UDI Initiatives Driving Change in the Health Care Supply Chain

June 25, 2015

Karen Conway, CMRP
AHRMM CQO Strategy Team
UDI Lead, Issues and Legislative Committee
Many different participants

Lack of standardization in process, technology and data

Increases variation and cost, lowers quality
Targeting Variation

In Outcomes, Costs, Process, and Data

Lots of debate over how to standardize clinical process, but data SHOULD be easier.
A Holistic Approach

Holistic - characterized by comprehension of the parts of something as intimately interconnected and explicable only by reference to the whole

AHRMM Cost, Quality and Outcomes (CQO) Movement refers to a more holistic view between cost, quality and outcomes as opposed to viewing each independently.

“This is not about just being able to identify devices. We (FDA) are talking about a holistic approach to integrating medical device information throughout the entire healthcare system. UDI will be a fundamental piece of everything we do going forward”

Jay Crowley, former Sr. Adviser for Patient Safety, U.S FDA Center for Devices and Radiological Health
Conforming Amendments

• 821.25 A manufacturer of a tracked device must include the UDI, lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of these devices.

• 821.30 Persons other than device manufacturers and distributors must include the UDI, lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device.

• 803.32 User facilities must include the UDI on the device label or on the device package in individual adverse event report submissions.
Being in sync is key
UDI is all about synchronization

Identifying the same product the same way across healthcare
Order Takers/Placers

Price Focused

Box Movers

Hospital Supply Chain: An Historic View
Supply Chain: The Evolution

- Cost, Quality, and Outcomes
- Utilization & Standardization
- Price Controls
In 2013, AHRMM launched the Cost, Quality, and Outcomes Movement, a new way of approaching supply chain.

Under the CQO movement, the supply chain can no longer focus exclusively on price, but rather the combination of product **cost**, the **quality** of care delivered, and the reimbursement **outcomes** to support healthcare’s new value-based models.
CQO Movement looks at the relationship between:

**Cost:** all costs associated with delivering patient care and supporting the care environment

**Quality:** patient-centered care aimed at achieving the best possible clinical outcomes

**Outcomes:** financial reimbursement driven by outstanding clinician care at the appropriate cost
When Supply Chain Owns the CQO Intersection: Case Study 1
CQO Asks:
*How Do We Reduce Needlestick Injuries in Healthcare?*

- >800,000/yr in US
- Risk of blood borne pathogens
- Education only
CQO Asks:

How Do We Reduce Needlestick Injuries in Healthcare?

- New syringes with improved safety mechanisms
CQO Asks:
What is Unique About its Clinical Performance to Justify its Cost?
Safety Syringes

- 1 Needlestick injury/6000 injections
- Average cost of testing/treatment after injury equals $3000
- Additional costs of treatment can add up to hundreds of thousands
### Case Costs: Conventional Safety Syringes

<table>
<thead>
<tr>
<th>Actual Historical Spend</th>
<th>Needlestick Injury Benchmark</th>
<th>Total Cost of Needlesticks/Needles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average purchase price</td>
<td>$0.2207</td>
<td>Needlestick Injuries 37</td>
</tr>
<tr>
<td>Units</td>
<td>158,700</td>
<td>Per Needlestick Cost $3000.00</td>
</tr>
<tr>
<td>Purchase Cost</td>
<td>$35,027.00</td>
<td>Total Needlestick Cost $111,000.00</td>
</tr>
</tbody>
</table>

**SUPPLY CHAIN INTERVETION: DECREASE SAFETY SYRINGE PRICE BY 15%**

<table>
<thead>
<tr>
<th>Average purchase price</th>
<th>Needlestick Injuries</th>
<th>Units</th>
<th>Per Needlestick Cost</th>
<th>Purchase Cost</th>
<th>Total Needlestick Cost</th>
<th>Total Cost of Needlesticks/Needles</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0.1876</td>
<td>37</td>
<td>158,700</td>
<td>$3,000.00</td>
<td>$29,772.95</td>
<td>$111,000.00</td>
<td>$140,772.95</td>
</tr>
</tbody>
</table>

**Total Savings**
- 15%
## Case Costs: New vs. Conventional Safety Syringes

<table>
<thead>
<tr>
<th>Actual Historical Spend</th>
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<td>158,700</td>
<td>Per Needlestick Cost $3000.00</td>
</tr>
</tbody>
</table>

