

#### Unique Device Identification (UDI) Implementation Webinar

### The Value of UDI Implementation for Healthcare Systems and Providers

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November 5<sup>th</sup>, 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')
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## Overview of Unique Device Identification (UDI) Implementation

**Gregory Daniel** 

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### Unique Device Identification – Operations Perspective

November 5, 2012

Laurel L Junk Vice President, Supply Chain Kaiser Permanente



### Largest U.S. Not For Profit Health System...

9+ Million Members

37 Medical Centers611 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



### Fast Facts:

- Approximately 35k-40k unique SKUs in OR
- >1200 Recalls in 2011
- Full inventory physicals are only done 1 time each year



### "Supply" Chain Vision



### **Proof of Concept Sites**

OphthalmologyUrology





OphthalmologyOrthopedics

Bariatric
Orthopedics
IR





Spine
General Surgery
IR



### **Proof of Concept Results**

	% Improvement	
Key Indicator	Low	High
Out of Stock Reduction	33%	97%
Inventory Reduction*	9%	28%
Contract Compliance**	Зрр	6рр
Clinician Satisfaction	Much Higher	

\*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?

#### **Patient Safety**

Supply Chain Efficiencies

#### **Supplier Integration**

Fraud & Waste

## Product & Practice Standardization

- How can we ensure the safest care possible?
- How can we make our supply chains more efficient?
- How can we work better with suppliers to lower costs?
- Were all products used in the service of our patients?
- How do we minimize variation to improve care with better outcomes?



#### **Patient Safety**

Supply Chain Efficiencies

#### **Supplier Integration**

#### Fraud & Waste

#### **Product & Practice Standardization**

- 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





#### **Patient Safety**

#### Supply Chain Efficiencies

#### **Supplier Integration**

#### Fraud & Waste

#### **Product & Practice** Variation

- 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



#### **Patient Safety**

#### Supply Chain Efficiencies

#### **Supplier Integration**

#### Fraud & Waste

#### Product & Practice Standardization

- 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



#### **Patient Safety**

Supply Chain Efficiencies

#### **Supplier Integration**

#### Fraud & Waste

#### **Product & Practice Standardization**

- Prevent introduction of counterfeit products into supply chain
- Estimated \$2000/bed/year supply leakage
- Reduction of expired product waste
- Reduction of excess waste and handling



#### **Patient Safety**

#### Supply Chain Efficiencies

#### **Supplier Integration**

Fraud & Waste

#### **Product & Practice Standardization**

- Enables comparative
   effectiveness
- Effective sourcing that goes beyond just price
- Enables formulary SKU standardization



## Healthcare Transformation Group (HTG)

GS1®

#### **Supply Chain Coalition**

- Geisinger Health System Intermountain Healthcare Share Best Practices. Drive
- Kaiser Permanente
- Mayo Clinic
- Mercy Health

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

CONTACT

- 110 Hospitals

#### www.healthcaretransformationgroup.com



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HTG to Host 2nd Annual HTG Summit in St.

top 20 suppliers, software providers and

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### 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



- 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



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

Poon, EG, Keohane CA, Yoon, CS, et.al. Effect of Bar-Code Technology on the Safety of Medication Administration. N Engl J Med 2010;362:1698-1707



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



## **UDI Across Health Care-Clinical Examples**

**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.



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

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- Efficiency for clinical team
- Error reduction

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



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



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



Blue=hospital, Purple=FDA, Red-research, Green=other

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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 Brookings. Unique Device Identification (UDI) Implementation Work Group Kick-Off. <u>http://www.brookings.edu/events/2012/07/16-udi-stakeholders</u> Brookings. Developing the Capabilities for Device Surveillance through the Medical Device Epidemiology Network. <u>http://www.brookings.edu/events/2012/04/09-device-surveillance-mdepinet</u>

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## **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 <u>http://www.fda.gov/MedicalDevices/DeviceRegulationandGuinandGuinance/UniqueDeviceIdentification/default.htm</u>
- FDA Website MDEpiNet <u>http://www.fda.gov/MedicalDevices/ScienceandResearch/Epi</u> <u>demiologyMedicalDevices/MedicalDeviceEpidemiologyNetwo</u> <u>rkMDEpiNet/default.htm</u>
- Brookings Institution UDI Implementation Work Group <u>http://www.brookings.edu/events/2012/07/16-udi-</u> <u>stakeholders</u>



#### **Discussion and Questions**