Unique device identifiers (udis) for coronary stent post-market surveillance and research: A report from the fda's medical device epidemiology network (mdepinet) udi demonstration

James E. Tcheng MD, Jay Crowley MS, Madris Tomes MBA, Terrie L. Reed MS, Joseph M. Dudas MBA, Kweli P. Thompson MD, Kirk N. Garratt MD, Joseph P. Drozda Jr. MD

PII: S0002-8703(14)00405-0
DOI: doi: 10.1016/j.ahj.2014.07.001
Reference: YMHJ 4667

To appear in: *American Heart Journal*

Received date: 18 December 2013
Accepted date: 2 July 2014

Please cite this article as: Tcheng James E., Crowley Jay, Tomes Madris, Reed Terrie L., Dudas Joseph M., Thompson Kweli P., Garratt Kirk N., Drozda Jr. Joseph P., Unique device identifiers (udis) for coronary stent post-market surveillance and research: A report from the fda's medical device epidemiology network (mdepinet) udi demonstration, *American Heart Journal* (2014), doi: 10.1016/j.ahj.2014.07.001

Unique Device Identifiers (UDIs) for Coronary Stent Post-market Surveillance and Research: A Report from the FDA's Medical Device Epidemiology Network (MDEpiNet) UDI Demonstration

James E. Tcheng, MD[1] Jay Crowley, MS[2], Madris Tomes, MBA[3], Terrie L. Reed, MS[4], Joseph M. Dudas, MBA[5], Kweli P. Thompson, MD[6] , Kirk N. Garratt, MD[7], Joseph P. Drozda, Jr, MD[8], on behalf of the MDEpiNet UDI Demonstration Expert Workgroup

[1]Duke University Medical Center, Durham, NC, [2]USDM-Life Sciences, Santa Barbara, CA (formerly [2]Center for Devices and Radiological Health, Food and Drug Administration, Silver Spring, MD), [3]Avalere Health, Washington, DC (formerly Center for Devices and Radiological Health, US Food and Drug Administration, Silver Spring, MD), [4]Duke Clinical Research Institute, Durham, NC (formerly Center for Devices and Radiological Health, US Food and Drug Administration, Silver Spring MD), [5]Mayo Clinic, Rochester, MN, [6]Medtronic Corporation, Minneapolis, MN, [7]North Shore Long Island Jewish - Lenox Hill Hospital, New York, NY, [8]Mercy Health, Chesterfield, MO

Contract Acknowledgement: This work is supported by contract DHHS/FDA-22320172C from the Center for Devices and Radiological Health, USA Food and Drug Administration.

Relationship with Industry: 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 and 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.

Short Title: Coronary Stent FDA Demonstration Panel Report

Word Count: 4643 (exclusive of appendix)

Appendix Word Count: 1468

References: 16

Figures/Tables: 7

Address for Correspondence:

Joseph P. Drozda, Jr., M.D.

Center for Innovative Care - Mercy

14528 South Outer Forty

Chesterfield, MO 63017

314-628-3864

Fax: 314-628-3471

Joseph.Drozda@Mercy.net

Abstract

Background. While 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 healthcare, the U.S. Food and Drug Administration (FDA) funded the Medical Device Epidemiology Network (MDEpiNet) initiative, including a Demonstration of the implementation of coronary stent UDI data in the information systems of a multi-hospital 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 (ACC) and the Society for Cardiovascular Angiography and Interventions (SCAI) was convened with representatives of industry, health system members of the Healthcare Transformation Group, the ACC National Cardiovascular Data Registry and FDA to articulate concepts needed to best use UDI-associated data. The Expert Panel identified three: 1) use cases for UDI-associated data (e.g., research), 2) a supplemental dataset of clinically relevant attributes (e.g., 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 (GUDID), nine 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.

Introduction

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 (UPC) 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 healthcare costs.