**Purchase Cost**

- $35,027.00
- Total Needlestick Cost $111,000.00
- Total Cost of Needlesticks/Needles $146,027.00

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**SUPPLY CHAIN INTERVENTION: CONVERT TO IMPROVED SAFETY SYRINGES**

<table>
<thead>
<tr>
<th>Average purchase price</th>
<th>Needlestick Injuries</th>
<th>Units</th>
<th>Per Needlestick Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0.3112</td>
<td>27</td>
<td>158,700</td>
<td>$3,000.00</td>
</tr>
</tbody>
</table>

**Purchase Cost**

- $49,387.44
- Total Needlestick Cost $81,000.00
- Total Cost of Needlesticks/Needles $130,387.44

**Total Savings**

- 41%
- -27%
- -10.71%
## Case Costs: Conventional vs. New Safety Syringes

<table>
<thead>
<tr>
<th>Actual Historical Spend</th>
<th>Needlestick Injury Benchmark</th>
<th>Total Cost of Needlesticks/Needles</th>
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<tr>
<td>Units</td>
<td>158,700</td>
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</tr>
<tr>
<td>Purchase Cost</td>
<td>$35,027.00</td>
<td>Total Needlestick Cost</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total Cost of Needlesticks/Needles</td>
</tr>
</tbody>
</table>

### SUPPLY CHAIN INTERVENTION: OBTAIN PERFORMANCE GUARANTEE

| Average purchase price  | Needlestick Injuries | 18                                |
| Units                   | 158,700              | Per Needlestick Cost              | $3,000.00 |
| Purchase Cost           | $49,387.44           | Total Needlestick Cost            | $54,000.00 |
|                         |                     | Total Cost of Needlesticks/Needles| $103,387.44 |
| Total Savings           | 41%                 | -51%                              | -29.2% |
Substantiating Evidence


CAUTI House Wide Annual Count NHSN

37% Reduction

65 Infections Prevented = $58,240 in Health Care Savings

1. $896/CAUTI JAMA Intern Med. Published online September 02, 2013. doi:10.1001/jamainternmed.2013.9763
36 Infections Prevented * = $1,649,304 in Health Care Savings

Linking Effectiveness with Inter-professional Processes

- **HAPU**
  Skin care bundle, bed making standards, skin champions

- **CLABSI**
  CHG Baths, alcohol caps, antimicrobial central line catheters, check lists, custom pack of supplies meeting CDC recommendations for CLABSI bundle, CLASBI champions

- **CAUTI**
  CHG Baths, CAUTI bundle, pilot units, EMR enhancements, CAUTI champions
AHA Moments

- All 3 projects increased net costs of products
- Return on investment to date = 2/1
- ROI for each calculated using established value analysis processes clinical evidence, quality, patient/staff safety, outcomes, costs, establishing and monitoring metrics to meet goals
Unique Position......Supply Chain Touches everyone

<table>
<thead>
<tr>
<th>Hospital/Clinic – Senior Leaders (C-Level, VP’s)</th>
<th>Corporate Senior Leadership (Corporate Staff)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Accountability</td>
<td>• “Systemness”</td>
</tr>
<tr>
<td>• Provider focused and based solutions – Assistance with goals- respect, value, recognition</td>
<td>• Relationship Management</td>
</tr>
<tr>
<td>• Leadership Collaboration</td>
<td>• Leadership (corporate)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Facility - Mid-Managers (Supervisors, Dir., Mgrs., VP’s)</th>
<th>Future Customers (Physicians, IDN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Harmonious with environment</td>
<td>• Value</td>
</tr>
<tr>
<td>• Communication, be heard, access to information</td>
<td>• Respect</td>
</tr>
<tr>
<td>• Respect</td>
<td>• Recognition</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinicians (Nurses, Pharmacists, Resp. – Lab tech)</th>
<th>Vendors</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Efficiency of product access</td>
<td>• Partnership Relationships</td>
</tr>
<tr>
<td>• Involvement in product decision making</td>
<td>• Equal Opportunity</td>
</tr>
<tr>
<td>• Quality of patient care delivery/ patient safety</td>
<td>• Profitability</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-Integrated Physicians</th>
<th>Industry Leaders (Influencers, Publishers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Autonomy</td>
<td>• Succinct Story</td>
</tr>
<tr>
<td>• Quality of life</td>
<td>• Advanced knowledge, involvement</td>
</tr>
<tr>
<td>• Quality of care/ Patient Safety</td>
<td>understanding the model – New ideas</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SC Co-workers</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Respect for individual input</td>
<td></td>
</tr>
<tr>
<td>• Compensation/benefits</td>
<td></td>
</tr>
<tr>
<td>• Tools to do the job</td>
<td></td>
</tr>
</tbody>
</table>

