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

James E. Tcheng, MD,[a] Jay Crowley, MS,[b,i] Madris Tomes, MBA,[c,i] Terrie L. Reed, MS,[d,i] Joseph M. Dudas, MBA,[e] Kweli P. Thompson, MD,[f] Kirk N. Garratt, MD,[g] and Joseph P. Drozda, Jr., MD[h], on behalf of the MDEpiNet UDI Demonstration Expert Workgroup *Durham, NC; Santa Barbara, CA; Washington, DC; Rochester, Minneapolis, MN; New York, NY; and Chesterfield, MO*

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.)

From the [a]Duke University Medical Center, Durham, NC, [b]USDM Life Sciences, Santa Barbara, CA, [c]Avalere Health, Washington, DC, [d]Duke Clinical Research Institute, Durham, NC, [e]Mayo Clinic, Rochester, MN, [f]Medtronic Corporation, Minneapolis, MN, [g]North Shore Long Island Jewish – Lenox Hill Hospital, New York, NY, and [h]Mercy Health, Chesterfield, MO.
[i]Formerly Center for Devices and Radiological Health, US Food and Drug Administration, Silver Spring, MD.
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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.
Submitted December 18, 2013; accepted July 2, 2014.
Reprint requests: Joseph P. Drozda Jr, MD, Center for Innovative Care – Mercy, 14528 South Outer Forty, Chesterfield, MO 63017.
E-mail: Joseph.Drozda@Mercy.net
0002-8703
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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.

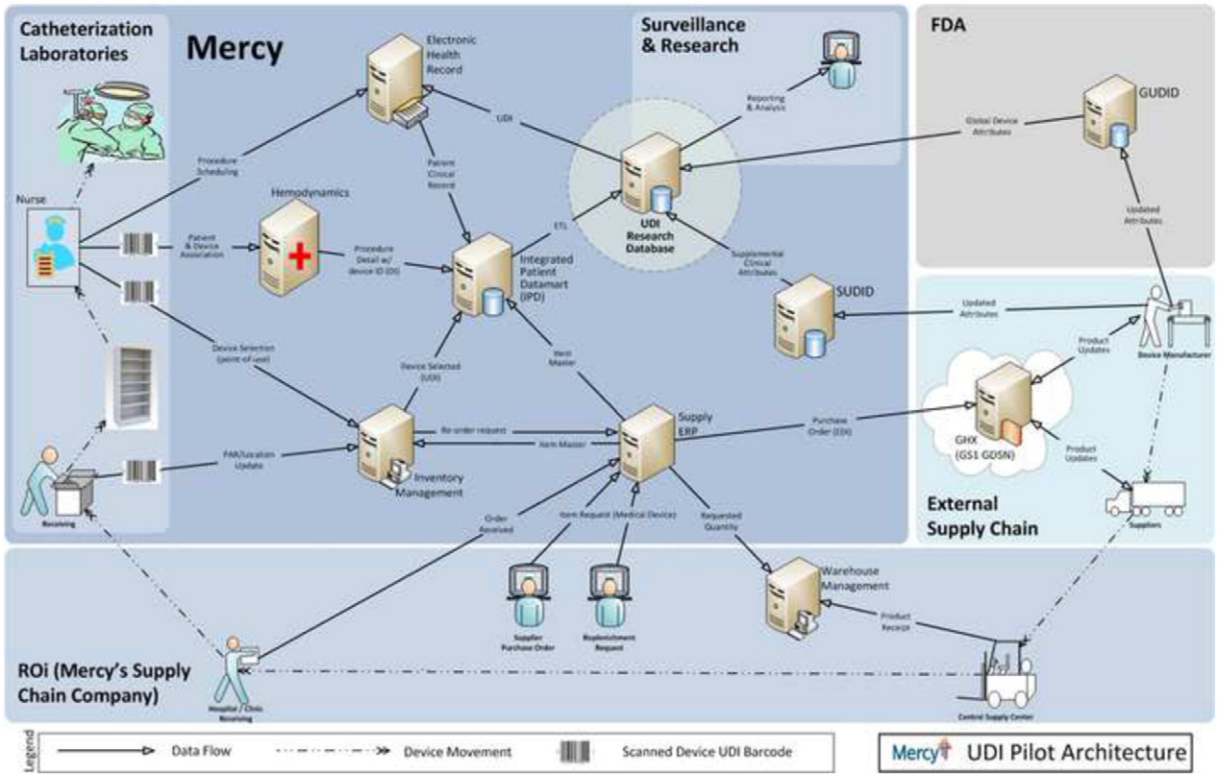
The demonstration project and Mercy Health