For several years, the U.S. 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 system in April, 2013.[5] The FDA Unique Device Identifier (UDI) final rule, published September 24, 2013, specifies that most devices are to include a numeric or alphanumeric code on the label, comprised of a device identifier specific to the device model or version, along with production (e.g., 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 1.[7] Data in the GUDID are to be specific to the level of the model and version of the device. Additionally, the Office of the National Coordinator for Health Information Technology has included the electronic capture and interchange of the UDI in its draft 2015 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 (WEDI), the information technology advisor to the Department of Health and Human Services.[8]

To accelerate improvements in post-market device surveillance, the FDA created the Medical Device Epidemiology Network (MDEpiNet), a collaborative through which the FDA Center for Devices and Radiological Health (CDRH) and external partners share information and resources to enhance our understanding of the post-market 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 multi-stakeholder Expert Workgroup in articulating the principles and approaches of the Demonstration Project. This paper 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, D.C., on August 6 and 7, 2012, and the teleconference discussions were held in October and November, 2012.

The Demonstration Project and Mercy Health

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 multi-hospital 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 post-market surveillance using the UDI.

Mercy Health is a 4 state integrated delivery system headquartered in St. Louis, Missouri 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. Five of Mercy's 34 hospitals have cardiac catheterization laboratories that collectively implant over 5,000 coronary stents annually. Mercy Health is serving 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, electronic health record (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 datasets. 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.

Multiple Mercy information systems are being extended to incorporate UDI data for the Demonstration Project. These include the Item Master contained in the Mercy Lawson S3 Enterprise Resource Planning (ERP) supply chain software solution; the cardiac catheterization laboratory clinical reporting software solution (Merge/Camtronics)[10]; and the EHR (EpicCare)[11]. UDI data will be sent from these systems to be aggregated in the Mercy Integrated Patient Data (IPD) database with attribute data from the SUDID, GUDID and patient level clinical data aggregated to create an analysis dataset. UDI 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

datasets containing the UDI (e.g., 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 US 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 (SCAI) 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 SCAI and vetted per the ACC Relationships With Industry policy.[12] The members of the Expert Panel and other members of the Expert Workgroup are listed in Table 2. Of note, while we believe the opinions and recommendations described herein reflect the consensus of the Expert Workgroup on behalf of

the healthcare community, these do not necessarily reflect the policies or positions (nor the formal endorsement) of the participating organizations.

Purpose

The Expert Panel identified five primary tasks for the Expert Workgroup:

- Review the FDA Unique Device Identification 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 dataset 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 one or more 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 ten for the coronary stent SUDID (Table 3). An unexpected finding was that the attributes (save one) selected to be included in the SUDID dataset are publically available. The single attribute (stent surface to artery ratio) not publically available was removed from the list of attributes in order to complete the Demonstration Project in the required timeframe (see below). Examples from each manufacturer of the resulting SUDID dataset data corresponding to a 2.5mm x 8mm stent is shown in Table 4.

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 was asked to articulate use cases where UDI data would be required and determine which device attributes in the GUDID and SUDID datasets 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 5). 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 dataset was confirmed as many use cases will not be satisfied by only the data maintained in the GUDID dataset.

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. While 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 employed 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 datasets 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, while the Demonstration Project is being performed with a well-established and studied technology (coronary stents), one potential supplemental data element, stent to 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 post-market 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 post-market device surveillance and research utilizing 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 post-market 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 a number of other important issues related to the establishment of a robust system of medical device surveillance that are summarized in the on-line 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.

Summary

We have herein described the specifics of a Demonstration Project for the implementation of coronary stent UDI-associated data in the information systems of a multi-hospital 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 post-market device surveillance and research. A key aspect of the Demonstration Project is the creation of a functioning partnership of key stakeholders, i.e., 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 of cardiology.

Future proposed work following the Demonstration Project includes the following:

- Incorporation of coronary stent UDI-associated data into the EHRs and other coronary stent datasets of the other large health systems of the Expert Workgroup
- Actualization of a shared, distributed network of health system datasets 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, e.g., implantable cardioverter-defibrillator and orthopedic devices
- Development of methodologies for capturing patient reported data on device performance

In conclusion, while medical devices are among the most efficacious treatments of chronic disease, these 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 post-market device surveillance system that can both address these concerns and support the ongoing development of life-improving and life-saving technologies.

Acknowedgement: The authors acknowledge the editorial assistance of Renata Slayton in preparation of this manuscript.

The authors are solely responsible for the drafting and editing of the paper and its final contents.

References

1. Normand SL, Hatfield L, Drozda J, Resnic FS. Postmarket surveillance for medical devices: America's new strategy. *BMJ.* 2012;345:e6848.

