Unique Device Identification (UDI) Implementation Webinar

The Value of UDI Implementation for Healthcare Systems and Providers

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November 5th, 2012
Welcome and Overview

Housekeeping:
• To minimize feedback, please confirm that the microphone on your telephone is muted.
• To mute your phone, press the mute button or ‘*6’. (To un-mute, press ‘*7’)
• There will be several opportunities for questions and discussion throughout today’s session. **Please use the Q & A tab on the top of your screen to submit your questions into the queue at any point** and we will call upon you to state your question.
• Call the Level 3 Conferencing at 1-888-447-1119 with technical problems.
Overview of Unique Device Identification (UDI) Implementation

Gregory Daniel

The Brookings Institution • Washington, DC
Monday, November 5, 2012
UDI Development and Implementation

Affixing/incorporating UDI during manufacturing

Use of devices that are not uniformly labeled with UDIs (current state)

Use of devices with UDIs in clinical practice

Routine capture of UDI in electronic data sources

UDI routinely available for valuable uses

UDI Development Phase

UDI Implementation Phase
UDI Development and Implementation

Affixing/incorporating UDI during manufacturing

Use of devices that are not uniformly labeled with UDIs (current state)

UDI Development Phase

Incorporating UDI into data collection fields and provider workflow

Use of devices with UDIs in clinical practice

Routine capture of UDI in electronic data sources

UDI Implementation Phase

UDI routinely available for valuable uses
UDI Development and Implementation

UDI Development Phase

Affixing/incorporating UDIIs during manufacturing

Use of devices that are not uniformly labeled with UDIs (current state)

UDI Implementation Phase

Incorporating UDI into data collection fields and provider workflow

Use of devices with UDIs in clinical practice

Developing methods and data infrastructure

Routine capture of UDI in electronic data sources

UDI routinely available for valuable uses

Use of devices that are not uniformly labeled with UDIs (current state)
UDI Development and Implementation

Affixing/incorporating UIDs during manufacturing

Use of devices that are not uniformly labeled with UDIs (current state)

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Use of devices with UDIs in clinical practice

Routine capture of UDI in electronic data sources

UDI routinely available for valuable uses

UDI Development Phase

UDI Implementation Phase

Proposed Initial Focus for UDI Implementation Work Group
UDI Implementation Roadmap

- FDA
- Payers
- Researchers
- Providers/Health Systems
- Manufacturers
- Patients
- Other Policy Makers
- Other Organizations/Stakeholders
- Other Policy Makers
UDI Implementation

- FDA
- Payers
- Researchers
- Providers/Health Systems
- Manufacturers
- Patients
- Other Policy Makers
- Other Organizations/Stakeholders
- Other Policy Makers
Largest U.S. Not For Profit Health System…

- 9+ Million Members
- 37 Medical Centers
- 611 Med Office Bldgs
- 16,700 Physicians
- 173,000 Employees
Supply Chain Is Integral to Patient Care Delivery

Supply Chain

Ensure our patients and caregivers have what they need when they need it - ensuring high quality and low cost.
A Day in the Life of a Caregiver

**Should Be:**
- Complete Focus on the Patient
- Supplies Always There When Needed
- No Risk of Expired Product
- No Risk of Recalled Product
- Standard, High Quality Products

**What It Is Currently:**
- Lots of “Hunting and Gathering”
- Lots of Inventory and No Inventory
- Constant Vigilance for Expired Product
- Very Manual Recall Process
- Total Value of Product Not Evident/Known
Approximately 35k-40k unique SKUs in OR

>1200 Recalls in 2011

Full Inventory in OR

Time each year

only done 1

physicals are

Full Inventory

in 2011

>1200 Recalls

Approximately

38%
“Supply” Chain Vision

Registries/Databases for Comparative Effectiveness & Surveillance
Proof of Concept Sites

- Ophthalmology
- Urology

- Bariatric
- Orthopedics
- IR

- Ophthalmology
- Orthopedics

- Spine
- General Surgery
- IR
## Proof of Concept Results

<table>
<thead>
<tr>
<th>Key Indicator</th>
<th>% Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Out of Stock Reduction</td>
<td>33%</td>
</tr>
<tr>
<td>Inventory Reduction*</td>
<td>9%</td>
</tr>
<tr>
<td>Contract Compliance**</td>
<td>3pp</td>
</tr>
<tr>
<td>Clinician Satisfaction</td>
<td>Much Higher</td>
</tr>
</tbody>
</table>

