UDI Roundtable Discussion

7 April 2011
Speakers

Chair

• Mike Wallace, Director Global Standards and Serialization, Abbott Laboratories

Panelists

• Terrie Reed, Senior Policy Analyst, FDA Center for Devices and Radiological Health
• Joe Pleasant, Senior VP & CIO, Premier Inc.
• Mike Sarachman, Manager, International Data Standards Adoption, Johnson & Johnson Health Care Systems, Inc.
UDI Database Roundtable

April 7, 2011
Agenda

• Abbott at a Glance
• What is Master Data?
• How does GS1 data fit with Master Data?
• What will the processes look like?
• The new paradigm
• The Panel
Medical Devices is one of Abbott’s Three Areas of Business

Medical Devices

- Diabetes Care
- Laboratory Diagnostics
- Molecular
- Point of Care
- Medical Optics
- Vascular
- Animal Health
What is Master Data?

Master Data is the *high value* information that an organization *uses repeatedly* across the enterprise and in many business processes.

– It describes the key business entities of a corporation, referred to as master records or data domains:
  
  • Customer, Material, Vendor, Chart of Accounts and Employee

– It includes the data elements that help define the master records in support of transactional and reporting activity.

– Naming conventions and the adoption of industry standards are implemented where applicable.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Data Element Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer</td>
<td>Account Number, Customer Name, Address, GS1 standard for GLN</td>
</tr>
<tr>
<td>Material</td>
<td>Material Number, adoption of UNSPSC codes for material classification (Material Group), GS1 standard for GTIN, Units of Measure</td>
</tr>
</tbody>
</table>
Where does Master Data fit?

- **Transactional Data** – Data created during course of business operations such as sales orders, purchase orders, invoices, accounting postings are considered transactional data.

- **Supplemental Data** – Non-transactional data such as pricing conditions and product hierarchies that is not considered master data.

- **Master Data** – Corporate data assets such as customers, vendors, materials, and chart of accounts.

- **Organizational Data** (a.k.a. Foundational Data) – Essential elements such as company code, sale organization that should be in place for all other data to exist.
How Master Data Fits

All GS1 Data is Master Data, but not all GS1 data is necessarily Enterprise Master Data.
GDSN/UDID OVERLAP

DATA TRANSFORMATION & VERIFICATION

GOVERNANCE REQUIRED

INTERNAL  EXTERNAL

CUSTOMERS

REGULATORS

DATA POOL?

DATA

DATA

DATA

DATA
GDSN/UDI Database processes mimic MDM

- Assign product GTINs
- Locate GTIN attribute data
- Identify data owners
- Modify/establish data governance process
- Assess attribute data v. GDSN/UDI Standards
- Complete and/or Transform attribute data as required
- Verify attribute data in correct formats for publication
- Publish data as appropriate to GDSN Data Pool/UDID
- Update GDSN/UDID as required for changes in products, attributes, customers, regulators
Device Identification – A Paradigm Change

<table>
<thead>
<tr>
<th>CURRENT</th>
<th>PROPOSED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary Identification – Manufacturers Catalogue Number</td>
<td>Open Identification – Manufacturers Standards-based UDI</td>
</tr>
<tr>
<td>Not Globally Unique</td>
<td>Globally Unique</td>
</tr>
<tr>
<td>Distributors may apply different proprietary identification number</td>
<td>Distributors use Manufacturers’ UDI number</td>
</tr>
<tr>
<td>Distributors do not capture lot or serial numbers</td>
<td>Distributors may use AutoID to capture lot or serial numbers</td>
</tr>
<tr>
<td>Hospitals may apply different proprietary identification number</td>
<td>Hospitals use Manufacturers’ UDI number</td>
</tr>
<tr>
<td>Hospitals do not capture lot or serial numbers</td>
<td>Hospitals use AutoID to capture lot or serial numbers</td>
</tr>
<tr>
<td>Non-standardized device information available on a limited, ad hoc basis</td>
<td>Standardized device information available in an FDA database</td>
</tr>
</tbody>
</table>
UDI Panel Participants

• Mike Wallace – Abbott (Moderator)

• Terri Reed – FDA CDHR

• Michael Sarachman – JNJ Standards Adoption

• Joe Pleasant – Premier CIO
FDA Center for Devices and Radiological Health: UDI Database & CDRH Informatics Strategy

GS1 Conference
Bethesda, MD
4/6/11
Overview

• Informatics Strategy at CDRH
• UDI as Master Data
• Ties to HL7 Standards
• Data Exchange as a Team Sport
CDRH Informatics Goal: Improve Data Quality

