Collaborative Communities: It Really Does Take a Village

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2018 Medical Device Safety Action Plan
Protecting Patients, Promoting Public Health

- Encourage innovation to improve safety, detect safety risks earlier, and keep doctors and patients better informed.
- Ensure that medical devices have a positive benefit-risk profile, have the right tools to identify and address potential safety concerns, and foster innovation of new products that are safer, more effective, or address unmet medical needs.
2018 Medical Device Safety Action Plan
Protecting Patients, Promoting Public Health

- Establish a robust medical device patient safety net in the United States
- Explore regulatory options to streamline and modernize timely implementation of postmarket mitigations
- Spur innovation towards safer medical devices
- Advance medical device cybersecurity
- Integrate the CDRH’s premarket and postmarket offices and activities to advance the use of a TPLC approach to device safety
2018 Medical Device Safety Action Plan
Protecting Patients, Promoting Public Health

UDI

• Key component of medical device patient safety net
• Standard identifier to be used across Total Product Life Cycle (TPLC)
• Essential to National Evaluation System for health Technology (NEST)
• Facilitates active surveillance decision making and innovation by:
  – Identifying the specific device used in the care of a patient
  – Providing opportunity for cost savings coupled with other benefits, such as near real-time access to high quality data to support decision making and access to better evidence
UDI in Real World Data

- 75 EHRs - hospitals implementing UDI; scanning products, linking to GUDID; creating implantable device lists; transmitting to other systems; providing feedback
- 470+ members of the Association for Healthcare Resource & Materials Management (AHRMM's) Learning UDI Community
- Government collaboration – FDA, ONC, NLM, VA, CDC
- UDI in registries - Demonstration Projects in 5+ device areas – Cardiovascular, Gastrointestinal, Prostate, Peripheral Artery, Women’s Health Technology
- UDI in claims
- UDI Coalition - Healthcare Manufacturers Management Council, Healthcare Industry Distributors Association, Manufacturers, AHRMM
- Infrastructure development – UDI in standards (e.g. ISO, HL7 CCDA, HL7 FHIR, NCPDP, X12)
Manufacturers and Distributors: Commitments and Shared Responsibilities (UDI Coalition Advisory Council – UDICAC)
HIDA
Commitment as a Trade Association

HIDA Initiatives
• Webinars
• UDI Workgroup
• Articles

HIDA Collaboration
• AHRMM LUC
• FDA
• HMMC
• Conferences
• UDICAC
Clinicians: Commitment and Shared Responsibilities
Collaboration

- **Regulatory Development**
  - FDA proposed UDI Rule 2013
  - AdvaMed’s Proposed UDI Strategies 2013
  - Support for AdvaMed’s Extension for UDI Class II implementation 2015

- **Collaborative Initiatives**
  - PEW Charitable Panel Speaker 2014
  - IAHCMM Proposal Collaboration 2014
  - SMI UDI Simulation Project – Duke Clinical Research Lab 2015
  - 2016 GS1 Non-sterile Implant Project – Baylor/Scott & White Health System
Collaboration

• Collaborative Initiatives (cont.)
  – CDC/FDA/ASPE UDI Assessment, Feasibility, and Use Case Development Project

• AORN Membership Development
  – 2017 Annual Conference – two UDI sessions (1 Executive Summit session, 1 gen educ session)
  – 2018 Annual Conference – two UDI general education sessions

• Standards Development
  • IHE Point-of-Care Medical Device Tracking Profile [http://wiki.ihe.net/index.php/Point-of-Care_Medical_Device_Tracking](http://wiki.ihe.net/index.php/Point-of-Care_Medical_Device_Tracking)
  • HL7 Medical Device Workgroups – CCDA and FHIR
- Billing
- Reimbursement (regulatory compliance)

Clinical

- POC UDI Data Capture
- Recalls
- Adverse Event Reporting
- Pt Outcomes (comparative effectiveness)
- Cost/Case

Financial

Operational (Supply Chain)

- Inventory Management
- Logistics
- Substitutions/Shortages
- Illegitimate/Counterfeit Products
- Purchasing (contract compliance/pricing)
ACCESSGUDID Database

