FDA UDI Demonstration

Joseph P. Drozda, Jr., M.D., F.A.C.C.
Mercy Health
34 ACUTE CARE HOSPITALS
4,396 LICENSED BEDS
36,917 CO-WORKERS
185 PHYSICIAN PRACTICE LOCATIONS
4,659 MEDICAL STAFF MEMBERS
1,235 INTEGRATED PHYSICIANS
$4.05 OPERATING REVENUE (Billions USD)
Why Mercy? The groundwork has been laid by Mercy IT:

The Epic EHR

• 8 years in the making

• All of our hospitals

• All of our integrated physician practices
Why Mercy+?

The groundwork has been laid by ROI:

The “Perfect Order”

- Fully automated purchase from order to payment
- Enablers
  - Adoption of GS1 standards
    - Global Trade Item Numbers, GTINs
    - Global Location Numbers, GLNs
  - Integration with software (Lawson, Omnicell and TECSYS)
  - Partnership with Becton, Dickenson and Company
The Mercy UDI Journey

• Next Steps
  • Integration of UDI into EHR
  • Creation of data sets containing clinical & device information
  • Linkage to other health systems & national registries (Distributed Data Network)
Something for everyone:

Supply chain team ➔ Find out what works for Mercy’s docs and patients

Clinical Support Team ➔ Make life easier

Physicians ➔ Improve Care
  Knowledge of patient’s device
  Communication of warnings and recalls (NDC’s)
  Ease of reporting Adverse Events
• Researchers ➔ Comparative effectiveness and safety research

  • Automated collection of significant variables

  • Ability to link with larger data sets
    – HIEs involving data sets of other providers
    – National registries

  • Enhanced safety monitoring
What is Really Important...

Three Fundamental Goals

CLINICAL
Good Patient Outcomes

FINANCIAL
Positive Bottom Line

OPERATIONAL
Happy Care Givers
CDRH Postmarket Strategy – launched 9/2012

➢ September 10: Strengthening the National Medical Device Postmarket Surveillance System

➢ September 11: MDEpiNet 2012: Partnership for Building Global Medical Device Surveillance Capabilities

➢ September 12-13: Leveraging Registries with Medical Device Data for Postmarket Surveillance and Evidence Appraisal Throughout the Total Product Life Cycle
Postmarket Strategy: Update and Next Steps 4/13

- 2013 Implementation Plan
- Postmarket Surveillance Website
- Planning Board
- Registry Task Force
Proposed Specific Actions to Strengthen Device Postmarket Surveillance

1) Establish a UDI System and Promote the Incorporation of UDI into Electronic Health Information
   - UDI critical for surveillance (including attributes)
   - UDI critical for leveraging distributed data sources

2) Promote the Development of National and International Device Registries for Selected Products
   - Need to be linked to other longitudinal data sources for effective longitudinal surveillance
3) Modernize Adverse Event Reporting and Analysis
   - Automated methods may enhance case ascertainment

4) Develop and Use New Methods for Evidence Generation, Synthesis, and Appraisal
   - Surveillance operating characteristics vary by study design, parameter specification, and data source
   - Need to understand and account for learning curve effects
Establishing a UDI System:
Four Steps

1. Develop a standardized system to create the unique device identifiers (UDI) - a foundational element – unambiguously identifies a specific device at its unit of use

2. Place the human and machine readable UDI on a device, its label, or both

3. Create and maintain the Global Unique Device Identification Database (GUDID)

4. Implementation
3rd Step – GUDID Data
Device Attributes (Examples)

For each DI:
• Manufacturer, Make/model, Brand/Trade Name
• Clinically relevant size
• Contact information
• Sterility information
• Natural Rubber Information
• FDA premarket authorization (510k, PMA)
• FDA product code (procode)
• Marketing Status/date
• For single-use
• Higher levels of packaging
• Rx – OTC
• GMDN/SNOMED
Pertinent Points from the Draft Rule

• Data must be Human Readable and encoded in an AIDC format

• Agnostic as to the machine readable standard: GS1, HIBCC, and ICCBBA (International Council for Commonality in Blood Banking Automation) are all currently recognized.
FDA MDEpiNet Initiative

MISSION

✓ To develop national/international infrastructure and innovative methodological approaches for conducting robust studies and surveillance to improve medical device safety and effectiveness understanding throughout the device life cycle through Public Private Partnership with academia and other stakeholders.
UDI Demonstration Project Aims

1. Implement a coronary artery stent UDI-based surveillance system in the EHR in a multi-hospital system (Mercy)

2. Identify obstacles to implementation of UDI in clinical information & to characterize the effectiveness of interventions to overcome them;