• Current data meets requirements of a particular regulation or business need

• **Standard** Data exchange methods not used

• Some electronic data must be re-entered

• Data cleansed and linked after received and stored

• **EXCEPTION:** eMDR - standard vocabulary and data exchange format,
Focus on Fundamentals: Sharing and Reuse of Data

– Common Data Exchange – **Getting from A to B and back again (SYNTAX)**

• **Standard Terminology** - **Building Blocks** - **Allows Reuse of Data (SEMANTICS)**
Master Data Management Plan

• Compliments development of standard data exchange and vocabularies

• Identifies the agreed to, standard critical business data (e.g., UDI info, device names, event codes, item codes, manufacturer names, GMDN codes) that can be shared across systems.

• Creates policies and procedures for creation, access, update, and overall management of this central resource.

• Emphasizes Data quality, Integration, Single version of the truth, Data stewardship.
Why Master Data Management

- Multiple master – No Authoritative data
- Inconsistent Data
- Semantic Differences
- Data Duplicates

Master Data

Data Hub- Single Master
- Harmonized
- Consistent Data
- Single Vocabulary
- Governed by a single group
UDI as Master Data

- Core data for Regulatory product safety/effectiveness – **DEVICE Information**
- Means to increase quality & consistency of **DEVICE Information**
  - Applying UDI to label of device
  - Requiring standardized electronic submission of UDI data
Establishing a UDI System

Combination of 4 distinct steps:

1. Develop a standardized system to establish the unique device identifiers (UDI)
2. Place the UDI in human readable and/or AutoID on a device, its label, or both
3. Create and maintain the UDI Database
4. Promote Adoption and Implementation
UDI: Ties to HL7 SPL r5

HL7 Data Exchange Standard

- Global authority on standards for interoperability of health information technology with members in over 55 countries

  • Individual Case Safety Report (ICSR) Adverse Event Reporting

  • Structured Product Labeling (SPL) - UDI - Product Information

Data Exchange Vision

SPONSOR PRODUCT DATA SOURCES – REGULATORY, QUALITY, MASTER DATA

Sponsor Pre-Market Database

Sponsor Complaint / Recall Database

Sponsor Database of Product on the Market

Sponsor UDI Database

VISION: PRODUCT DATA

Agency Pre-Market Database

Agency Adverse Event Database

Agency Registration & Listing

Agency UDI Database

RPS

ICSR

SPL

SPL/CPM
UDI Database – Benefits of Adoption

FDA/Manufacturer adoption --
• Improves ability to link internal databases around product information
• Provides improved device information in regulatory submissions

Healthcare adoption -
– EHR as a rich data source for device-specific safety surveillance/observational studies
– Provides method to obtain ‘real-world’ data for pre-market decisions (registries)
– Improves ability to link Healthcare databases
Data Exchange/Reuse Efforts lead to..

- Improved Data Sharing with:
  - Regulated Industry
  - Professional Organization Registries
  - Healthcare IT Departments
  - Materials Management
  - Federal Health Partners
Which leads to….

- Improved Patient Care – Device Info
- Improved Public Health
  - Improved Quality and Timeliness of Data
    - Improved Information from Clinical Research
    - Improved AE Reports (ASTER-D, PDRNet)
      - Improved Signal Detection
    - Improved Directed Inspections
    - Improved Recalls
## Data Exchange is a Team Sport

<table>
<thead>
<tr>
<th>Type</th>
<th>Group</th>
<th>UDI/Informatics Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulated Industry</td>
<td>AdvaMed, GHTF,</td>
<td>• Coordinate FDA data standards with industry</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Educate and Facilitate Submissions</td>
</tr>
<tr>
<td>Standards Development</td>
<td>GS1, HL7, ISO, AAMI CDISC, GMDN IHTSDO,</td>
<td>• CDRH advocate</td>
</tr>
<tr>
<td>Development Organizations</td>
<td>(SNOMED), NCPDC, X12</td>
<td>• Apply Stds at Agency and Center Level</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Educate and Promote Adoption</td>
</tr>
<tr>
<td>Supply Chain</td>
<td>GS1, HIBCC Group Purchasing, Material Mgt,</td>
<td>• Promote UDI Adoption</td>
</tr>
<tr>
<td></td>
<td>Hospitals, Distributors</td>
<td></td>
</tr>
</tbody>
</table>
Questions?