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

Figure 1



Coronary stent UDI tracking system—The arrows represent UDI data flow starting with the assignment of a UDI by a supplier, moving through the market place (GHX) into Mercy's supply chain and electronic health record systems. Arrows also illustrate movement of device attribute data from the Food and Drug Administration's Global Unique Device Identifier Database, Supplemental Unique Device Identifier Database, and the electronic health record into a research and surveillance database (UDIR). ERP, Enterprise Resource Processing Software; GDSN, Global Data Sychronisation Network: a network of companies and suppliers built around the GS1 Global Registry that allows for sharing device identification data (http://www.gs1.org/gdsn); GHX, a multistakeholder owned company whose purpose is to optimize health care supply chain efficiency (http://www.ghx.com/); GS1, one of the companies that set standards for the display of device identifiers including bar codes (http://www.gs1.org/); ROi, Mercy's supply chain company.

as the test environment for modeling the incorporation of UDI data into health system information management solutions. The system design for the demonstration project is depicted in Figure 1. The approach envisions an end-to-end (manufacturer to point of consumption) UDI tracking system with incorporation of UDI data into the Mercy supply chain, catheterization laboratory, EHR, and associated information systems. Ultimately, a data set containing both EHR clinical data and UDI-associated device attribute data will be created for surveillance and research purposes. Data from clinical and supply chain systems are anticipated to be available in a more timely fashion than claims data, making this approach more suitable for device surveillance. This approach also anticipates the establishment of a larger network spanning multiple health systems that uses a national device registry as the hub for the sharing of UDI and UDI-related data sets. This will necessarily drive the specification and establishment of data-sharing protocols, controlled vocabularies, and research methodologies to be used by the network. Of note, these latter 2 phases are out of scope for this demonstration project.

Data reflecting key clinically relevant coronary stent device attributes (such as stent design, composition, and dimensions) are included in the flow of data. Given that these data may not be included as discrete data in the GUDID, it was recognized that supplemental attributes would be needed to satisfy the data requirements of the potential uses of this information. Having this information readily available through the association of data with UDIs and joining it with clinical data from the EHR will enable a robust system of device surveillance and research. For the demonstration project, the supplemental attributes are to be housed at Mercy in a reference database termed the Supplemental UDI Database (SUDID). As described below, selection of the supplemental attributes was a work product of the expert panel and the expert workgroup meeting attendees.

Table II. Demonstration project work group members

Expert panel members
James Tcheng, MD, FACC, FSCAI, chair, Duke University Medical Center
Kirk Garratt MSc, MD, FACC, FSCAI, Lenox Hill Heart and Vascular Institute of New York
Kalon K.L. Ho, MD, MSc, FACC, FACP, FSCAI, FAHA, Beth Israel Deaconess Medical Center
John McB. Hodgson, MD, FACC, FSCAI, Technology Solutions Group
J. Brent Muhlestein, MD, FACC, FAHA, Intermountain Medical Center Cardiology
FDA
Jay Crowley, MS, senior advisor for patient safety
Behnaz Minaei, public policy analyst
Terrie L. Reed, MS, director of informatics
Madris Tomes, MBA, PMP, UDI external program manager
Health system representatives
Mercy Health
Joseph P. Drozda Jr, MD, FACC, principal investigator, director of outcomes research
Curtis Dudley, vice president, integration technology solutions and account implementation
Paul Helmering, executive director, enterprise architecture
Priscilla Smith, project development specialist
Mitzi Sutton, director, operations Mercy Health research
Mayo Clinic
Joseph Dudas, MBA, vice chair, category management
Robert F. Rea, MD, cardiology
Intermountain Healthcare
J. Brent Muhlestein, MD, FACC, FAHA, Intermountain Medical Center Cardiology
Geisinger Medical Center
James Blankenship, MD, FSCAI, MACC, director, cardiology
Kevin Capatch, director of supply chain technology and process engineering
Deborah Templeton, RPh, MHA, vice president, supply chain services
Kaiser Permanente
Scott Adelman, MD, FACC, chair, cardiology technology committee, Northern California
Laurel Junk, MBA, vice president, supply chain
Manufacturer representatives
Abbott Vascular
Judith Fairchild, BSN, RN, MBA, director, AV quality
Krishna Sudhir, MD, PhD, FRACP, FACC, divisional VP, medical affairs and product performance
Boston Scientific Corporation
Dominic Allocco, MD, FACC, vice president, clinical, division of interventional cardiology
Medtronic
Roberta Dressen, MBA, vice president, Global Post Approval Network
Kweli P. Thompson, MD, MPH, group vice president of clinical research for the cardiac and vascular group
Professional societies
ACC
Kathleen Hewitt, MSN, RN, CPHQ, associate vice president
Society for Cardiovascular Angiography and Interventions
Joel Harder, director for quality initiatives and clinical documents
NCDR
Nichole Kallas, MLIS, CCBA, associate director, IT business analyst