- **Tonsil Sponges - 20749915000760**
  - Tonsil Sponges 1.25" X-Large
  - **Company Name**: AMERICAN SURGICAL COMPANY, LLC
  - **Version or Model**: 50-02

- **Tonsil Sponges - 20749915000746**
  - Tonsil Sponges 3/4" Medium
  - **Company Name**: AMERICAN SURGICAL COMPANY, LLC
  - **Version or Model**: 50-00

- **Tonsil Sponges - 20749915000753**

- **AVID TruCustom - 10809160082898**
  - No Description
  - **Company Name**: AVID MEDICAL, INC.
  - **Version or Model**: VMLR0010-08_000

- **AVID TruCustom - 10809160082508**
  - No Description
  - **Company Name**: AVID MEDICAL, INC.
  - **Version or Model**: ILSM005-02_0010

- **AVID TruCustom - 10809160082102**
AORN’s Commitment

We know the Rule will result in changes to processes in the perioperative setting and as a changing healthcare environment, we accept that.

We advocate that the adoption and implementation of the processes mandated by the UDI Rule, increase patient safety and increase patient engagement in their care.
AHRMM Learning UDI Community: Commitment and Shared Responsibilities

http://www.ahrmm.org/LUC
Collaboration

- The AHRMM Learning UDI Community is a healthcare collaborative effort designed to address issues impacting the implementation and use of unique device identifiers by developing a common understanding and approach to UDI adoption within the healthcare setting.
- Establishing a consistent and unbiased platform for collaboration, communication, and education between all healthcare stakeholders.
- LUC membership and content is open to all those who are interested in advancing UDI adoption within the healthcare field.
- Seek. Solve. Share.
Leading Practice Resources:

- UDI Capture Case Studies
- Unit of Use Report and Webcast series
- Clinically Relevant Size work group Report
- Catalog Number work group Report
- Low Unit of Measure Supply Chain Best Practices Report
- Business Case for the Benefits of UDI Comprehensive Report and Presentation
- Human Cellular Tissue Product Guidance Document and Presentation
- Data Value White Paper Series
External Activities and Resources:

- General UDI and healthcare data standards information
- Building UDI into Longitudinal Data for Medical Device Evaluation (The BUILD Initiative)
- FDA AccessGUDID
- Medical Device Epidemiology Network Initiative (MDEpiNet)
- Registry Assessment of Peripheral Interventional Devices (RAPID Initiative)
- FMOLHS-GS1 US Data Standards Master Process Implementation Plan
- Report of the MDEpiNet AUDI Workgroup

Issuing Agency Resources

- GS1 – Global Trade Identification Number
- HIBCC Universal Product Number
- ICCBBA Processor Product Identification Code (PPIC)
It takes a village…

Committed to UDI Application

- UDI Coalition
- Learning UDI Community
- Professional Societies
- Researchers
- Device Regulator
- Standards Organizations
- Supply Chain
- Vendors
- Health Systems
- Third Party Submitters
- Issuing Agencies
- Health Regulators
- Payers
- Researchers
Appendix
The Need for an Integrated Platform Approach

- Manufacturer
  - User Feedback
  - New Product Enhancements
- FDA
  - Evidence Generation
  - Surveillance Studies
  - Synthesis & Appraisal
  - FDA Discretionary Studies
- FDA GUDID
  - Post Approval Studies
  - Post Market Surveillance Studies
  - Administrative & Claims Data
- UDI
  - Medical Device Reporting
  - eMDR
  - Medical Product Safety Network
  - Improved Traceability Throughout the Distribution Network
- Provider
  - National & Intl Device Registries
  - Modernize Reporting & Analysis
- Clinician
  -

UDIconference.com
Healthcare Provider Benefits Enabled by UDI

What do Healthcare Providers want to know?

• I want quality (safety, effectiveness, reliability, patient preference, usability, compatibility and availability) information for specific devices from a consistent, unbiased and current source so that I can make appropriate purchasing decisions.

• I want the UDI of implantable devices to be linked to the patient that received them to be able to notify patients when their device is recalled.