3. Assess the validity and utility of data obtained from the EHR and incorporated UDIs for purposes of post-market surveillance
Key Components of UDI Demonstration

- Create **Draft UDIs** & associate with base attributes in the FDA’s Global UDI Database (GUDID)
- Create clinically meaningful supplemental **attributes** to be stored in a reference database
- Create **UDI data flow** through ERP to cath lab to EHR to UDI data set
- Create UDI fields in the **CathPCI Registry**
- Perform **studies** to demonstrate validity and reliability of data
- Identify **obstacles** to incorporating UDIs into EHR and explore solutions
What we needed to do

- Create *partnerships* to establish a UDI system
  - *Health Systems* (HTG: Mayo, Geisinger, Intermountain, Kaiser-Permanente, Mercy)
  - *Professional Societies* (American College of Cardiology and the Society for Cardiovascular Angiography & Interventions)
  - *National Registry* (National Cardiovascular Data Registry’s CathPCI Registry)
  - *Industry* (Abbott, Boston Scientific, Medtronic)
  - *FDA*

- Propose appropriate *governance* of the UDI system for long term sustainability
So, where are we?
Project Status Report

- Began work on system design: April, 2012
- Expert Work Group Meeting and teleconferences: August-November, 2012
- Stood up SUDID: October, 2012
- Implementation of stent scanning and data capture: November 1, 2012
- Stood up UDI Research & Surveillance Database (UDIR): February, 2013
- Currently optimizing UDIR
- Performing preliminary analyses
The Expert Work Group

- The Expert Panel: Five interventional cardiologists appointed in conjunction with ACC and SCA&I

- “Ex officio” members
  - FDA representatives
  - Coronary Stent manufacturer representatives
  - HTG system representatives
  - NCDR representatives
Expert Work Group Members

Expert Panel Members
- James Tcheng, MD (Chair), Duke University Medical Center
- Kirk Garratt MSc, MD, Lenox Hill Heart and Vascular Institute of New York
- Kalon K.L. Ho, MD, MSc, Beth Israel Deaconess Medical Center
- John McB. Hodgson, MD, FACC, FSCAI, Technology Solutions Group
- J. Brent Muhlestein, MD, FACC, Intermountain Medical Center Cardiology

FDA Representatives
- Jay Crowley, Senior Advisor for Patient Safety
- Behnaz Minaei, Public Policy Analyst
- Terrie L. Reed, MSIE, Director of Informatics
- Madris Tomes, UDI External Program Manager
Expert Work Group Members

Health System Representatives

**Mercy Health**
- Joseph P. Drozda, Jr., MD (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, Vice Chair, Category Management
- Robert F. Rea, MD, Cardiology

**Intermountain Healthcare**
- J. Brent Muhlestein, MD, FACC, Intermountain Medical Center Cardiology

**Geisinger Medical Center**
- James Blankenship, MD, 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, Vice President, Supply Chain
Expert Work Group Members

Manufacturer Representatives

**Abbott Vascular**
- Judith Fairchild, 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, Vice President, Global Post-Approval Network
- Kweli P. Thompson, MD, MPH, Group Vice President of Clinical Research for the Cardiac and Vascular Group
Expert Work Group Members

Professional Societies

American College of Cardiology
  Kathleen Hewitt, Associate Vice President

Society for Cardiovascular Angiography and Interventions
  Joel Harder, Director for Quality Initiatives and Clinical Documents

NCDR
  Nichole Kallas, Associate Director, IT Business Analyst
Tasks for Expert Work Group

• Develop a constrained list of **coronary stent clinical attributes** to supplement the GUDID attributes (Expert Panel)

• Propose a permanent home for UDI clinical attribute database (**SUDID**)

• Recommend a **governance structure** for the SUDID

• Develop a proposal for an **organization and processes** for ongoing maintenance of the SUDID
Expert Work Group Outputs