Multiple Mercy information systems are being extended to incorporate UDI data for the demonstration project. These include the Item Master (Infor Lawson, New York, NY) contained in the Mercy Lawson S3 Enterprise Resource Planning supply chain software solution, the cardiac catheterization laboratory clinical reporting software solution (Merge/Camtronics, Merge Healthcare, Chicago, IL)[10], and the EHR (EpicCare, Epic, Verona, WI).[11] Unique device identifier data will be sent from these systems to be aggregated in the Mercy Integrated Patient Data database with attribute data from the SUDID, GUDID, and patient-level clinical data aggregated to create an analysis data set. Unique device identifier information retained in these systems will be available to clinicians, allowing for links to current product and recall information at the patient level. Finally, the catheterization laboratory software will transmit the UDI to the ACC National Cardiovascular Data Registry (NCDR) CathPCI Registry along with the standard set of data required for registry participation. This will enhance the ability of the NCDR to link with other data sets containing the UDI (eg, claims) and allow for evaluation and modeling in safety surveillance and device research.

Expert panel and expert workgroup proceedings

Participants

Critical to the demonstration project and to the larger UDI strategy was the establishment of a partnership of key stakeholders of coronary stent UDI-associated data. For this reason, we identified pertinent stakeholders and invited representatives to participate in an expert workgroup in-person meeting and follow-up teleconferences. These included stent manufacturers, health system supply chain divisions, cardiology professional societies, and the NCDR. Specifically, the 3 companies manufacturing all of the FDA-approved coronary stents marketed in the United States at the beginning of the project (Abbott Vascular, Abbott Park, IL; Boston Scientific, Natick, MA; and Medtronic, Minneapolis, MN) agreed to participate. In addition to Mercy, 4 large health systems of the Healthcare Transformation Group (Geisinger, Intermountain Healthcare, Kaiser Permanente, and Mayo Clinic) were engaged to ensure generalizability. Finally, the ACC, the Society for Cardiovascular Angiography and Interventions, and NCDR were solicited to participate in various aspects of the demonstration project. Representatives from each of these stakeholder entities comprised the membership of the expert workgroup.

The expert workgroup meeting was led by 5 interventional cardiologists (the expert panel) selected via recommendations of the ACC and Society for Cardiovascular Angiography and Interventions and vetted per the ACC relationships with industry policy.[12] The members of the expert panel and other members of the expert

Table III. SUDID clinical attributes and parameters

Attribute	Definition	Parameter	Data type
Length	Nominal length per manufacture specification	Fractional dimension in mm	4 Significant digits, w/ 1 precision
Diameter	Nominal (inner) diameter per manufacturer specification	Fractional dimension in mm	4 Significant digits, w/ 2 precision
Nonconventional property	Stent having nonconventional design, variable or multiple length/diameter parameters	Covered stent Bifurcation stent Tapered stent	Alphanumeric
Structural material	Composition of principal structural element	Constrained list eg, L605 cobalt chromium –Constrained list to be developed	Alphanumeric
Coating(s)	Nonstructural material covering surface of structural element	Constrained list –Constrained list to be developed –Need to handle multiples –Name that would be mostly referenced –Start with what is in the IFU –Accommodate multiple coatings	Alphanumeric
Drug(s)	Active agent released from stent	NDC directory (default) –Use name if no applicable NDC code—do it uniformly	Alphanumeric
Strut thickness	Maximum nominal thickness of stent struts on a radius from the center of the stent	Dimension in microns	4 Integer digits
Surface/artery ratio*	Percentage of the surface area of the artery covered by the stent at nominal expansion of the stent		3 Significant digits, w/ 1 precision
Expansion method	Method used to achieve nominal stent deployment	Balloon self	Alphanumeric
MRI compatibility†	MRI compatibility category per testing	4 categories per existing standard: –Safe –Conditional –Unsafe –Not tested	4 Categories

Abbreviations: w/, With; *IFU*, instructions for use; *NDC*, national drug code.
* This attribute was originally selected by the expert panel but subsequently withdrawn.
† Subsequent to its selection for its inclusion in the SUDID, this attribute was also added to the GUDID.

workgroup are listed in Table II. Of note, although we believe the opinions and recommendations described herein reflect the consensus of the expert workgroup on behalf of the health care community, these do not necessarily reflect the policies or positions (nor the formal endorsement) of the participating organizations.