Franciscan Missionaries of Our Lady Health System
UDI: At the Center of the CQO Movement
Supply Chain (Item Master) as Source of Truth for Providers

- ERP/EHR
- Item Master/Charge Master
- Disaster Preparedness
- Comparative Effectiveness
- Clinician and Patient Satisfaction
- Recalls Adverse Events
- Contracting
- Inventory
- Value Analysis
Definitions - Quality

• Quality means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.
FDA AHRMM Collaboration

• AHRMM survey developed with input from the FDA to better understand:
  – how users define medical device quality
  – the quality criteria used when making medical device purchasing decisions
  – and how these criteria factor into the medical device evaluation process
Initial Survey Analysis

• Respondents replied that other data sources are considered when making purchasing decisions including:
  – FDA medical device adverse event reports (71%)
  – Clinical trial data (71%)
  – Comparative benchmark reports (66%)
  – Third party analytics (51%)
Manufacturer designs and markets product

Regulators and customers receive accurate information about product

Demand and efficacy data available

Product and clinical attribute efficacy understood; necessary actions taken

Product purchased/shiped/ received

Product consumption documented at point of use in EHR

Product data captured in registries

Visibility = Value
Focus on Implantables: The Federal Government Is!
Medical Devices – A growing (and expensive) part of healthcare delivery

- Total joint replacements
  - 711,000 knee replacements in 2011
  - 450,000 hip replacements in 2011

- Coronary stents
  - > 1million in 2012
  - $18,560/case → 6% of health care expenditures
“60% of my O/R spend is on consignment products and I have zero visibility into what I’m spending”
- VP, Supply Chain

“We closely track our $500,000 in hospital supplies, but I have a closet with over $3M in consignment inventory that I am not tracking at all”
- Director, Materials Mgmt

- **Implants can contribute 50-80% of the cost of some procedures.**
- **Higher costs to serve contribute to up to 45% of total implant costs.**