2. Gross TP, Crowley J. Unique device identification in the service of public health. *N Engl J Med.* Oct 2012;367(17):1583-1585.

3. Strengthening our National System for Medical Device Postmarket Surveillance. 2012; http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301924.pdf. Accessed October 8, 2012.

4. Roadmap for Implementation of UDI System. [Internet]. 2012; http://www.imdrf.org/workitems/wi-udisystem.asp. Accessed July 23, 2013.

5. Commission recommendation of 5 April 2013 on a common framework for a unique device identification system for medical devices in the Union. 2013; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:099:0017:0024:EN:PDF. Accessed July 26, 2013.

6. Unique Device Identification System. A rule of the Food and Drug Administration. 2013; https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system. Accessed November 4, 2013.

7. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Surveillance and Biometrics, Informatics Staff. Global Unique Device Identification Database (GUDID), draft guidance for industry. September 24, 2013; http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf. Accessed February 19, 2014.

8. Department of Health and Human Services. Office of the Secretary. 45 CFR Part 170. Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements. 2014; http://www.gpo.gov/fdsys/pkg/FR-2014-02-26/pdf/2014-03959.pdf. Accessed February 29, 2013.

9. Medical Device Epidemiology Network Initiative (MDEpiNet). 2012; http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm. Accessed October 8, 2012, 2012.**10.** Merge Hemo (TM). Chicago, IL. 2013; http://www.merge.com/Solutions/Cardiology/Merge-Hemo.aspx. Accessed February 15, 2013.

11. Epic. Verona, WI. 2013; http://www.epic.com/. Accessed February 15, 2013.

12. Principles for Relationships with Industry. 2012; http://www.cardiosource.org/~/media/Files/ACC/Relationships%20with%20Industry/Principles%20for%20Relationships%20with%20Industry.ashx. Accessed November 20,2012, 2012.

13. Brown J, Syat B, Lane K, Platt R. Blueprint for a Distributed Research Network To Conduct Population Studies and Safety Surveillance - Research Report - Final | AHRQ Effective Health Care Program. *Effective Health Care Program Research Reports.* 2010;27.

14. Maro JC, Platt R, Holmes JH, et al. Design of a national distributed health data network. *Ann Intern Med.* Sep 2009;151(5):341-344.

15. FS R, ST N. Postmarketing surveillance of medical devices - filling in the gaps. *N Engl J Med.* 2012;366:875-877.

16. Kramer DB, Xu S, Kesselheim AS. Regulation of medical devices in the United States and European Union. *N Engl J Med.* Mar 1 2012;366(9):848-855.

Table 1: Selected Data Elements of the FDA Global Unique Device Identifier Database (GUDID)

- Primary device identifier number
- 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 (pre-market product classification)
- Marketing status
- For single-use
- MRI safety status

Table 2: 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, R.Ph., 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
American College of Cardiology
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

FDA = Food and Drug Administration; NCDR = National Cardiovascular Data Registry

Table 3: 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
Non-conventional 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 e.g. L605 cobalt chromium -- Constrained list to be developed	Alphanumeric
Coating(s)	Non-Structural 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 to 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 used to achieve nominal	Balloon	Alphanumeric

Method	stent deployment	Self	
MRI Compatibility‡	MRI compatibility category per testing	4 categories per existing standard: --Safe --Conditional --Unsafe --Not tested	4 Categories

*This attribute was originally selected by the Expert Panel but subsequently withdrawn

SUDID = Supplemental Unique Device Identifier Database; IFU = Instructions for Use; NDC = National Drug Code; MRI = Magnetic Resonance Imaging

‡Subsequent to its selection for its inclusion in the SUDID, this attribute was also added to the GUDID.