Purpose

The expert panel identified 5 primary tasks for the expert workgroup:

- Review the FDA UDI system proposed rule (FDA-2011-N-0090-0001) and gain a greater understanding about FDA expectations of manufacturers, researchers, providers, and other stakeholders.
- Identify and describe the use cases where UDI-associated data would be essential or useful.
- Identify key device attributes of coronary stents not included in the FDA GUDID data set that would need to be systematically managed in an SUDID.
- Discuss approaches to the operations and governance of a permanent SUDID system.
- Discuss future opportunities to leverage the findings and recommendations of the demonstration project, including the incorporation of SUDID and EHR data into a distributed data-sharing network and the governance and operational issues related to such a network.

Proposed supplemental stent-specific attributes

The expert panel was tasked with identifying supplemental coronary stent attributes not captured in the GUDID that would be needed in ≥1 of the dimensions of patient care, process and quality management, and clinical outcomes assessment. The task of selecting this high-value set of attributes was accomplished with substantial input from the entire expert workgroup. The panel identified several dozen potential attributes and agreed upon 10 for the coronary stent SUDID (Table III). An unexpected finding was that the attributes (save 1) selected to be included in the SUDID data set are publically available. The single attribute (stent surface/artery ratio) not publically available was removed from the list of attributes to complete the demonstration project in the required timeframe (see below). Examples from each manufacturer of the resulting SUDID data set data corresponding to a 2.5 × 8-mm stent is shown in Table IV.

Use cases

To test the validity of GUDID and SUDID data, another key task of the expert workgroup was to develop a list of representative use cases for UDI data. The workgroup

Table IV. Examples of SUDID clinical attribute data

Manufacturer	Product	Length	Diameter	Nonconventional property
Abbott	Xience V Everolimus Eluting Coronary Stent System	8 mm	2.5 mm	N/A
Boston Scientific	Taxus Express Monorail	8 mm	2.50 mm	N/A
Medtronic	Resolute Integrity Zotarolimus-Eluting Coronary Stent System	8 mm	2.50 mm	N/A

Abbreviation: *N/A*, Not applicable; SIBS, poly(styrene-b-isobutylene-b-styrene)

was asked to articulate use cases where UDI data would be required and determine which device attributes in the GUDID and SUDID data sets would be needed to support each use case. The expert workgroup identified 18 use cases and determined whether each use case could be supported with only GUDID data or if SUDID attributes were also needed (Table V). A key and unexpected observation was that the use cases could be divided into 2 groups: ones where only GUDID data are needed and ones where both data from the GUDID and the SUDID are required. The relevance of the SUDID data set was confirmed as many use cases will not be satisfied by only the data maintained in the GUDID data set.

Industry perspectives and concerns

Expert workgroup discussions included perspectives raised by the industry participants related to the requirements of the demonstration project itself and to the future development of a device surveillance and research data-sharing system.

Burden of providing and maintaining SUDID data. Although the specific data for the 9 supplemental attributes are in the public domain, the preparation of this material for submission and upload to the prototype SUDID system required resources. Scaling and sustaining this process for all devices in perpetuity will potentially be challenging and burdensome, particularly without a single, centralized SUDID system.

Concerns about analytics methodologies. Industry representatives and other expert workgroup participants pointed out the need to establish a system of review to ensure the adequacy of methodologies used in analyses of data aggregated via data-sharing networks. The challenges of using observational data, particularly biases and unrecognized confounding, were acknowledged by the workgroup. For example, irregular follow-up and incomplete data capture can be expected to deprecate the quality, validity, and accuracy of longitudinal follow-up data acquired via EHR systems. Linked administrative and claims data may reduce, but will likely not eliminate, ascertainment bias and other confounders.