Source: HFMA, ASU
<table>
<thead>
<tr>
<th>Surgeon</th>
<th>MSDRG 470 Total Knee Volume</th>
<th>Total Knee Volume</th>
<th>Total Spend</th>
<th>Not to Exceed Group Average</th>
<th>25 Percentile</th>
<th>Best in Class $8,070</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon 1</td>
<td>$8,070</td>
<td>1</td>
<td>$8,070</td>
<td>$8,070</td>
<td>$8,070</td>
<td>$8,070</td>
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<tr>
<td>Surgeon 2</td>
<td>$8,273</td>
<td>89</td>
<td>$736,311</td>
<td>$736,311</td>
<td>$736,311</td>
<td>718,262</td>
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<tr>
<td>Surgeon 3</td>
<td>$8,879</td>
<td>1</td>
<td>$8,879</td>
<td>$8,879</td>
<td>$8,879</td>
<td>8,070</td>
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<tr>
<td>Surgeon 4</td>
<td>$9,167</td>
<td>50</td>
<td>$458,368</td>
<td>$458,368</td>
<td>$458,368</td>
<td>403,518</td>
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<tr>
<td>Surgeon 5</td>
<td>$9,244</td>
<td>4</td>
<td>$36,976</td>
<td>$36,976</td>
<td>$36,976</td>
<td>32,281</td>
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<tr>
<td>Surgeon 6</td>
<td>$9,802</td>
<td>13</td>
<td>$127,431</td>
<td>$127,431</td>
<td>$127,431</td>
<td>104,915</td>
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<tr>
<td>Surgeon 7</td>
<td>$9,936</td>
<td>63</td>
<td>$625,989</td>
<td>$625,989</td>
<td>$625,989</td>
<td>508,433</td>
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<tr>
<td>Surgeon 8</td>
<td>$10,183</td>
<td>27</td>
<td>$274,940</td>
<td>$274,940</td>
<td>$268,261</td>
<td>217,900</td>
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<tr>
<td>Surgeon 9</td>
<td>$10,227</td>
<td>105</td>
<td>$1,073,809</td>
<td>$1,060,142</td>
<td>$1,043,314</td>
<td>847,388</td>
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<tr>
<td>Surgeon 10</td>
<td>$10,374</td>
<td>121</td>
<td>$1,255,306</td>
<td>$1,221,687</td>
<td>$1,202,295</td>
<td>976,514</td>
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<tr>
<td>Surgeon 11</td>
<td>$10,379</td>
<td>18</td>
<td>$186,827</td>
<td>$181,739</td>
<td>$178,854</td>
<td>145,266</td>
</tr>
<tr>
<td>Surgeon 12</td>
<td>$10,404</td>
<td>1</td>
<td>$10,404</td>
<td>$10,097</td>
<td>$9,936</td>
<td>8,070</td>
</tr>
<tr>
<td>Surgeon 13</td>
<td>$10,455</td>
<td>9</td>
<td>$94,099</td>
<td>$90,869</td>
<td>$89,427</td>
<td>72,633</td>
</tr>
<tr>
<td>Surgeon 14</td>
<td>$10,468</td>
<td>5</td>
<td>$52,340</td>
<td>$50,483</td>
<td>$49,682</td>
<td>40,352</td>
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<tr>
<td>Surgeon 15</td>
<td>$10,676</td>
<td>57</td>
<td>$608,549</td>
<td>$575,505</td>
<td>$566,371</td>
<td>460,011</td>
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<tr>
<td>Surgeon 16</td>
<td>$10,747</td>
<td>33</td>
<td>$354,646</td>
<td>$333,187</td>
<td>$327,899</td>
<td>266,322</td>
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<tr>
<td>Surgeon 17</td>
<td>$11,019</td>
<td>93</td>
<td>$1,024,785</td>
<td>$938,983</td>
<td>$924,078</td>
<td>750,543</td>
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<tr>
<td>Surgeon 18</td>
<td>$11,263</td>
<td>11</td>
<td>$123,888</td>
<td>$111,062</td>
<td>$109,300</td>
<td>88,774</td>
</tr>
<tr>
<td>Surgeon 19</td>
<td>$11,706</td>
<td>10</td>
<td>$117,056</td>
<td>$100,966</td>
<td>$99,363</td>
<td>80,704</td>
</tr>
<tr>
<td></td>
<td>711</td>
<td></td>
<td>$7,178,674</td>
<td>$6,949,352</td>
<td>$6,870,824</td>
<td>$5,738,026</td>
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<td></td>
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<td></td>
<td>$10,097</td>
<td>$9,774</td>
<td>$9,664</td>
<td>$8,070</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>$229,321</td>
<td>$307,849</td>
<td>$1,440,648</td>
</tr>
</tbody>
</table>

Potential Savings $229,321 $307,849 $1,440,648

Drilling down: The cost of care
<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>MSDRG Name</th>
<th>Total Volume</th>
<th>Supply Cost per patient</th>
<th>Total Cost per patient</th>
<th>Margin per patient</th>
<th>Clinically Adjusted LOS Per Case</th>
<th>Risk-Adjusted Mortality Index (RAMI)</th>
<th>Risk-Adjusted Complications Index (RACI)</th>
<th>Risk-Adjusted Readmission Index (RARI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>470</td>
<td>Major joint replacement or reattachment of lower extremity w/o MCC</td>
<td>42</td>
<td>$5,257</td>
<td>$6,912</td>
<td>3.1</td>
<td>0.00</td>
<td>0.67</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>81.51</td>
<td>TOTAL HIP REPLACEMENT</td>
<td>13</td>
<td>$6,349</td>
<td>$5,907</td>
<td>$8,663</td>
<td>$4,405</td>
<td>3.2</td>
<td>0.00</td>
<td>0.00</td>
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<tr>
<td>81.52</td>
<td>PARTIAL HIP REPLACEMENT</td>
<td>2</td>
<td>$4,399</td>
<td>$3,055</td>
<td>$6,299</td>
<td>$5,722</td>
<td>3.3</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>81.54</td>
<td>TOTAL KNEE REPLACEMENT</td>
<td>27</td>
<td>$5,131</td>
<td>$6,626</td>
<td>$7,783</td>
<td>$5,183</td>
<td>3.0</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

**LEGEND**

- **GOAL MET** = Green
- **GOAL UNMET** = Red

**Accounting for Cost of Care**
Even with electronic implant recording capability, most nurses use paper and stickers for recording usage during procedure.

