

The Role of UDI in Product Life Cycle Management

Dennis Black, UDI Program Director
GHWP
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BD is a dynamic global medical technology leader that touches billions of patients around the world

37B +

devices made annually

190 +

countries served

\$1B +

annual R&D investment and five global enterprise R&D centers of excellence

77,000 +

BD associates worldwide



Device Manufacturers have made a tremendous investment in UDI

UDI Device Identifier

UDI-DI = 30382903830269

UDI Bar Code



UDI Data Base



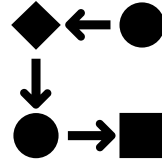
- To provide full value, UDI requires implementation and adoption by healthcare providers

Device Manufacturer UDI investments include :



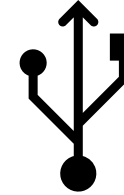
People

- In-country Teams
- Subject Matter Experts
- Project Managers
- Data Creators and Verifiers
- Global Support



Process

- Policies, Procedures, Work Instructions
- Governance
- Change Control
- Embed UDI in Complaint Handling
- Revised Commercial Practices
- UDI-DI Assignment



Technology

- Label Printing Technology
- Product Information Management System
- Bar Code Verification System
- Scanners
- Warehouse Management System
- Enterprise Resource Planning (ERP)

How is UDI utilized throughout the healthcare system?

Potential UDI Impact on the Healthcare Eco-System

Governments

- Product Safety
- Identify imports

Regulators

- Product Recalls
- Safety & Surveillance
- Counterfeiting
- Enforce Product Registration

Customs

- Reduce Counterfeiting
- Tariff Enforcement

Healthcare Providers

- Cost/Quality/Outcomes
- Product Utilization
- Patient Safety
- Recall Effectiveness
- Supply Chain Efficiency

Clinicians

- Product Research
- Point-of-Care Tracking
- Product/Company Info.
- Substitutes

Payors

- Reduce Fraud
- Cost/Quality/Outcomes
- Reimbursement

Researchers

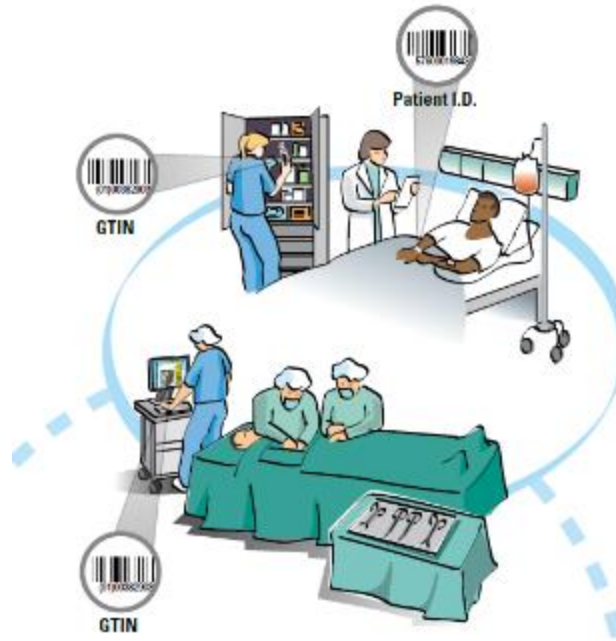
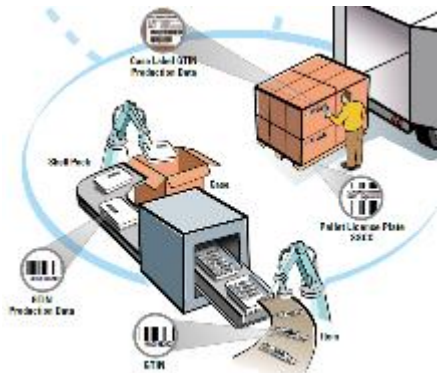
- Outcomes Analysis
- Implant Registries

