Incorporating the Unique Device Identifier (UDI) into Health Care Delivery

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Problems with Device Surveillance

- Currently, when implanted medical devices are found to be unsafe by the FDA and recalled by device makers, there is no way to ensure that affected patients and their doctors are informed.
  - Owners of recalled cars have more information than patients with dangerously defective pacemakers
  - According to a 2011 report by the Government Accountability Office, when devices are recalled, medical device companies are able to locate fewer than half the defective devices.
- Inability to quickly identify problems with medical devices
  - Inaccurate adverse event reports
- Poor data to establish long-term outcomes
Recent medical device failures demonstrate the need for more rigorous and timely evaluation of the safety and quality of products once they are on the market.

- Metal-on-metal hips
- Implantable cardioverter-defibrillator recalls

Yet, medical devices are among the *only* products that do not rely on a standard unique method of identification.

- It’s easier to identify dog food or a pack of gum.
Congress Intervenes

Food and Drug Administration Amendments Act (2007)

- Instructed FDA to develop a UDI system

Food and Drug Administration Safety and Innovation Act (2012)

- Mandated implementation timelines for the UDI

Final Rule released September 2013
Unique Device Identifier (UDI)

- Unique Device Identifier (UDI) – an identifier that adequately identifies a device through its distribution and use.
- A UDI is composed of:
  - (1) A device identifier (DI) - a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device and
  - (2) 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 the device:
    - The lot or batch within which a device was manufactured;
    - The serial number of a specific device;
    - The expiration date of a specific device;
    - The date of a specific device was manufactured;
    - And for a human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device, the distinct identification code required by 1271.290(c)

\[ UDI = DI + PI \]
Unique Device Identifier (UDI)

- Obtained from an accredited issuing agency
- Located on device labels, and directly on re-usable and reprocessed devices
- To obtain information regarding a device, the DI can be used to query the Global Unique Device Identification Database (GUDID).
  - Free, public access to the device information via search or web services
Base Package
Primary DI = 00884838035683

Oral/Enteral Syringe, 60ml
Device Count = 1

Base Package is the lowest level of a medical device package containing a full UDI

Package DI = 30884838035683

Oral/Enteral Syringe, 60ml, Box of 100
Contains 100 units of
Base Package DI 00884838035683
Quantity per package = 100

Package Configurations of the Base Package

Package Configurations inherit the Base Package device attribute values, except for attributes specific to the particular package
## UDI Implementation Timeframe

<table>
<thead>
<tr>
<th>Compliance Date</th>
<th>Requirement</th>
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<tbody>
<tr>
<td>1 year after publication of the final rule (September 24, 2014)</td>
<td>The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Data for these devices must be submitted to the GUDID database. § 830.300. A 1-year extension of this compliance date may be requested under § 801.55; such a request must be submitted no later than June 23, 2014. Class III stand-alone software must provide its UDI as required by § 801.50(b).</td>
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<td>2 years after publication of the final rule (September 24, 2015)</td>
<td>The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. A device that is a life-supporting or life-sustaining device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. § 801.45. Stand-alone software that is a life-supporting or life-sustaining device must provide its UDI as required by § 801.50(b). Data for implantable, life-supporting, and life-sustaining devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.</td>
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| 3 years after publication of the final rule (September 24, 2016) | Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.  
The labels and packages of class II medical devices must bear a UDI. § 801.20.  
Dates on the labels of these devices must be formatted as required by § 801.18.  
Class II stand-alone software must provide its UDI as required by § 801.50(b).  
Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300. |
| 5 years after publication of the final rule (September 24, 2018) | A class II device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.  
The labels and packages of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI. § 801.20.  
Dates on the labels of all devices, including devices that have been excepted from UDI labeling requirements, must be formatted as required by § 801.18.  
Data for class I devices and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.  
Class I stand-alone software must provide its UDI as required by § 801.50(b). |
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<td>7 years after publication of the final rule (September 24, 2020)</td>
<td>Class I devices, and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI, must bear UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. $ 801.45.</td>
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Benefits

- Adverse event identification
- Reduce medical errors
- Increase patient safety
- Enhance analysis of devices on the market
- Recalls
- Provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion, reduce fraud and abuse, and prepare for medical emergencies
- Lead to the development of a medical device identification system that is recognized around the world
- Provide for more rapid development of solutions to reported problems
- Better focused and more effective FDA safety communication
- Supply chain
- Educational and informational material
To achieve these benefits, though, UDI must be adopted by physicians, hospitals and health plans.
Questions and Discussion