Privacy concerns. The proposed data-sharing network raises potential ethical and legal issues with respect to the sharing of SUDID data. For instance, who should host or maintain these data sets and who should have access to them? A related dimension is information considered proprietary by a manufacturer, which the workgroup concluded should be protected from discovery. For instance, although the demonstration project is being performed with a well-established and studied technology (coronary stents), 1 potential supplemental data element, stent/artery ratio, was considered proprietary. In the end, this attribute was removed from the SUDID list for this reason and because the clinical relevance was unclear. Of note, this paradigm may not hold true for newer technologies where the need for postmarket surveillance and research is even more pressing. An example from the coronary stent arena is the anticipated market release of bioabsorbable stents and bioabsorbable polymer drug-eluting stents, where a priori knowledge of additional stent attributes may prove beneficial. The specific mechanisms for dealing with clinically important but proprietary device attributes will need to be discussed and resolved.

Future development of a UDI-based device surveillance system

The expert workgroup took advantage of the face-to-face meeting to initiate discussions about the creation of a robust system of postmarket device surveillance and research using UDI-associated attributes and clinical data from EHRs and national registries. Expanding the current demonstration project with coronary stents to include interchange of UDI data with the NCDR CathPCI Registry among all of the participating health systems was proposed by Mercy as a way of testing the strategy of a distributed data network.[13]

The utility of the UDI system in postmarket device surveillance and research would be substantially enhanced by a distributed network of health system databases containing both EHR and UDI-associated device data linked to the CathPCI Registry, which would function as the hub[14] (Figure 2). It was envisioned that this model should be applicable to other classes of implanted devices.

Additional discussion topics

The expert workgroup engaged in discussions of several other important issues related to the establishment of a robust system of medical device surveillance that are summarized in the online Appendix. The topics discussed included the following:

- Technological and operational framework of SUDID
- Data ownership and governance of SUDID services
- Financial support of SUDID services
- Conceptual model of a distributed network.

Structural material	Coating(s)	Drug(s)	Strut thickness	Expansion method	MRI compatibility
L-605 cobalt chromium alloy	Everolimus and polymers	Everolimus	0.0032 in 81 μm	Balloon	Conditional
316L SS	Translute polymer (SIBS)	Paclitaxel	132 μm	Balloon	Conditional
MP35N cobalt alloy	Biolynxpolymer and parylene	Zotarolimus	88.9 μm	Balloon	Conditional

Table V. Use case attributes

Use case name	Description	Attributes needed (GUDID/SUDID)
Point of care UDI scan	Query device attributes immediately prior to use	GUDID & SUDID
Catalog/device ordering	Ordering by attribute, device, substitution, tracking devices in disasters	GUDID & SUDID
Medical documentation	Procedure reporting, health care communication	GUDID & SUDID
EHR/patient portal	Attributes stored as data outside procedure report, patient education	GUDID & SUDID
Queries (by attribute)	Support for process measurement, QI projects	GUDID & SUDID
Extending indications for use	Support of alternative processes for device labeling	GUDID & SUDID
CER	Support of comparative effectiveness	GUDID & SUDID
Registries	Process, performance, quality outcomes, education, performance improvement CME	GUDID & SUDID
PHR/consumer	Information to patient, education, public communication, health care advocates	GUDID & SUDID
Supply chain management	Competitive bidding by attributes	GUDID & SUDID
Advance notice of expiration	Inventory management	GUDID
Administrative uses	Asset and financial management	GUDID
Device recall	Easily identify patients who received the affected lots and locate unused product in clinical use areas	GUDID
Federated data exchange	Increased ability to report outcomes across products	GUDID
Adverse event reporting	Increased ability to report adverse events and outcomes	GUDID
Anticounterfeiting	Increased protection against fraud	GUDID
Tracking of patients with multiple devices	Allow providers to learn information about prior device implantation, even when prior medical records are not available	GUDID
Federal (postmarket surveillance)	Specify device exposure and usage for linkage with safety and research outcomes	GUDID

Abbreviations: *QI*, Quality improvement; *CER*, Comparative effectiveness research; *CME*, Continuing medical education; *PHR*, Personal health record.