- Constrained list (9) of supplemental coronary stent attributes
- Use cases for UDID in clinical data sets
- Recommendations re governance and operations of Supplemental UDI Database (SUDID)
- Recommendations re broader registry-centered data sharing network for device surveillance
<table>
<thead>
<tr>
<th>Attribute</th>
<th>Definition</th>
<th>Parameter</th>
<th>Data Type</th>
</tr>
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<tbody>
<tr>
<td>Length</td>
<td>Nominal length per manufacture specification</td>
<td>Fractional dimension in mm</td>
<td>4 significant digits, w/1 precision</td>
</tr>
<tr>
<td>Diameter</td>
<td>Nominal (inner) diameter per manufacturer specification</td>
<td>Fractional dimension in mm</td>
<td>4 significant digits, w/2 precision</td>
</tr>
<tr>
<td>Non-conventional Property</td>
<td>Stent having unconventional design, variable or multiple length/diameter parameters</td>
<td>Covered stent Bifurcation Stent Tapered Stent</td>
<td>Alphanumeric</td>
</tr>
<tr>
<td>Structural Material</td>
<td>Composition of principal structural element</td>
<td>Constrained list e.g. L605 cobalt chromium -- Constrained list to be developed</td>
<td>Alphanumeric</td>
</tr>
<tr>
<td>Coating(s)</td>
<td>Non-Structural material covering surface of structural element</td>
<td>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</td>
<td>Alphanumeric</td>
</tr>
<tr>
<td>Drug(s)</td>
<td>Active agent released from stent</td>
<td>NDC directory (default) -- Use name if no applicable NDC code—do it uniformly</td>
<td>Alphanumeric</td>
</tr>
<tr>
<td>Strut Thickness</td>
<td>Maximum nominal thickness of stent struts on a radius from the center of the stent</td>
<td>Dimension in microns</td>
<td>4 integer digits</td>
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<tr>
<td>Surface to Artery Ratio*</td>
<td>Percentage of the surface area of the artery covered by the stent at nominal expansion of the stent</td>
<td>Balloon Self</td>
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</tr>
<tr>
<td>Expansion Method</td>
<td>Method used to achieve nominal stent deployment</td>
<td>4 categories per existing standard: -- Safe -- Conditional -- Unsafe -- Not tested</td>
<td>4 Categories</td>
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<tr>
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<td>MRI compatibility category per testing</td>
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*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.
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## Use Cases for Attributes

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<th>Description</th>
<th>Attributes Needed (GUDID/SUDID)</th>
</tr>
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<tbody>
<tr>
<td><strong>Point of Care UDI Scan</strong></td>
<td>Query device attributes immediately prior to use</td>
<td>GUDID &amp; SUDID</td>
</tr>
<tr>
<td>Catalog/device ordering</td>
<td>Ordering by attribute, device, substitution, tracking devices in disasters</td>
<td>GUDID &amp; SUDID</td>
</tr>
<tr>
<td>Medical Documentation</td>
<td>Procedure reporting, health care communication</td>
<td>GUDID &amp; SUDID</td>
</tr>
<tr>
<td><strong>EHR/Patient Portal</strong></td>
<td>Attributes stored as data outside of procedure report, patient education</td>
<td>GUDID &amp; SUDID</td>
</tr>
<tr>
<td>Queries (by attribute)</td>
<td>Support for process measurement, QI projects</td>
<td>GUDID &amp; SUDID</td>
</tr>
<tr>
<td>Extending indications for use</td>
<td>Support of alternative processes for device labeling</td>
<td>GUDID &amp; SUDID</td>
</tr>
<tr>
<td><strong>Comparative effectiveness research</strong></td>
<td>Support of comparative effectiveness</td>
<td>GUDID &amp; SUDID</td>
</tr>
<tr>
<td>Registries</td>
<td>Process, performance, quality outcomes, education, performance improvement Continuing Medical Education</td>
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<td><strong>PHR/Consumer</strong></td>
<td>Information to patient, education, public communication, healthcare advocates</td>
<td>GUDID &amp; SUDID</td>
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<td><strong>Supply chain management</strong></td>
<td>Competitive bidding by attributes</td>
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</tr>
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<td><strong>Advance notice of expiration</strong></td>
<td>Inventory management</td>
<td>GUDID</td>
</tr>
<tr>
<td><strong>Administrative uses</strong></td>
<td>Asset and financial management</td>
<td>GUDID</td>
</tr>
<tr>
<td><strong>Device Recall</strong></td>
<td>Easily identify patients who received the affected lots and locate unused product in clinical use areas</td>
<td>GUDID</td>
</tr>
<tr>
<td><strong>Federated Data Exchange</strong></td>
<td>Increased ability to report outcomes across products</td>
<td>GUDID</td>
</tr>
<tr>
<td><strong>Adverse Event Reporting</strong></td>
<td>Increased ability to report adverse events and outcomes</td>
<td>GUDID</td>
</tr>
<tr>
<td><strong>Anti-counterfeiting</strong></td>
<td>Increased protection against fraud</td>
<td>GUDID</td>
</tr>
<tr>
<td><strong>Tracking of patients with multiple devices</strong></td>
<td>Allow providers to learn information about prior device implantation, even when prior medical records are not available</td>
<td>GUDID</td>
</tr>
<tr>
<td><strong>Federal (post-market surveillance)</strong></td>
<td>Specify device exposure and usage for linkage with safety and research outcomes</td>
<td>GUDID</td>
</tr>
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UDI Demonstration Project
High Level Architecture

