 Actor Descriptions and Actor Profile Requirements](#BKM_AC41EDA6_7099_4BAB_AC5D_3FE95F9FB9CD) ):



Figure 10: Implantable Device Registration - Actors Only

The following diagram describes the interactions required to support the use Device and Procedure resources recorded at the point-of-care. This diagram focuses on the actors involved (see [1.1.1 Actor Descriptions and Actor Profile Requirements](#BKM_AC41EDA6_7099_4BAB_AC5D_3FE95F9FB9CD) ):



Figure 11: Search Implantable Device from Device Registry - Actors Only

The following diagram describes the interactions required to support device tracking and registration based on information recorded at the point-of-care. It includes the business trigger (i.e. user actions) and identifies the type of information that is acquired at the point of care. This diagram expands on the [PDMT Interactions : Implantable Device Registration - Actors Only](#BKM_B93BFDE8_E140_4503_9176_BE0B9BC78776) diagram:



Figure 12: Implantable Device Registration

The following diagram describes the interactions required to support patient-to-device association for vital signs monitoring using information acquired at the point-of-care. This diagram shows the users and devices required to trigger the interactions. This diagram expands on the [PDMT Interactions : Point-of-Care Monitoring - Actors Only](#BKM_2CB1F36B_9FEC_4BB7_B7A9_0AD41D4E1B4F) diagram:



Figure 13: Point-of-Care Monitoring

The following diagram describes the interactions required to support the use Device and Procedure resources recorded at the point-of-care. This diagram shows how a clinician or inventory specialist may use this Medical Device registry to identify what devices where implanted for a specific patient. This diagram expands on [PDMT Interactions : Search Implantable Device from Device Registry - Actors Only](#BKM_D7657305_E8F6_4D50_BFCE_D45DD6F0B845) interaction diagram:



Figure 14: Search Implantable Devices from Device Registry

#### 1.5 Security Consideration

In many other uses of the HTTP/REST pattern, applications are accessing far less sensitive information than patient identifiers and protected health information. When the mobile environment comes into use, the challenges of security and privacy controls are unique, simply because the devices are harder to physically control. The PMDT Profile provides access to the patient identifiers and other protected health information managed in healthcare. These factors present a unique and difficult challenge for the security model. It is recommended that application developers utilize a Risk Assessment in the design of the applications, and that the operational environment utilize a Risk Assessment in the design and deployment of the operational environment. l.

There are many reasonable methods of security for interoperability transactions, which can be implemented without modifying the characteristics of the PMDT Profile transactions. The use of TLS is encouraged, as is the use of the ATNA Profile (see ITI TF-1:9).

User authentication on mobile devices and browsers is typically handled by more lightweight authentication schemes such as HTTP Authentication, OAuth2, or OpenID Connect. IHE has a set of profiles for user authentication including: Enterprise User Authentication (EUA) on devices using HTTP and Internet User Authorization (IUA) for REST-based authentication. In all of these cases, the network communication security, and user authentication are layered in the HTTP transport layer and do not modify the interoperability characteristics defined in the DCP Profile. The use of strong trust keys is encouraged.

The Resource URL pattern defined in this profile means many requests may include Patient ID, names, or other demographic data as parameters for query. The advantage of this pattern is ease of implementation and clear distinction of a patient’s identity. The URL pattern does present a risk when using typical web server audit logging of URL requests and browser history. In both of these cases the URL with the Patient ID or Name query parameters is clearly visible.

#### 1.6 Cross Profile Considerations

This profile is related to existing technical frameworks (IHE ITI, IHE PCD) and the items discussed and documented as [Relationship to IHE Patient Care Devices (PCD) Technical Framework](#BKM_BCF0DAE0_ED18_427E_ABC7_C810C1B70F4B).

##### *IHE PCD DEC*

IHE PCD De Device Observation Reporter and Device Observation

This specification is localized for use in the US, therefore the device unique identifier used in the PCD-01 transactions and any terminology requirements will be adapted to apply in the context of US enterprises that employ Meaningful Use certified EHR system.

###### 