Summary

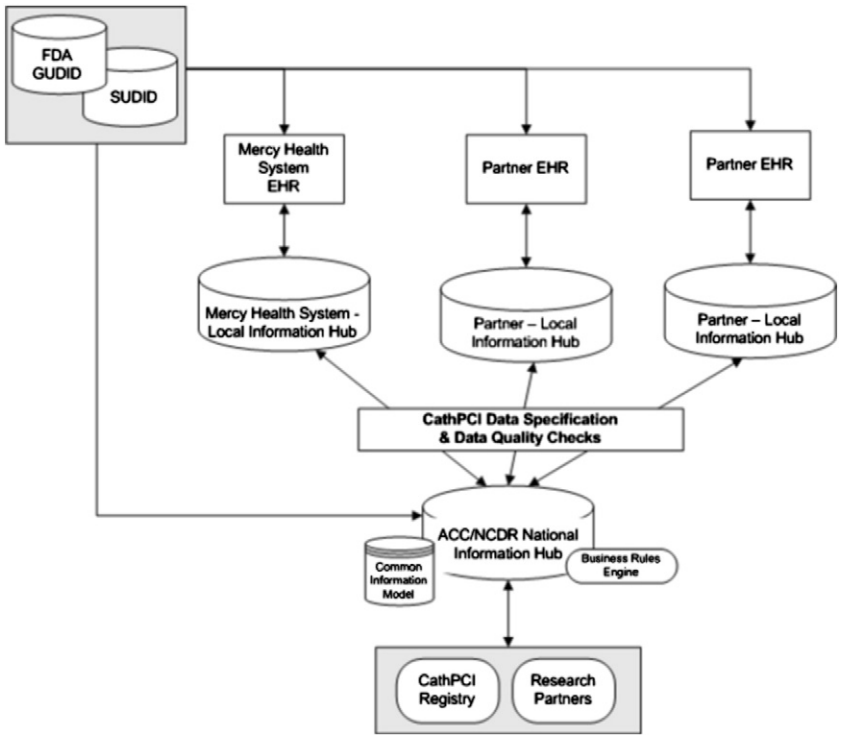
We have described the specifics of a demonstration project for the implementation of coronary stent UDI-associated data in the information systems of a multihospital health system. We anticipate that the systematic redesign of enterprise information systems will improve operational and supply chain efficiencies, facilitate the care of patients, provide interoperable data that can be linked via registries such as the NCDR CathPCI Registry, and enable postmarket device surveillance and research. A key aspect of the demonstration project is the creation of a functioning partnership of key stakeholders, that is, manufacturers, health systems, FDA, the NCDR Registry, and professional societies representing product users. We believe the model we have created for this demonstration project will have applicability across additional device types, although that hypothesis will have to be tested with other devices and in specialties outside cardiology.

Future proposed work after the demonstration project includes the following:

- Incorporation of coronary stent UDI-associated data into the EHRs and other coronary stent data sets of the other large health systems of the expert workgroup
- Actualization of a shared, distributed network of health system data sets with the CathPCI Registry as the hub
- Development of appropriate methodologies for analyzing data generated by the network while assuring privacy of the data
- Expansion of the work to other devices, for example, implantable cardioverter defibrillator and orthopedic devices
- Development of methodologies for capturing patient-reported data on device performance.

In conclusion, although medical devices are among the most efficacious treatments of chronic disease, these

Figure 2



Coronary stent distributed data sharing network—Attribute data from the Global Unique Device Identification Database and Supplemental Unique Device Identification Database are incorporated into health system electronic health records. Device-related data from the electronic health records and other internal systems are integrated into Local Information Hub data sets. The Local Information Hubs are linked to the CathPCI Registry and researchers through the American College of Cardiology/National Cardiovascular Drug Registry National Information Hub, which provides data specifications including a common data model and a business rules engine along with data quality checks. CER, Comparative Effectiveness Research.

devices commonly have high financial cost and can have disabling and occasionally fatal device-related adverse events. The need to monitor device performance closely in "the real world" has never been greater. The ability to quickly track use of a specific device to high (or low) adverse clinical event rates should enhance quality of care, improve the ability of manufacturers and regulatory bodies to respond promptly, and facilitate clinical research. Current methods for device tracking are inefficient, cumbersome, and incomplete.[15,16] The demonstration project described herein envisions the development of a more robust UDI-based postmarket device surveillance system that can both address these concerns and support the ongoing development of life-improving and life-saving technologies.

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Disclosures

Dr Thompson is an employee of Medtronic, Inc. Mr Crowley is an employee of USDM Life Sciences. Ms Tomes is an employee of Avalere. Dr Garratt is a consultant for Boston Scientific Corporation and The Medicines Company and has equity holdings with Infarct Reduction Technologies (IRT). Dr Drozda's son is a sales representative for Boston Scientific Corporation. All other authors have no relevant relationships with industry to declare.

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Glossary

CathPCI Registry: An National Cardiovascular Data Registry of diagnostic cardiac catheterization and percutaneous coronary intervention procedures.