Table 4: Examples of SUDID Clinical Attribute Data

Manufacturer	Product	Length	Diameter	Non-conventional Property	Structural Material	Coating(s)	Drug(s)	Strut Thickness	Expansion Method	MRI Compatibility
Abbott	Xience V Everolimus Eluting Coronary Stent System	8mm	2.5mm	N/A	L-605 Cobalt Chromium Alloy	Everolimus and Polymers	Everolimus	0.0032'' 81 µm	Balloon	Conditional
Boston Scientific	Taxus Express Monorail	8mm	2.50mm	N/A	316L SS	Translute Polymer (SIBS)	Paclitaxel	132 µm	Balloon	Conditional
Medtronic	Resolute Integrity Zotarolimus -Eluting Coronary Stent System	8mm	2.50mm	N/A	MP35N Cobalt Alloy	Biolynxpolymer & Parylene	Zotarolimus	88.9 µm	Balloon	Conditional

SUDID = Supplemental Unique Device Identifier Database; MRI = Magnetic Resonance Imaging

Table 5: 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 of 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, healthcare 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
Anti-counterfeiting	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 (post-market surveillance)	Specify device exposure and usage for linkage with safety and research outcomes	GUDID

GUDID = Global Unique Device Identifier Database; SUDID; Supplemental Unique Device Identifier Database; UDI = Unique Device Identifier; EHR = Electronic Health Record; QI = Quality Improvement; CER; Comparative Effectiveness Research; CME = Continuing Medical Education; PHR = Personal Health Record