• I want to use the UDI in recalls and link it with my inventory management system data to be able to effectively remove all affected recalled devices.

• I want to have a system that is useful for multiple purposes besides device evaluation, e.g., inventory management and billing.

• I want the UDI to be the primary identifier and index of the inventory management, to facilitate and/or improve inventory management and reduce costs.

Source: UDI cross-stakeholder collaboration and coordination team
Clinician Benefits Enabled by UDI

What do Clinicians want to know?

• I want to be able to compare my performance with those of other clinicians performing the same treatments so that I can use the best devices and the best procedures for my patients.

• I want to rely on clinical evidence and research based upon clear evaluation of patient outcomes at the device model level so that I can be confident in my clinical decision making.

• I want to use research that compares device models (DI of UDI) and key device attributes (e.g. clinically relevant size in GUDID and AUDI) so I can select the device that best meets my patients’ clinical characteristics.

• I want to have a record of the UDI(s) for my patients’ implants to use to inform patient assessment and evaluation when they present with a particular set of potentially device related symptoms (e.g., allergy, pain).

• I want device data brought into point of care clinical / procedure documentation via direct query of the GUDID so that the information is accurate and to reduce documentation burden.

Source: UDI cross-stakeholder collaboration and coordination team
Patient Benefits Enabled by UDI

What do Patients want to know:

- I want to quickly and easily know how a device is performing so that I can take part in my health care with my provider.
- I want the balanced neutral information on all treatment options so that I can determine the most value I can get.
- I want to be able to scan the UDI with my phone so that I can link to information in a timely fashion (labeling, recalls, etc.) about my device, and report adverse events and have them link to the right device model number and manufacturer.
- I want to know what implantable device model (DI of UDI) my doctor is considering and be able to use that information to research the outcomes of patients like me who have received a similar device.
- I want the CCDS to have the UDI so that when I go from one state to another and need medical care the providers can have essential details on my devices.

Source: UDI cross-stakeholder collaboration and coordination team
Manufacturer Benefits Enabled by UDI

What do Medical Device Manufacturers want to know:

• I want a way to use RWE for label expansion so that real device performance can be used to inform indications for use

• Right now I use model number, listing number, 510(k)/PMA number, FEI and other hospital specific numbering schemes when talking to various stakeholders. I want to use a single number across all my stakeholders so that I can better understand product performance.

• I want customers to include UDI in their complaints so that I can trace problems back and understand the root cause.

• I want a system that will enable timely capture of real world device performance in order to identify performance issues early and iterate quickly to eliminate problems and improve functionality thereby avoiding costly recalls and reduce the costs of product revisions.

• Demand Planning - I want better data on product usage/tracking/my inventory so that I can save money by obsoleting product that doesn't pay to keep on the books

Source: UDI cross-stakeholder collaboration and coordination team
Payer Benefits Enabled by UDI

What do Payers want to know?

- I want to be able to compare the performance of similar device models (DI of UDI) so that I can begin to identify a formulary of devices with high value/outcome.
- I want the DI of UDI to be captured as part of patient charge information so that it is easier to track rebates from manufacturers back to the payer or provider.
- I want the DI of UDI to be captured as part of patient charge information so I know the device models used (DI of UDI) on my patient populations and to calculate and compare total costs and outcomes.
- I want to be able to track device performance systematically and be able to assess the effect of devices on the overall cost and quality of care.
- I want to know if the medical devices that I as payer paid for were recalled or have been subject to adverse events.

Source: UDI cross-stakeholder collaboration and coordination team
Researcher Benefits Enabled by UDI

What do Researchers/Data Aggregators want to know?

- I want to be able to pull together and link data from a variety of sources to pose and answer research questions.
- I want to be able use valid device identifiers and standard code sets to mine data and perform effective analyses.
- I want to use the data in GUDID so that I can enhance existing tools used to evaluate device outcomes.
- I want to be able to evaluate outcomes from use of selected UDIs on patient populations to enhance quality and cost effectiveness of future care protocols.
- I want consistent data elements so that they interface with other data systems in expected ways.

Source: UDI cross-stakeholder collaboration and coordination team