Controlled vocabulary: A carefully selected and vetted list of words (or terms) that describe units of information. The purpose of controlled vocabularies is to enable and facilitate information communication and knowledge retrieval. Examples of controlled vocabularies include subject indexing schemas, subject headings, thesauri, taxonomies, and other knowledge organization systems. In contrast to natural language (where there are no restrictions on vocabulary), controlled vocabularies require the use of predefined, authorized, and constrained terms to capture and convey information.

Enterprise Resource Planning software: A business process management software that allows an organization to use a system of integrated applications to manage the business and automate back office functions. Enterprise Resource Planning software integrates all facets of business operations, including human resource and supply chain management.

Global Unique Device Identification Database: A publicly searchable database administered by the FDA that will serve as a reference catalog for every device with an identifier and that contains device attributes such as "contains latex" or magnetic resonance imaging compatibility. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/default.htm.

Item Master: A master record for a type of inventory item. The item master includes the item description, materials and handling specifications, sales and fulfillment specifications, and warehouse-specific information. The term is commonly used to refer to a document or database containing such information on all items that an organization has in inventory.

Lawson S3: The brand of the Enterprise Resource Planning supply chain software used by Mercy.

Mercy Integrated Patient Data: Inclusive of clinical, administrative, and operational data derived from multiple data sources across the Mercy Health system and housed together in a database.

Merge: The brand of cardiac catheterization laboratory clinical reporting software solution used by Mercy (Camtronics).

Supplemental UDI Database: A reference database similar to the GUDID that contains attributes specific to a particular class of devices, for example, coronary stents.

Unique Device Identifier: A unique numeric or alphanumeric code that contains 2 types of information: a device identifier, which is specific to a device model, and a production identifier, which includes the current production information for that specific device, such as the lot or batch number, the serial number, and/or expiration date. Although the UDI will appear on the label and packaging of devices, in some cases, the UDI would be marked on the device itself (eg, implantable devices and devices that are intended to be used multiple times and sterilized after each single use). Low-risk devices that are not completely exempted from the rule will only be required to have a device identifier on their labels. http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm310872.htm.

Use case: A description of the set of interactions between and among actors (eg, humans, roles, or information systems) that are needed to achieve a specific task or goal.

Appendix. Technological and operational framework of SUDID

For the Demonstration Project, Mercy will create and operate a prototype SUDID. If this approach proves successful, a permanent and sustainable solution for storing and accessing clinically relevant supplemental attributes will need to be created and an organization empowered to manage SUDID operations. The Expert Workgroup deliberated on the best approach for providing a permanent SUDID solution and associated services. In addition, the Workgroup recognized that the generalizability of their recommendations with respect to the technological and operational framework of the coronary stent SUDID would require testing in other device types and specialty areas as a single SUDID solution for all devices may not be sufficient or appropriate.

Organization to provide SUDID services

The Expert Workgroup reached agreement that there were 3 logical options for managing SUDID operations. Firstly, there was consensus that the FDA should continue to be involved in operations as well as governance in order to ensure ongoing coordination between the SUDID and GUDID. The option of actually housing the data at FDA and integrating the collection of the supplemental attributes into the FDA process for collecting GUDID device attributes was strongly favored as a means of simplifying data submission for manufacturers. In this scenario, the GUDID and SUDID would be stand-alone databases with different processes for determining the content and operations of each.

However, as a regulated governmental entity, the activities and actions of FDA are not necessarily in concert with the extended needs of the manufacturing, clinical, and research environments. The processes that the FDA is required to follow could result in challenges to the nimbleness of the SUDID, making clinically relevant modifications of the database cumbersome. Particularly problematic is the differential between FDA-approved indications and actual real-world (particularly off-label) uses of devices, a difference that could limit the FDA's ability to provide device-specific SUDID information for use in analyzing device performance and might require specific regulatory authorization.

A second option was for medical professional society registries such as the NCDR to manage SUDID operations. NCDR, being an established national repository for cardiac procedural data with an extensive record of high-quality data analysis and publication, would bring many advantages to providing SUDID services. NCDR is already positioned to systematically collect stent implantation data, and having the SUDID operationally close to the NCDR and readily available to registry users should provide a data management advantage. Also, as there are a multitude of implantable devices used in the cardiovascular space, another advantage is extensibility and scalability to other classes of cardiovascular devices. While the SUDID would be a stand-alone database and function independently of the NCDR registries, proximity would foster integration of the SUDID data with registry datasets that would facilitate outcomes and CER. Establishing NCDR administration of an SUDID related to cardiac interventional products could serve as a template for future development of similar relationships between non-cardiovascular product SUDIDs and other specialty registries. However, the NCDR focus on cardiovascular medicine could make generalizability to other branches of medicine a challenge.