*These are actual realized, all sites identified 20%+ inventory reduction opportunities that will be seen before year’s end

**Extrapolated to Total Spend Based on Proof of Concept Service Lines
# Why is UDI Critical to the Care Improvement?

<table>
<thead>
<tr>
<th>Patient Safety</th>
<th>How can we ensure the safest care possible?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply Chain Efficiencies</td>
<td>How can we make our supply chains more efficient?</td>
</tr>
<tr>
<td>Supplier Integration</td>
<td>How can we work better with suppliers to lower costs?</td>
</tr>
<tr>
<td>Fraud &amp; Waste</td>
<td>Were all products used in the service of our patients?</td>
</tr>
<tr>
<td>Product &amp; Practice Standardization</td>
<td>How do we minimize variation to improve care with better outcomes?</td>
</tr>
</tbody>
</table>
# UDI – The Key to a Better Future

## Patient Safety
- Faster and more efficient recall management
- Prevent introduction of counterfeit product
- Maximized nursing focus on the delivery of care
- Ensure right product used on the right patient

## Supply Chain Efficiencies

## Supplier Integration

## Fraud & Waste

## Product & Practice Standardization
## UDI – The Key to a Brighter Future

### Patient Safety

### Supply Chain Efficiencies
- Replenishments driven by actual usage
- Par levels set to ensure service levels
- Optimized inventory levels to minimize cash flow
- Increased productivity through optimized ordering
- Linkage to OR schedules to further minimize inventories

### Supplier Integration

### Fraud & Waste

### Product & Practice Variation
## UDI – The Key to a Brighter Future

### Supplier Integration
- Demand planning and forecasting for suppliers to better plan production
- Reduced costs of consigned inventories
- Early detection of product quality issues
- Reduce total costs of doing business to offset impact of Medical Device Tax
- Opportunities for SKU rationalizations
UDI – The Key to a Brighter Future

Patient Safety

• Prevent introduction of counterfeit products into supply chain

Supply Chain Efficiencies

• Estimated $2000/bed/year supply leakage

Supplier Integration

• Reduction of expired product waste

Fraud & Waste

• Reduction of excess waste and handling

Product & Practice Standardization
UDI – The Key to a Brighter Future

- Enables comparative effectiveness
- Effective sourcing that goes beyond just price
- Enables formulary SKU standardization
Healthcare Transformation Group (HTG)

Supply Chain Coalition

- Geisinger Health System
- Intermountain Healthcare
- Kaiser Permanente
- Mayo Clinic
- Mercy Health

- >$60B Revenue
- 14M Members
- 330,000 Employees
- 110 Hospitals

www.healthcaretransformationgroup.com

Latest News
HTG to Host 2nd Annual HTG Summit in St. Louis, Missouri. The event will include HTG’s top 20 suppliers, software providers and supply chain executives from each provider organization. >> Learn More
Thank You!
The Value of UDI Implementation for Healthcare Systems and Providers
Clinical Perspective
Brookings Institution Webinar
November 5, 2012

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UDI Across Health Care

• Manufacturers labeling devices with UDI sets the foundation for use of UDI across health care
  • Operations
  • Financial
  • Clinical Care
  • Post-market Surveillance
• UDI establishes common language for medical devices & ability to track across device lifecycle
UDI Across Health Care-Clinical Care

1. Standard to facilitate safe & accurate device use at point of care
2. Standard to document devices used on or implanted in patient
3. Standard to facilitate recalls for devices used on or implanted in patient
4. Standard to support post-market surveillance of devices
5. Standard to support lower health care costs
UDI Across Health Care-Clinical Care

Standard to facilitate safe & accurate device use at point of care

- Scan UDI and patient wrist band
- Expected benefits
  - Assure specified device
  - Notification of patient allergy – latex or other
  - Recalled device
  - Enhanced patient safety
- Analogous to medication verification & administration @ bedside
- Research has shown statistically significant reduction of medication error with use of e-MAR

UDI Across Health Care-Clinical Care

Standard to document devices implanted in patient

- Current process across health care
  - Not a standard for documentation of implantable devices
  - Barcode on device package scanned @ point of use may not be connected to EHR
  - Device info may be entered manually
  - Product labels put on sheet
  - Physicians dictate/enter descriptive info into operative/procedure report
  - Physician may take product label or copy of OR record to office
Revision Orthopedic Joint Replacement Surgeries

