Unique Device Identification and the EHR

EHR Workgroup
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FDA, Center for Devices & Radiological Health
Types of Medical Devices and Examples

- **Capital Equipment**
  - cribs, beds, scales, wheelchairs, IV poles, infusion pumps, bathing tubs, blood pressure equipment, MRI and CAT scanners, radiology equipment

- **Instruments**
  - surgical staplers, glucose meters, orthopedic tools and hardware

- **Monitoring Systems**
  - cardiac, telemetry, vital sign monitors, pulse oximeters

- **Disposables & Accessories**
  - ventilator breathing circuits, filters
  - needles, syringes, trocars, IV catheters, IV tubing, foley catheters, feeding tubes, gloves
  - electrodes

- **Implantable**
  - defibrillators, breast implants, ventriculoperitoneal shunts, tissue expanders, pacemakers

- **Clinical Lab**
  - Reagents
  - Chemistry analyzers

- **Computerized Medical Systems**
  - Workstations, hardware
  - software
Identifying a **BD 1/2 mL Insulin Syringe/28 G needle**

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Easier to identify the dogfood you bought at the grocery store…..
UDI Legislation: Standardizing Device Identification
FDAAA 2007; FDASIA 2012

Not later than December 31, 2012, the Secretary shall issue proposed regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number. The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.
Unique Device Identifier (UDI)

A globally unique device Identifier:

- To be obtained from an accredited issuing agency
- To be applied by manufacturer to the label of devices
- To be submitted by manufacturer to Globally Unique Device Identification Database (GUDID).
- To be made publically available at no charge
- To be used by FDA applications (MAUDE, RECALLs) and external systems as the device ID standard
What is UDI?

- **UDI = DI (Device Identifier) + PI (Production Identifier)**
  - On the Device Label
  - DI is lookup key for pulling out other attributes from GUDID
  - Computers can parse out lot, serial, expiration and manufacturer date (if available)
### Parsing a UDI (EXAMPLE):

(01) 51022222233336(11)141231(17)150707(10)A213B1(21)1234

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**Ex of Human Readable Barcode:** (01) 51022222233336(11)141231(17)150707(10)A213B1(21)1234
Global Unique Device Identification Database - GUDID

- Stores DI and other regulatory device identification information
- Download, Webservice and Search for Device Information – no charge from FDA
- Potential to link device information in procurement, inventory control, recalls, clinical care (including registries and clinical trials), clinical material management, incident systems etc.
GUDID Data Attributes (sample)

For each DI:

- Manufacturer, model, Brand Name
- Clinically relevant size
- Company Contact information
- Sterility information
- Natural Rubber Latex information
- FDA premarket authorization (510k, PMA)
- FDA product code (PROCODE)
- For single-use
- GMDN - *Examples* - Biventricular Pacemaker; Dual-Chamber Pacemaker, demand; Pacemaker/defibrillator lead; Internal orthopaedic fixation system, plate/screw, non-biodegradable
GUDID – Points to Remember

• Device Catalog - Contains static device information
• NOT a Patient Registry - does NOT contain patient or
device specific production information, such as lot or serial
numbers
• NOT for track/trace or other similar purposes requiring the
full UDI
• Provides link to product information- not a replacement for
FDA Recalls/Adverse Event Databases
• GUDID is not a requirement for hospitals – it is a tool that
will provide the following benefits if all stakeholders buy in -
EHRs, Claims, Inventory Systems, Incident Systems,
Clinical Maintenance…
Global UDI Database

Manufacturer (Acme) → DI + Structured Data → 3rd Parties (GDSN) or Web based tool or Bulk HL7 SPL → Business Rules → GUDID

Distribution → Other FDA Systems

Download → Web Service

Public User Interface
Future: Possible Adoption of UDI in EHR

UDI of device linked to the receiving patient as part of documentation of his/her care in EHR and other relevant systems by:

• Using UDI as the standard code to document device use (scan, link through charge master, or other means)
• Parse UDI and store
• Use DI portion of UDI to obtain other relevant device identification attributes (from GUDID or other ‘source of truth’)
• Store DI, PI and sufficient other data attributes to maximize benefit to patient, care providers, hospital systems (materials management, biomedical engineering, risk management)
UDI and Implants: The First Use Case

• Implants are:
  – High Risk and Prevalent
  – Complete Data Source - All implants must be submitted 2 years from Final Rule.
  – Device/ID Not visible to human eye
  – Persistent to Patient beyond origin
  – Coordination of care issues
    • Contrast to devices tied to patient visit (IV pump, ventilator, bed)
  – Device data often already captured to support patient charging
Medication Reality as Model for Device Future

1. Document drug used at time of use
2. Access between drug information system and EMR
3. Drugs associated with patient in all EHR modules and at discharge
4. Clinical Decision Support available in EHR
**Operative Case Record**

**Manufacturer:** [Redacted]
**Site:** Clavicle, Left

**Screw/Other Part List:**

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The Possibilities

• The UDI of an implanted medical device could be captured upon implant and become a permanent part of a patient’s medical record. Then:
  – A clinician could view all of the patient’s implanted devices and associated UDI’s in the same manner as a medication list is viewed.
  – This hospital would be able to report adverse events using the UDI (and appropriate associated attributes) linked to the EHR patient record.
  – If an implantable device recall occurred, the hospital or physician would be able to use the UDIs of the recalled devices to pull up all patients in their EHR that have in their record the device identifier, and lot/batch/serial number combination specified in the recall notice.
Devices would be better identified as part of care

• UDI and other implantable device information could be provided at time of patient transition in:
  – View, Download and Transmit functions (VDT)
  – Summary of Care documents
  – Transition of Care documents
  – After visit summary documents
Making the Link between Patient & Device.

Clinical Care Benefits

• Supports Care Coordination in hospital
• Informs future patient care
• Improves Recall effectiveness
• Improves ability to conduct Active Surveillance by hospital
• Makes device available for Summary Views of Patient – patient lists, summary documents
• Links device to Diagnosis and other elements of Patient Care
• Enables device maintenance – Vascular Access Port, Pacemaker
• Provides rapid access to accurate, standardized device information when needed (ER, MRI, Recall)
• Enables building of meaningful quality and performance measures and clinical decision support tools – natural rubber latex, MRI capability
Unique Device Identification

www.fda.gov/UDI

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