Finally, the possibility of a third party contractor to manage SUDID operations was discussed. It was observed that there are existing organizations which have commercialized databases that are self-sustaining through licensing fees. Examples include GHX, IMS, and First Data Bank. An important consideration in utilizing such an organization for database operations is that the for-profit entities might be more likely to make the initial investment necessary for "start-up" while not-for-profits would likely need seed money from donations or grants.

SUDID operational considerations

Any organization responsible for SUDID operations will face the task of making SUDID data readily available to users. Determining whether real-time data are needed or whether the users would be best served with periodic downloads of the data will be important and is a question being explored in the Demonstration Project. The need for real-time access to the information should also be balanced against the time needed for quality checks, data matching, and validation. For example, Web services have the ability to provide data immediately to the user, but are reliant upon network connectivity and system availability. Managing data locally through a cached process may improve data availability at the cost of synchronization with the authoritative source of information.

It was concluded that the ultimate solution for SUDID operations must consider end-to-end needs, meet stakeholder requirements, and be generalizable to other device types. Understanding the potential relationships between EHRs, clinical software (e.g. catheterization procedure documentation and reporting systems) and the SUDID at the outset of system creation will allow it to be built in a scalable manner that will meet future needs. Creating a system that is easily populated, maintained, and relevant is of the utmost importance. The data interoperability standards need to ensure that data are uniform and consistent, and the SUDID itself must be replicable for devices outside coronary stents.

Data ownership and governance of SUDID services

Data ownership and database governance with respect to a permanent solution were recognized as important issues to discuss at this early stage in SUDID development in order to increase transparency and to build trust among the stakeholders. With respect to data ownership, the attributes used to build the database are publically available although the specifications of the data were originally generated by the manufacturers and are thus "owned" by the manufacturers. An SUDID system thus serves as a data aggregation service, facilitating public access to these data without altering ownership of the data itself.

It was recognized that governance of the SUDID and related services is a question separate from ownership of the data itself. SUDID services encompass the process by which attributes are chosen and kept current along with the functionalities that make the attributes available to users for incorporation into EHRs, registries, and device databases. Governance of the SUDID and related services refers to the organizational structure and processes by which policy decisions are made regarding the content of the database and the scope and nature of SUDID services. The governing body has ultimate responsibility for and authority over the SUDID and would be established by the entity or entities that have ownership of the database.

The group identified 4 potential options for database governance. The first was establishing the Expert Panel as the governing body. The second was a multi-stakeholder executive committee or governing board derived from the Expert Workgroup's participating organizations; and the third was a not-for-profit, possibly international entity. Finally, the FDA was discussed as the potential governing body, although it was felt that the Agency might be challenged in this capacity for reasons noted previously.

Financial support of SUDID services

Potential funding mechanisms considered for supporting the SUDID were: cost sharing, public support, industry support, subscription fees, or a combination of these mechanisms. Arguably, costs should be shared by those who benefit from the SUDID service. These include hospitals, industry, FDA and other governmental entities, and individual data consumers (e.g., clinicians, patients). The FDA is currently covering the costs of GUDID services, and a publically supported approach to SUDID services would seem to be a financially beneficial choice since FDA could facilitate submission and storage of SUDID data and coordinate it with GUDID data submission. This would also minimize incremental costs to industry. Industry user fees or subscription user fees are also possible alternatives including fees for those outside of the data sharing surveillance network.

Conceptual model of a distributed network

It was suggested during Expert Workgroup deliberations that the proposed distributed network should leverage existing common data models and network approaches rather than building and implementing new solutions. Existing data models that may prove useful include the Observational Medical Outcomes Partnership (OMOP) Common Data Model.[17] OMOP was a public-private partnership established by the Foundation of the National Institutes of Health involving Pharmaceutical Research and Manufacturers of America (PhRMA) and FDA for the primary purpose of supporting pharmaceutical surveillance and research.[18] The OMOP data model has been transitioned through the Reagan-Udall Foundation to the Observational Health Data Sciences and Informatics Program at Columbia University.[19]

3M's Healthcare Data Dictionary (HDD) platform[20] or the data sharing model of the Agency for Healthcare Research and Quality (AHRQ) sponsored DEcIDE Network[21] are other options. The Workgroup agreed to explore the possibility of establishing a data sharing network involving the health systems participating in the current Demonstration using a common data model although this work is out of scope for the current Demonstration Project.

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