terrie.reed@fda.hhs.gov
Unique Device Identification Database: Managing UDI Data

April 2011

Michael Sarachman
Manager, Industry Standards Adoption
Johnson & Johnson Health Care Systems Inc.
Impact of Unique Device Identification (UDI) Adoption

**Current State**
- Manufacturer: #742G
- Distributor: #003774
- Health Care Provider: #360013

**Future State**
- Manufacturer: 12345
- Distributor: 12345
- Health Care Provider: 12345
Perceived Benefits of UDI

- Accurate sales orders
- Accurate and efficient recalls
- Accurate procurement
- Enable electronic health record usage
- Patient safety
- Efficient delivery of clinical care
- Foundational for track & trace
UDI Benefits

• Standardized & consistent safety data
  – Leverage common database
  – Ensure positive product identification

• Standardized production data collection
  – AutoID of Production Data
    • Lot Code
    • Serial Number

• Complements current data collection
UDI Usage

510K Notification No. K953442
UDI System Components

• The identifier
  – Global Trade Item Number + LOT
  – Global Trade Item Number + Serial Number

• The carrier
  – Bar code symbol

• The database
  – Global Trade Item Number
  – No LOT or Serial Number data
  – Additional attributes
    • Clinical size
    • Brand Name
    • Market authorization
Data Sources

Marketing
- Brand name

Regulatory
- FDA Market authorization

Engineering
- Clinical size
- Sterilization state
- Sterilization method

Others
- Contents of concern
- GMDN Code

Master Data

UDI
Data Source Impacts

• Master Data
  – Transformed from commercial data to product labeling

• Initial data load
  – Collect data from disparate sources
    • Regulatory filings
    • Product labels & specifications

• Ongoing maintenance
  – Identification of new master data owners
    • Regulatory
    • Marketing and commercial
    • Engineering
  – Error handling
    • How will interface errors be flagged and resolved?
Label Example

- **Device Identifier**
- **Storage Conditions**

**Clinical Size**
- 33 mm
- 3.50 mm

**Production Data**
- LOT: W0197999
- Use By: 9999-01

**Storage Temperature**: 25°C
UDI Exemption Considerations

- The form factor of the product
- The clinical acuity of the product
- Complexity of the supply chain
  - The logistical/physical supply chain
  - The information supply chain
# UDI Database Example

<table>
<thead>
<tr>
<th>UDID Attribute</th>
<th>Value</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier Type</td>
<td>GS1</td>
<td>Some have both</td>
</tr>
<tr>
<td>Static UDI Code</td>
<td>20705032028421</td>
<td>HIBCC or GS1 GTIN</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Cordis Corporation</td>
<td></td>
</tr>
<tr>
<td>Contact</td>
<td>Nancy Coulson</td>
<td></td>
</tr>
<tr>
<td></td>
<td>430 Route 22 East</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bridgewater, NJ 08807</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Phone: 908-5414908</td>
<td></td>
</tr>
<tr>
<td>FDA Market Authorization</td>
<td>P020026</td>
<td>First or last?</td>
</tr>
<tr>
<td>FDA Listing Number</td>
<td>TBD</td>
<td></td>
</tr>
<tr>
<td>BRAND/Trade Name</td>
<td>CYPHER®</td>
<td></td>
</tr>
<tr>
<td>Model/REF number</td>
<td>CXS33350</td>
<td></td>
</tr>
<tr>
<td>UOM/Package Level/Quantity</td>
<td>EA</td>
<td></td>
</tr>
</tbody>
</table>
# UDI Database Example

<table>
<thead>
<tr>
<th>UDI Attribute</th>
<th>Value</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production Control</td>
<td>LOT</td>
<td></td>
</tr>
<tr>
<td>GMDN Code</td>
<td>34179</td>
<td></td>
</tr>
<tr>
<td>GMDN Term</td>
<td>Stent, cardiovascular</td>
<td></td>
</tr>
<tr>
<td>Storage Conditions</td>
<td>25°C</td>
<td></td>
</tr>
<tr>
<td>Single Use State</td>
<td>Single Use</td>
<td></td>
</tr>
<tr>
<td>Sterility State</td>
<td>Sterile EO</td>
<td></td>
</tr>
<tr>
<td>Contents of Concern</td>
<td>NA</td>
<td>(e.g., Latex)</td>
</tr>
<tr>
<td>Clinically Relevant Size</td>
<td>3.50 mm I.D. 33 mm L</td>
<td></td>
</tr>
</tbody>
</table>
UDI and GDSN

Why are they Important? Provider and GPO Perspective

Joe M. Pleasant
Sr. VP and CIO
Premier Inc.
Topics

1. The Premier healthcare alliance.
2. Why is UDI and GDSN important to Premier and our members?
4. What are Premier and our members doing to support UDI and GDSN?
Over 2,500 hospitals, more than 72,000 non-acute sites
- Using the power of collaboration to improve the health of communities
- Nation’s largest clinical/operational/supply chain comparative databases
- 2010 member validated savings of $1.4 billion
- Safety, Diversity and Environmentally Preferred Purchasing programs
- $36 billion in annual group purchasing volume
- 2006 recipient of Malcolm Baldrige National Quality Award
- Three-time recipient of Ethisphere’s Most Ethical Companies award.