Distributors

- Transactional Efficiency
- Managing Inventory
- Supply Chain Effectiveness

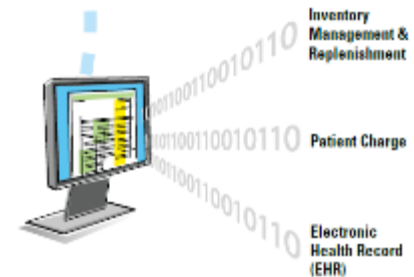
GPOs

- Price Comparison
- General Analysis



Patients

- Product Research
- Recall Effectiveness
- Product Safety

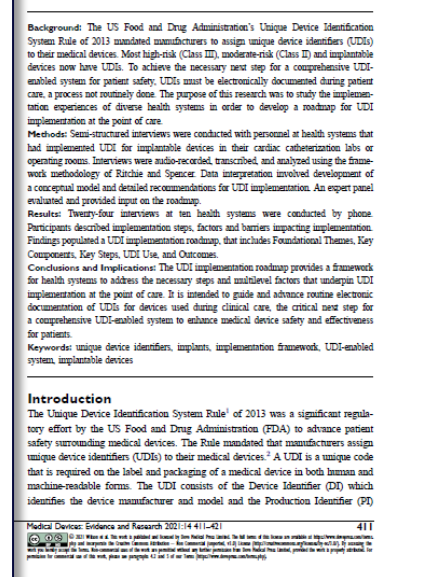
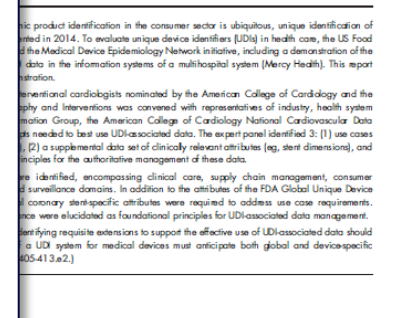
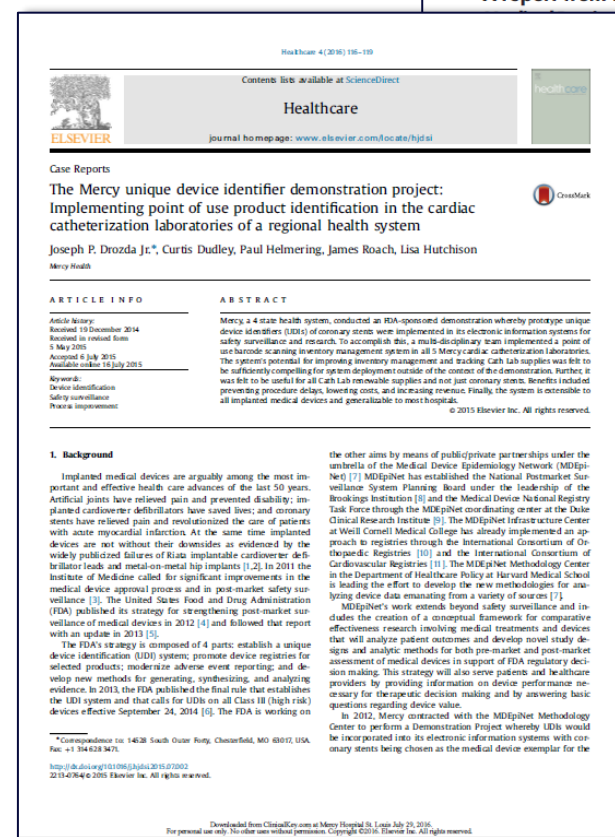
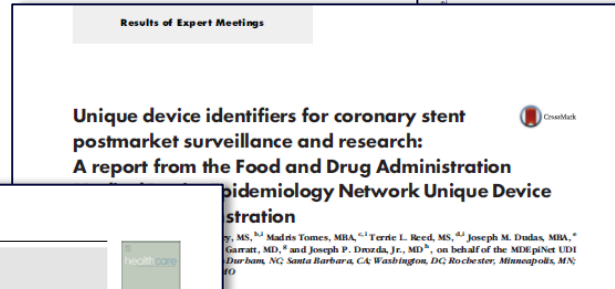
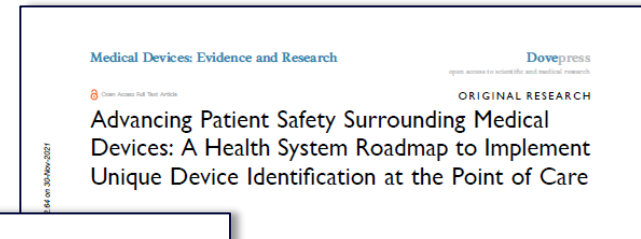


