Unique device identifiers for coronary stent postmarket surveillance and research: A report from the Food and Drug Administration Medical Device Epidemiology Network Unique Device Identifier Demonstration

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Background Although electronic product identification in the consumer sector is ubiquitous, unique identification of medical devices is just being implemented in 2014. To evaluate unique device identifiers (UDIs) in health care, the US Food and Drug Administration (FDA) funded the Medical Device Epidemiology Network initiative, including a demonstration of the implementation of coronary stent UDI data in the information systems of a multihospital system (Mercy Health). This report describes the first phase of the demonstration.

Methods An expert panel of interventional cardiologists nominated by the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions was convened with representatives of industry, health system members of the Healthcare Transformation Group, the American College of Cardiology National Cardiovascular Data Registry, and FDA to articulate concepts needed to best use UDI-associated data. The expert panel identified 3: (1) use cases for UDI-associated data (eg, research), (2) a supplemental data set of clinically relevant attributes (eg, stent dimensions), and (3) governance and administrative principles for the authoritative management of these data.

Results Eighteen use cases were identified, encompassing clinical care, supply chain management, consumer information, research, regulatory, and surveillance domains. In addition to the attributes of the FDA Global Unique Device Identification Database, 9 additional coronary stent-specific attributes were required to address use case requirements. Recommendations regarding governance were elucidated as foundational principles for UDI-associated data management.

Conclusions This process for identifying requisite extensions to support the effective use of UDI-associated data should be generalizable. Implementation of a UDI system for medical devices must anticipate both global and device-specific information. (Am Heart J 2014;168:405-413.e2.)

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Abbreviations: ACC, American College of Cardiology; AHRQ, Agency for Healthcare Research and Quality; CDRH, Center for Devices and Radiological Health; EHR, Electronic Health Record; ERP, Enterprise Resource Planning; FDA, U.S. Food and Drug Administration; GUDID, Global Unique Device Identification Database; HDD, Healthcare Data Dictionary; IPD, Integrated Patient Data; MDEpiNet, Medical Device Epidemiology Network; NCDR, National Cardiovascular Data Registry; OMOP, Observational Medical Outcomes Partnership; PhRMA, Pharmaceutical Research and Manufacturers of America; SCAI, Society for Cardiovascular Angiography and Interventions; SUDID, Supplemental Unique Device Identifier Database; UDI, Unique Device Identifier; UPC, Universal Product Code.
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Table I. Selected data elements of the FDA GUDID

- Primary device identifier no.
- UDI issuing agency
- Company name (manufacturer)
- Brand name (proprietary/trade/brand name)
- Version or model number
- Catalog number
- Size (parameter, value, unit of measure)
- Device description (text)
- Packaging information
- Support contact information
- Sterility information
- Natural rubber information
- FDA premarket authorization status
- FDA product code (premarket product classification)
- Marketing status
- For single use
- MRI safety status

Abbreviation: *MRI*, Magnetic resonance imaging.

Unique product identifiers are ubiquitous in the consumer market, improving inventory control while reducing costs to manufacturers, wholesalers, retailers, and consumers. The Universal Product Code bar code system is widely embraced, allowing for the precise identification of products and enabling the automation of inventory management. With medical devices, unique identification has a myriad of potential benefits, including improved patient access to device-specific information, provision of authoritative and current data to providers at the point of care, improved care coordination, reduced medical errors, efficiencies in supply chain management, targeted approaches to active device surveillance and recalls, opportunities to create device-specific alerts and clinical decision support, facilitation of research, more accurate claims payment processes, and overall reductions in health care costs.

For several years, the US Food and Drug Administration (FDA) worked to develop requirements of a unique device identification system for medical devices as directed by the FDA Amendments Act of 2007 and FDA Safety and Innovation Act of 2012 (www.fda.gov).[1-3] The FDA has also been working with regulators in other countries to develop an international solution.[4] The European Union published recommendations on a common framework for a unique device identifier (UDI) system in April 2013.[5] The FDA UDI final rule, published September 24, 2013, specifies that most devices are to include a numeric or alphanumeric code on the label, composed of a device identifier specific to the device model or version along with production (eg, lot, batch, or serial number) and expiration date information, if applicable.[6] The UDI rule also stipulates that FDA will create and manage the Global Unique Device Identification Database (GUDID) containing a standard set of attributes such as those listed in Table I.[7] Data in the GUDID are to be specific to the level of the model and version of the device. In addition, the Office of the National Coordinator for Health Information Technology has included the electronic capture and interchange of the UDI in its draft 2015 electronic health record (EHR) certification criteria, and a field for the UDI is proposed for inclusion in the standard hospital claim form by the Workgroup for Electronic Data Interchange, the information technology advisor to the Department of Health and Human Services.[8]

To accelerate improvements in postmarket device surveillance, the FDA created the Medical Device Epidemiology Network (MDEpiNet), a collaborative through which the FDA Center for Devices and Radiological Health and external partners share information and resources to enhance our understanding of the postmarket approval safety and effectiveness of medical devices.[9] MDEpiNet includes a demonstration project to evaluate the logistics and utility of a prototype UDI system, including the integration of the UDI into the information systems of a large health system (Mercy Health). Management of coronary stent data was chosen as the archetype for the demonstration project. To develop and refine the deliverables, an expert panel of interventional cardiologists was identified to lead a multistakeholder expert workgroup in articulating the principles and approaches of the demonstration project. This manuscript describes the specifics in detail, reporting on key aspects of the face-to-face meeting and 2 subsequent teleconferences of the expert panel and the expert workgroup. The in-person meeting took place at the American College of Cardiology (ACC) headquarters in Washington, DC, on August 6 and 7, 2012, and the teleconference discussions were held in October and November 2012.

The demonstration project and Mercy Health

The MDEpiNet includes 2 major "work streams": a methodology work stream contracted to the Methodology Center at Harvard University and an infrastructure work stream assigned to Cornell University. The methodology work stream houses the UDI demonstration project. The UDI demonstration project has 3 principal aims:

- To implement a prototype UDI solution for coronary stents in the information systems of a multihospital system,
- To identify obstacles to implementation of the prototype UDI solution and to characterize the effectiveness of interventions to overcome them, and
- To assess the validity and utility of data obtained from an EHR system in postmarket surveillance using the UDI.

Mercy Health is a 4-state integrated delivery system headquartered in St. Louis, MO, that owns 34 hospitals with a total of 4,396 licensed beds ranging from small, critical access rural facilities to large, tertiary care urban medical centers. Of Mercy's 34 hospitals, 5 have cardiac catheterization laboratories that collectively implant >5,000 coronary stents annually. Mercy Health is serving