Cost Reduction
Group Purchasing & Supply Chain Improvement, Labor Management

Quality Improvement
Quality Measurement & Benchmarking, Safety Surveillance

Risk Mitigation
Liability, Benefits & Risk Management

Advocacy
Shaping policy and advocating for members

Execution Engine
Comprehensive, accelerated approach to improving financial, operational and clinical performance.
Why is UDI and GDSN important?
Healthcare spending: Unsustainable

Health care represents 15% of U.S. GDP.
Why is UDI and GDSN important?
Provider Gaps and Cuts

Missing information affects care

- Delays in care: 25%
- Additional laboratory testing: 22%
- Additional visits: 11%
- Additional imaging: 21%

Payment cuts to hospitals: $157B

- Medicaid DSH: $14B
- Medicare DSH: $22.1B
- Readmissions: $7.1B
- Hospital Acquired Infections: $1.4B
- Market Basket Reductions & Productivity Adjustment: $112B

Hospital Payment Cuts in Public Law No: 111-148 - Patient Protection and Affordable Care Act
CBO/JTC Estimate, CMS Actuary Estimate 2010 - 2019 (in billions)
Why is UDI and GDSN important?
Product Identification

Same Product, Different Numbers:

3M 8630
DuraPrep™ Surgical Skin Prepping Solution

DISTRIBUTORS

TM-8630  AmerisourceBergen
MMM-8630  Buffalo Hospital Supply
567008630  Burrows
1143890  Cardinal
01645.8630  Harris
MINN8630  Kreisers
4513-8630  Midwest Medical
4509008630  Owens & Minor
000104280  PHS

... plus different numbers in each Hospital Group’s MMIS.
Premier’s Product Item Master has 7 Million products with 2.5M Manufacturer ID’s and over 4.5M distributor ID’s.
## Why is UDI and GDSN important?

### Poor Information throughout the Supply Chain

<table>
<thead>
<tr>
<th>Percentage of Errors</th>
<th>Manufacturer</th>
<th>Distributor</th>
<th>GPO</th>
<th>Customer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing Middle Levels of Pkging</td>
<td>15-20%</td>
<td>1-4%</td>
<td>20-25%</td>
<td>15-25%</td>
</tr>
<tr>
<td>Hard “Packaging Quantity” Errors</td>
<td>1%</td>
<td>1%</td>
<td>2%</td>
<td>2-5%</td>
</tr>
<tr>
<td>Unit of Measure Confusion/Misuse</td>
<td>2-6%</td>
<td>1-3%</td>
<td>2-5%</td>
<td>Unknown</td>
</tr>
<tr>
<td>Missing Packaging—not Middle Level</td>
<td>3-8%</td>
<td>3-8%</td>
<td>3-7%</td>
<td>5%</td>
</tr>
<tr>
<td>Manufacturer Name Problems</td>
<td>NA</td>
<td>2-5%</td>
<td>1-4%</td>
<td>30%</td>
</tr>
<tr>
<td>Obsolete Products</td>
<td>1-4%</td>
<td>2-5%</td>
<td>1-8%</td>
<td>5-15%</td>
</tr>
<tr>
<td>Missing Product Brand Names</td>
<td>2-5%</td>
<td>5-10%</td>
<td>5-10%</td>
<td>20-25%</td>
</tr>
<tr>
<td>Incomplete Item Descriptions</td>
<td>5-15%</td>
<td>3-12%</td>
<td>5-15%</td>
<td>10-20%</td>
</tr>
<tr>
<td>Wrong Customer Unit Prices</td>
<td>Unknown</td>
<td>1-2%</td>
<td>NA</td>
<td>1-2%</td>
</tr>
<tr>
<td>Customer Paid More Than Lowest Contract Price</td>
<td>NA</td>
<td>Unknown</td>
<td>NA</td>
<td>3-6%</td>
</tr>
</tbody>
</table>

*Source: Department of Defense Data Synchronization Study*
Why is UDI and GDSN important?
An Efficient Healthcare Supply Chain

Healthcare Supply Chain

Manufacturing → Distributing → Provider

Cash and Information

Efficient Supply Chain

Product Flow

Production → Distribution → Consumption

Manufacturer → Distributor → Provider

Information and Cash Flow

PATIENT

PATIENT
Why is UDI and GDSN important?