Only 10% of entry is based on barcodes or RFID.

Survey conducted by GHX with OR nurses attending the 2011 AORN Conference N = 326
Survey conducted by GHX with OR nurses attending the 2011 AORN Conference N = 326
Survey conducted by GHX with OR nurses attending the 2011 AORN Conference  N = 326

LACK OF STANDARDIZATION INCREASES INEFFICIENCIES AND ERRORS, WHILE REDUCING VISIBILITY
Before Procedure

Boxed & In-Tray Items Require Different Documentation

No barcodes, no stickers, difficult to see by circulating nurse; requires reconciliation after the procedure.
Stickers

There are around 30 patient stickers printed on an 8 ½ x 11 sheet of paper.

Some patient stickers have barcodes (the top two rows) while the others do not.
Documentation Processes vary by Procedure, Team and Patient

Example: Some surgeons would like the Circulator to document implant usage on the progress notes form, while others do not.
Many providers and manufacturers still use separate, manual processes to collect usage data that must match.

**Example: Hospital Version**

![Hospital Version Image]

**Example: Manufacturer Version**

<table>
<thead>
<tr>
<th>Item Type</th>
<th>Hospital Version</th>
<th>Manufacturer Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any connected or non-connected femur</td>
<td>12490</td>
<td>22747.50</td>
</tr>
<tr>
<td>Any connected or non-connected MT/MT</td>
<td>12400</td>
<td>22747.43</td>
</tr>
<tr>
<td>Any CPD/MT Insert</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any portals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any non-connected femur</td>
<td>12401</td>
<td>22747.43</td>
</tr>
<tr>
<td>Any connected/fixed bearing blade</td>
<td>12407</td>
<td>22747.43</td>
</tr>
<tr>
<td>Any fixed bearing insert</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any portal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any connected femur</td>
<td>12455</td>
<td>22747.35</td>
</tr>
<tr>
<td>Any connected/fixed bearing blade</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any fixed bearing insert</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any portal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Wasted Items**

- $25.00
Data Capture May Be Electronic, but Typically Requires Lots of Manual Data Entry - on Multiple Screens and/or Systems

“In our fully electronic system, when there is a problem with charge capture, the clinician did not pick or document something correctly.”

- Hospital CFO
Different departments and staff (e.g. Accounts Payable, the surgeon) need different forms and records from the procedure.
What’s wrong with this picture?
What’s wrong with this picture?
What's wrong with this picture?
Implant sheet with three different types of implant stickers from three different vendors. Note that one sticker does not have a bar code.
No Set Reconciliation Between Vendor Rep & Circulator
Mercy UDI Demo Project 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.
Broad Benefits

Overall reduction in healthcare costs

• One provider estimated that UDI enables saving thousands of hours of clinician time per year by eliminating non-value-add activities

Revenue

• Increased charge accuracy
• Claims processing efficiencies

Courtesy: Mercy
Broad Benefits

- More accurate purchase orders, invoicing and payment
  - 30% reduction in days payable outstanding;
  - 73% reduction in discrepancies related to part number and UOM
- Real-time product usage and consumption
  - Automated replenishment
  - Demand-driven supply chain
  - Enables Point of Use systems and processes

Courtesy: Mercy
Broad Benefits

Inventory Management/Recalls

• “It takes us hundreds of hours to locate a device when there is an incident or recall, and even then we’re not sure we’ve located them all.” - Hospital Staff Member

• Inventory was thought to be approximately $800,000; value was actually $1.9 million; in 6 months inventory reduced to $1.56 million

• Eliminate re-labeling activities

• Expiration date management
  • One vendor’s product had $300,000 of expired product in 6 months

Courtesy: Mercy
Broad Benefits

Adverse Event Reporting/Recalls

• “I feel exposed and anxious that if there is a recall I won’t know if I have that cardiac device. How will I find out if I have that device? And I don’t think my doctor has it.” - Patient

Comparative Effectiveness Research

Courtesy: Mercy
Focus on Implantables

Challenges with non-sterile implants
How do we label all the pieces and parts with UDI?
Non-Sterile Implant Extension

• Nov. 2014 – FDA extends “point of use” label compliance date for many class II (FDASIA) non-sterile implants from 2015 to 24 Sep 2016

• GUDID submissions are still required in 2015.