- Current process to identify components of original implant
  - Multiple methods used
  - Obtain prior records
  - Device information may not be complete or correct

- Impact
  - Clinical inefficiency in preoperative planning and perioperative period
  - Patient could have more extensive surgery
UDI Across Health Care-Clinical Examples

Interventional Cardiology

- Re-stenosed stent
  - Need device information from the procedure report
  - Getting device information not always straight-forward
  - May need additional imaging such as fluoroscopy or ultrasound

Impact

- Time factor under urgent circumstances
- Patient may require extra imaging
- Clinical inefficiency
UDI Across Health Care-Clinical Examples

Many other procedures & implantable devices to consider (Class II&III)

- AICDs
- Cochlear implants
- Neurostimulators
- Breast implants
- Insulin pumps
- Mesh
- Slings
- Bands
- Etc., etc.
UDI Across Health Care-Clinical Care

Standard to document devices implanted in patient

• Improved Process
  • Automated capture of UDI @ point of use
  • Connectivity to EHR
• Expected benefits
  • Standard for documentation & location of implantable device information for patient care
  • Efficiency for clinical team
  • Error reduction
UDI Across Health Care-Clinical Care

Standard to facilitate recalls for devices implanted in patient

• Current Process
  • UDI in EHR not the standard
  • Recall information floods hospitals/providers
  • Often manual & laborious process to determine affected patients

• Improved Process
  • Automated capture of UDI @ point of use ➔ link to patient
  • UDI in EHR ➔ standard place of documentation
UDI Across Health Care-Clinical Care

Standard to facilitate recalls for devices implanted in patient

Expected benefits

• Ability to query clinical IT system using UDI
• Comprehensiveness in identifying patients that received recalled devices
• Heightened efficiency of process
• Enhanced patient safety
UDI Across Health Care-Clinical Care

*Standard to support post-market surveillance of devices*

- Important activities to monitor devices once in the market & used on many patients
- Informs patient care
- Current limitations
  - Completeness & clarity of adverse event reports
  - Medical device data from EHR and claims
  - Lack of standard for device data entry into registries
  - Lack of standard device identifier in data sets used for research
  - Means to link data on devices between FDA data systems
UDI Across Health Care-Value Beyond the Point of Use in a Patient

- UDI in EHR
  - Device ID for patient care
  - Post Market Studies
  - FDA Sentinel System
  - Population Databases
  - Comparative Effectiveness Research
  - Link to Other Registries
  - Link to Other Databases
  - Adverse Event Reporting
  - Recalls

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UDI Across Health Care-Post-market Surveillance

*Standard to support post-market surveillance of devices*

Benefits that ultimately impact patient care

- UDI in adverse event reports
- Flow of UDI from EHR and claims data
- UDI as device identification in clinical registries
- UDI in data sets
- Link FDA databases, premarket & post-market
- Potential to determine need for recalls earlier
UDI Across Health Care-Support Lower Health Care Costs

Expected impact on cost

- Improved operational and clinical efficiency
- Enhanced data
  - Analysis of procedure, device, cost, outcomes, readmissions, etc.
  - Improved datasets for research, internal registries
- Potential to determine need for recalls earlier
  - Less patients impacted
  - Less cost to system
UDI Across Health Care-Ongoing Work

- FDA’s MDEpiNet UDI Work
  - Brookings Institution UDI Implementation Work Group
  - UDI Coronary Stent Demonstration Project
  - UDI in Orthopedics
  - ASTER-D (adverse spontaneous triggered events reporting)
- Ongoing discussion with ONC & CMS on UDI

FDA. Medical Devices. MD Epidemiology Network Initiative (MDEpiNet).
http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm

http://www.brookings.edu/events/2012/07/16-udi-stakeholders

Brookings. Developing the Capabilities for Device Surveillance through the Medical Device Epidemiology Network.
http://www.brookings.edu/events/2012/04/09-device-surveillance-mdepinet
UDI Across Health Care

FDA’s UDI Rule sets the foundation for use of UDI across health care

Full value of UDI across health care will be achieved through implementation and adoption of UDI for operational, financial, clinical and post-market surveillance purposes.
Resources

• FDA Website - UDI
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

• FDA Website – MDEpiNet
  http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm

• Brookings Institution UDI Implementation Work Group
  http://www.brookings.edu/events/2012/07/16-udi-stakeholders
Discussion and Questions