Healthcare Reform: requires paradigm shift and delivery system changes

- Value-based purchasing
- Accountable Care Organizations
- Bundled payments
- Non-payment for preventable readmissions
- Non-payment for infections and HACs
- Transparency initiatives
- Drive to tackle waste, fraud and abuse
Why is UDI and GDSN important?
The next horizon: Accountable Care Organizations (ACO’s)

A group of providers willing and capable of accepting accountability for the total cost and quality of care for a defined population.

- Builds patient centric systems of care
- Improves quality and cost for delivery system components
- Coordinates care across participating providers
- Uses IT, data and reimbursement to optimize results
- Builds payer partnerships & accepts accountability for the total cost of care
- Assesses and manages population health risk
- Reimbursed based on savings & quality – value

Payer Partners:
- Insurers
- CMS
- Employers
- States
Why is UDI and GDSN important?
ACO’s are coming

As of 1/27/2011
Why is UDI and GDSN important?
ACO’s are coming

As of 1/27/2011
Information Technology and Data
At the heart of the ACO population health framework

Characteristics of the ACO Health Information Integration Platform (HIIP)

- Enables Transparency of Clinical, Cost, and Patient Related Data/Information
- Scalable to Accommodate Population & Stake Holder Fluctuations
- Provides Connectivity to RHIO’s, HIEs’ and NHIN
- ACO is “Easy to Do Business With” For All Stake Holders
- Foundational Infrastructure for Care Coordination & Collaboration
- Promotes Clinical Integration & Evidence Based Care Delivery Models

Source: Premier health alliance, © 2010
Information Technology and Data

Health Information Technology for Economic and Clinical Health (HITECH) Act

The Office of the National Coordinator for Health Information Technology (ONC) is at the forefront of the administration’s health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care.

The Health IT Standards Committee is charged with making recommendations to the National Coordinator for Health IT on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information.
What are we doing to support UDI and GDSN?
IBM Premier Integrated Healthcare Model supporting Accountable Care

UDI and GDSN are critical components in the interoperability of the future healthcare system!
What are we doing to support UDI and GDSN?

Global Data Synchronization Pilots

Manufacturers
- BD
- KCI
- gojo
- COOK
- Baxter
- Kimberly-Clark
- 3M
- Medline
- CardinalHealth

Distributors
- CardinalHealth
- OM & Minor
- SutureExpress

Payer

On Boarding
- ONTUET

GDSN
- Global Registry
- GS1

Data Pool
- 1SYNC

GPO
- Premier
- Amerinet
- Novation

Retail
Crosswalk

Providers
- Baptist Health South Florida
- MayoClinic.com
- PROMEDICA
- University Health Care System
- Norton Healthcare
- Boston Medical
- SISTERS OF MERCY HEALTH SYSTEM
- Ascension Health
- Atlantic Health
- Kettering
- DukeHealth
- St. Alexius PrimeCare
- Johns Hopkins Institutions Shared Services
- Orlando Regional Healthcare
- Sentara
- Novant Health
- Geisinger
- Lawson MMIS
- McKesson
- Caduceus Systems
What are we doing to support UDI and GDSN?
Premier’s Synchronization

Subscribed to the 1Sync Data Pool in 2010

*Synchronized with 103 Suppliers.*

- Healthcare 39
  (Includes 23 Healthcare Retailers)
- Retail 21
- Food 43

*Products synchronized = 14,510*

- Healthcare 6,575
- Retail 854
- Food 7,081
What are we doing to support UDI and GDSN?
Premier and Member Hospital Pilots
Pilot provided GDSN data along with Premier enriched data.

Pilot included GDSN data along with Premier enriched data.

Participants - Allegiance Health, Boston Medical Center, Geisinger

Objectives - Combine data from GDSN with Premier contract data and member-specific tier pricing, and share data forward in a format that can be easily uploaded into the member MMIS.

Findings - Compiling data into MMIS-readable format was successful for MediClick and Lawson systems. Combining GDSN with Premier contract data required bridging different systems – should be easier once GDSN is integrated into PIM.
Thank you

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