• AdvaMed had requested or 2 additional years (2017).

• “Most of the devices that meet these … criteria are supplied non-sterile by the manufacturer” and are “intended to be sterilized (or cleaned and sterilized) before use.”
More Time, But a Higher Bar

“FDA is initiating this extension to allow time for the development and implementation of an alternative that would provide for more accurate and precise device identification than the requirements of 21 CFR 801 subpart B.” [Labeling Requirements for Unique Device Identification – which requires the label of every medical device to bear a UDI]
Success depends on your Customer
UDI is not DIY
Orthopaedic devices present unique challenges for UDI compliance:

- Funky supply chain – hi touch/low control
- No “real estate” for UDIs on products
- Many products cycle through system multiple times
- Labeling systems need to enable capture of the UDI at the point of use
- Products are often removed from their original package and placed in trays.
Data Carrier Tags

- Tag is affixed to product by manufacturer and bears UDI information in human readable and/or AIDC technology
- OR staff removes tag and captures UDI information manually or via scanner
- Scanned information can be electronically captured and downloaded into EHR system
- Product is intended to remain tagged until point of use; once removed,
  - it cannot typically be re-attached
Data Carrier Strips

- Implants from the same LOT are attached to plastic strip where each implant has its own compartment
- Individual compartments can be snapped off strip as needed
- The plasticized paper UDI label remains with each implant on strip until point of use
- Plastic strips are loaded into trays
- Staff break off and remove needed number of implants from plastic strip and retrieve UDI information
Individual Sterile Packaging

• Sterile supplied devices are common practice for many implantable medical devices, including some spine and trauma products.

• It is not common practice for large set configurations due to:
  – increased packaging waste
  – limited space in O.R.
  – increased O.R. time due to removing packaging for each implant information
Direct Part Mark

- Implants are etched with a human readable and/or AIDC readable UDI
- Larger implants that have sufficient space for the UDI in human readable format will have the device identifier (DI) and production identifier (PI) marked
- Medium implants may have sufficient space for only the device identifier to be marked and will require an exemption from PI marking
- Small implants will not have sufficient space for any human readable text and will require an exemption from PI and DI marking
Inventory Sheets

- Sheet is a map of the items in the implant tray
- Circulating nurse will document implants used and quantities on the inventory sheet.
- Inventory sheet could have UDI and a bar code for scanning or keying into electronic health record
SMI/FDA Initiative

• Clinical Documentation in Surgery: Current State
Simulated Surgeries
Simulated Surgery
Circulator

Surgeon

Scrub Nurse
Initial Observations

- Data collection process variation
- Protecting the sterile field
- Participant education on UDI
- Maintaining surgeon’s pace
- Workflow and process variation in both SPD and OR
- Scanning systems can work
- Backend cross referencing critical
MEpiNet SMART Working Group

BUILD

‘Building UDI Into Longitudinal Data for Surveillance & Research’

Leverage UDI as the index to connect data sources to identify devices for patients, clinicians, & others

1. Extend UDI implementation pilot
2. Medical device data capture and exchange: Leading practices & future directions – AHRMM Involvement
3. ePULSE – Electrophysiology structured reporting Providing UDI for Leads and devices Using industry Standards to Electronic health records and CVIS systems
Why don’t clinical trials give us all of the answers?

• Performed –
  By the best centers and best doctors
  On a well screened population of patients
  For narrow indications

  Not indicative of what will happen in the wild.

• Small numbers of patients –

  Problems picking up small safety signals.
How do we leverage device and clinical data to find the answer?

- Have to link the device with the patient.
- Have to link clinically meaningful attributes to the device.
- Have to combine device/attribute data with clinical (EHR) data in a database for effectiveness and safety analyses.
Improve Population Health

Improve Patient Satisfaction

Decrease Cost