**1. Proposed Work Item: Implantable Medical Device Registry Workflow Definition (IMDR-WD)**

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**2. The Problem**

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.

**3. Key Use Case**

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.

**4. Standards and Systems**

C-CDA HL7 v2.8 (UDI)

Possibly - FHIR – Device (Resource) HAPI 1.6

STU3

IHE PCD

GS1/HIBCC

**5. Discussion**

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.