Glossary:
- UDIR = UDI Research database
- GUDID = Global UDI Attributes
- SUDID = Supplemental UDI Attributes
- IPD = Integrated Patient Datamart
- ETL = Extract/Transform/Load of data

Facilitate/negotiate GTIN, UDI, and attribute adoption

HTG
Mercy, Mayo, Kaiser, Intermountain, Geisinger

Facilitate/negotiate GTIN, UDI, and attribute adoption

Device Attribute Repositories

GTIN, UDI, device attributes and labeling

Device Manufacturers

GUDID
SUDID

Patient - Device Identification
Post-market Device Surveillance
Comparative Effectiveness Research

Mercy IT Infrastructure

ETL

UDIR

IPD

Inventory
Supply Chain
EHR
Hemo

Item Master
Real-time Message-Hub

ACC, SCA&I
Supplemental Device Attributes

GS1 Supply Network

GS1 GDSN

CATHPCI Registry

ACC NCDR
Single EHR UDI Tracking System Data Flow

- Global Unique Device Identification Database (GUDID)
- Electronic Health Record (EHR)
- Enterprise Resource Processing (ERP)
- Unique Device Identification Research Database (UDIR)
- Supplemental Unique Device Identification Database (SUDID)
- Integrated Patient Dataset (IPD)
- Merge Hemodyamic Software (Hemo)
Obstacles

• **Technical**: Biggest problem so far is Merge

• Agreeing on:
  
  • Industry-wide standards
  
  • Device attributes
  
  • Organizational infrastructure and support for designing and maintaining a UDI system
  
  • The business case for all stakeholders
Performance Solutions - What we did...

Changes to Cath Lab Process

- The UDI project required us to make changes to how the Cath Lab process works
- The changes we made improved many aspects of the workflow in the Cath Lab
Goal: Enable capture of the UDI to the patient... Apply automation to highly manual process
Several key data points are now captured per patient that have never been captured before... These data point will lead to other improvement opportunities.
UDI Research & Surveillance Database (UDIR)

- A **functional database** for device surveillance and research that is the ultimate output of the Demonstration Project
- **Contains:**
  - Key clinical data from the EHR
  - SUDID attribute data
  - GUDID attribute data
- **Provides:**
  - Exposure data
  - Adverse outcome data
  - Evaluations by stent brand and by attribute
Example Use Case

FDA Query:

- 10 cases of heart attack & death within 3 months of stent X implant reported to FDA (UDIs of involved stents provided)
- Request all data on stent X:
  - UDI of each implanted stent and associated GUDID and SUDID attributes
  - Date of implant
  - Baseline (time zero) patient characteristics—
    - Patient demographics including date of birth, sex, race/ethnicity
    - All available laboratory values
    - Key implant data including the coronary artery in which the stent was implanted along with all other coronary stents implanted at the time of the same procedure along with their UDIs
  - All subsequently collected patient variables including laboratory values with associated dates
  - All patient outcomes/safety events defined as Major Adverse Cardiovascular Events (MACE) and dates of their occurrence
    - For MACE that involve repeat catheterization, include UDIs and attributes on any coronary stents implanted during the procedure along with all available laboratory values.
Device attribute: Drug
Patient characteristics: All
Outcome: Mortality

- 18 patients, 0 deaths $P=0.9863$
- 631 patients, 15 deaths $P<0.0001$
- 109 patients, 3 deaths $P=0.0186$
- 38 patients (DES Type > 1), 3 deaths
- 93 patients, 11 deaths

![Survival vs. Time Graph](Image)
Where do we go from here?

• Complete current Demonstration Project by 12/31/13

• Continue planning for “UDI Phase 2”
Vision for UDI Phase 2

Create a robust system of medical device surveillance and research to support FDA and physicians in keeping patients safe and to enhance research on innovative technologies.
UDI Phase 2

• **Purpose:**
  Build a national network of UDI enabled EHR data sets around national registries for device surveillance and research.

• **The UDI Alliance:**
  • HTG Health Systems (Mercy, Mayo, Geisinger, Intermountain, and Kaiser)
  • National medical societies and registries (ACC, SCAI/NCDR)
  • Industry (Medtronic, Abbott, Boston Scientific)
  • Consumer groups/patient representatives)
Coronary Stent Distributed Data Sharing Network
Thanks!

Joseph P. Drozda, Jr., M.D., F.A.C.C.
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