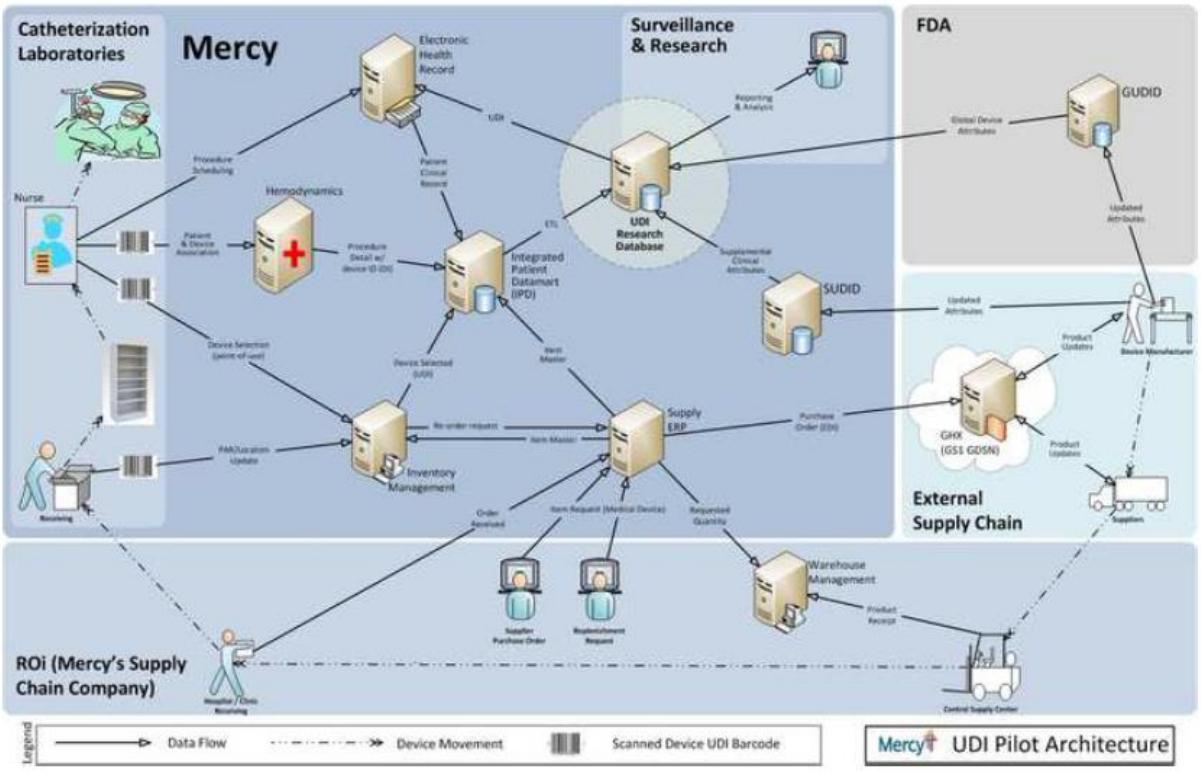

Figure 1

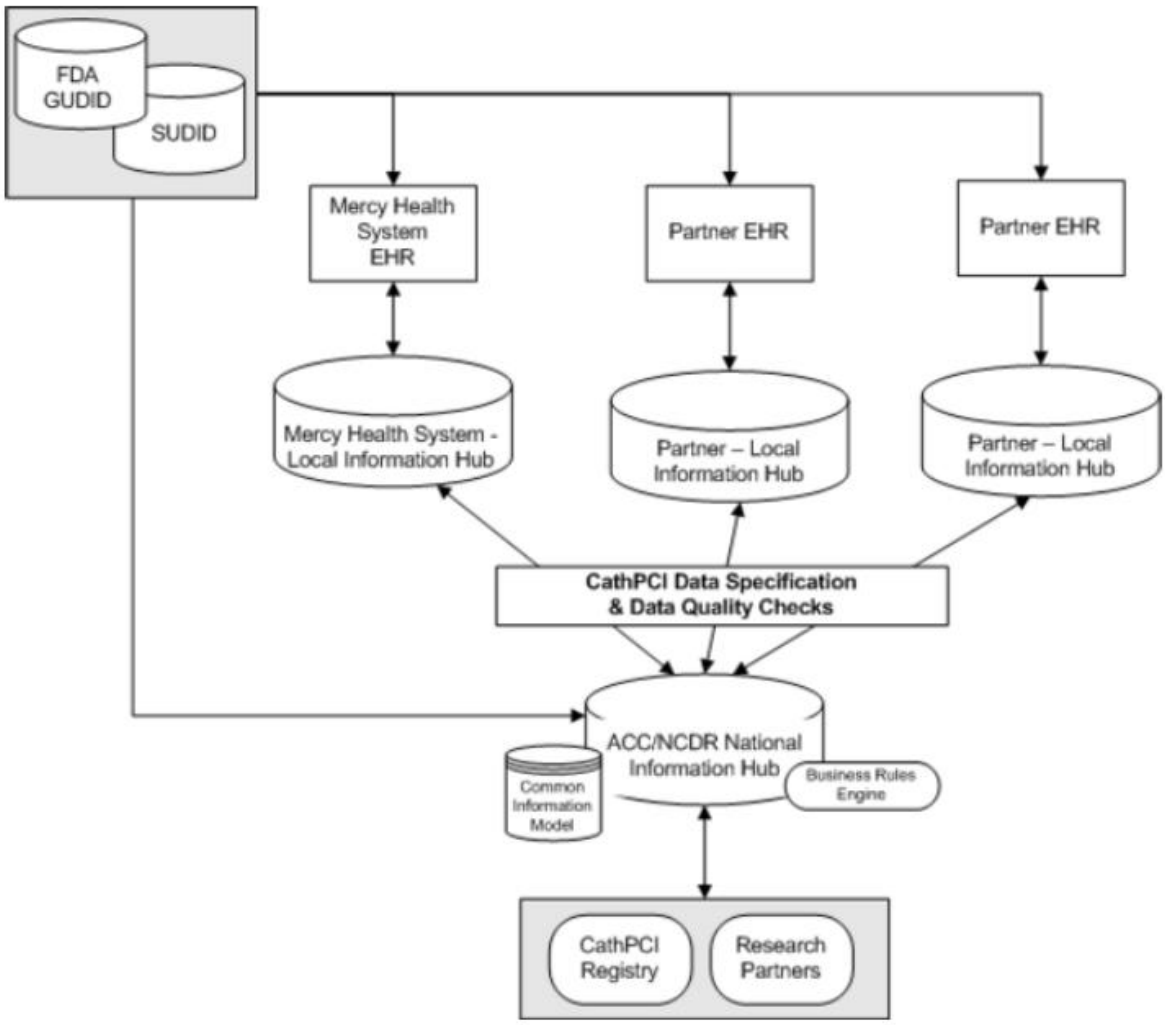

Figure 2

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

Glossary

CathPCI Registry	A 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 (ERP)	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. ERP software integrates all facets of business operations, including human resource and supply chain management.
Global Unique Device Identification Database (GUDID)	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 (IPD)	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 (SUDID)	A reference database similar to the GUDID that contains attributes specific to a particular class of devices, e.g., coronary stents.
Unique Device Identifier (UDI)	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. While the UDI will appear on the label and packaging of devices, in some cases the UDI would be marked on the device itself (for example, 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 (e.g., humans, roles, or information systems) that are needed to achieve a specific task or goal.