Publications and Cases Studies on UDI Benefits

- There are multiple case studies that document and extoll the benefits of UDI for healthcare providers.
- The scope and focus of UDI implementation efforts vary tremendously.
- Successes range from enhanced procurement processes, to recall efficiency, to enhanced patient care.

Special thanks the following organizations for sharing their insight on UDI adoption:

- AHRMM <https://www.ahrmm.org/resources/learning-udi-community>
- GS1 Healthcare <https://www.gs1.org/industries/healthcare>

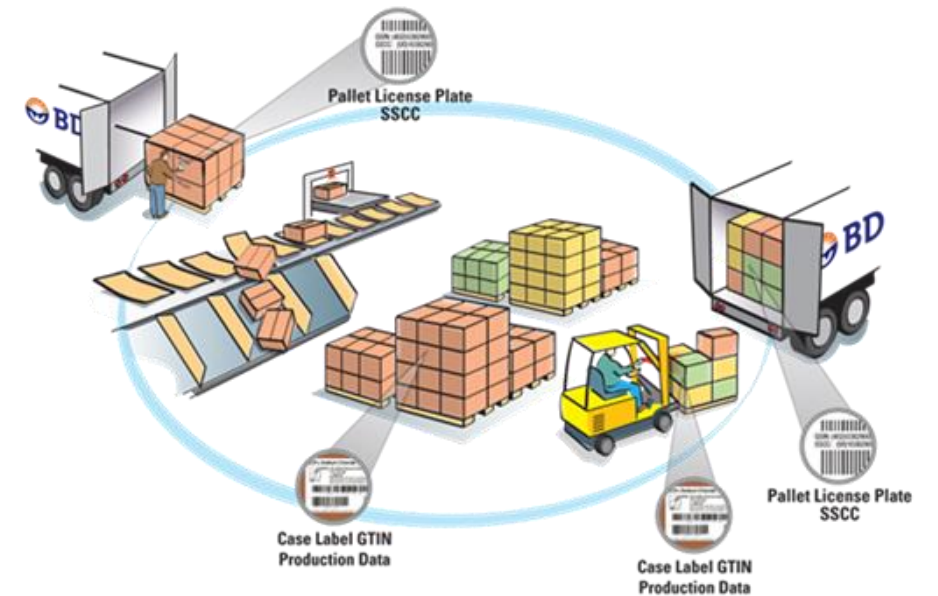


Use of UDI by Device Manufacturers

Many Device Manufacturers use UDI for product tracking, safety/surveillance and to support healthcare provider initiatives.

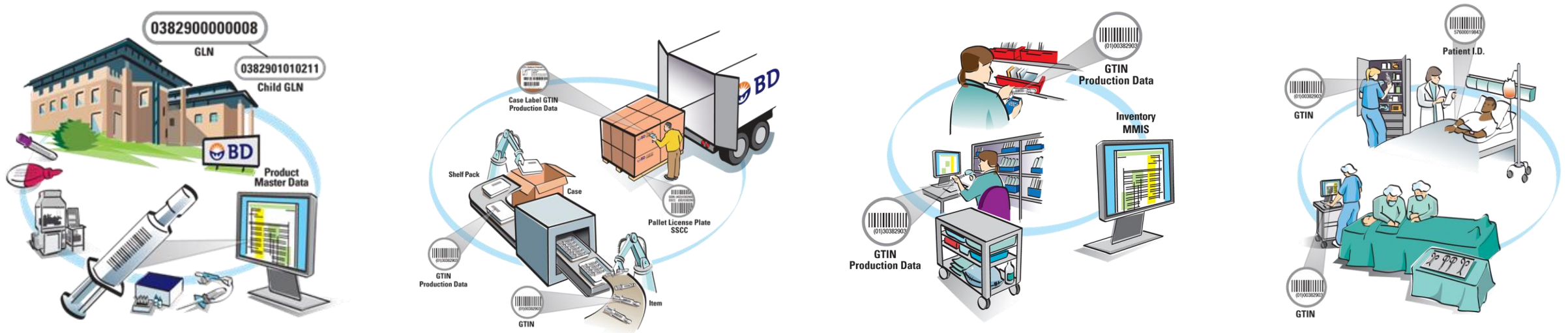
Supply Chain Benefits Include:

- Accurate Shipments
- Supply Chain Efficiencies
- Product Tracking
- Accurate Transactions



Use of UDI by BD with a leading Healthcare Provider (Mercy Health)

Pilot project proved that GTINs (UDI) could be utilized in end-to-end processes between Manufacturer & Healthcare Provider



- Achievement of “Perfect Order”
- More accurate purchase orders, invoicing and payment
- Clean data on delivery locations and account information
- Up-to-date item master and vendor master
- Real-time product usage and consumption
- Better product and lot number tracking
- Improved infrastructure and data accuracy for future patient care initiatives and the recall process

Use of UDI by BD with a leading Healthcare Provider (Mercy Health)

Each Level GTIN in a GS1-128 barcode



00382903065073

Shelf Pack Level GTIN and Production Data in GS1-128 barcodes



30382903065074

Case Level GTIN and Production Data in GS1-128 barcodes



50382903065078

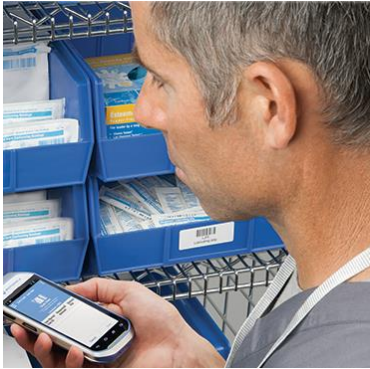
Challenges Included:

- Reconciling data
- Using BD's UDI data in Mercy systems
- Mutually learning to transact using UDI data
- Need for a common data source

Use of UDI by Healthcare Providers

- Healthcare providers are using UDI to enhance multiple processes
- Hospitals often have a different view of how UDI can be utilized:

Supply Chain



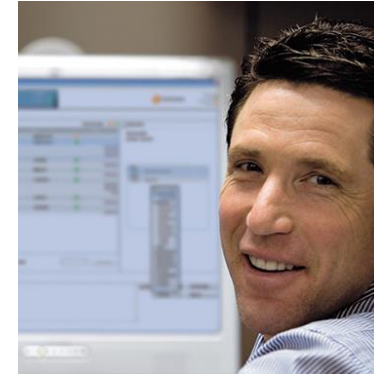
Recalls



Traceability of Products



Outcomes Analysis



See additional examples: <https://www.gs1.org/industries/healthcare/implementation>

Use of UDI by Healthcare Providers: Supply Chain

UDI may be used specifically for procurement or supply chain purposes

Examples:

- Item Master Organization
- Common Item Identification system amongst device manufacturers
- Electronic Procurement Processes
- “Perfect Order”
- Enhance internal supply chain processes



Use of UDI by Healthcare Providers: Supply Chain

UT Southwestern Medical Center (Texas, USA) used UDI to reduce costs and waste on Crash Carts

Key Themes:

- Hospital created a composite identifier by aggregating all UDI data.
- Clever use of the Trays, expiration date capture, and technology has enabled considerable savings



The Savings

- **\$8,000 per cart** by standardizing the process
 - Working together with Nursing, Supply Chain and Logistics to create a more efficient workflow
 - Short dated trays can be tracked and moved to high usage carts to reduce loss from expiration
- **\$30,000 in labor** – managed by only 1 employee now
 - Expiration reporting provides exact tray and cart to streamline removing and replacing trays instead having to check every tray across the 160 carts

Next steps to bring savings to Ambulatory side and use technology to support procedure carts.

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Use of UDI by Healthcare Providers: Recalls

Leeds (UK) has implemented GS1 Standards and UDI and has enhanced their recall processes.

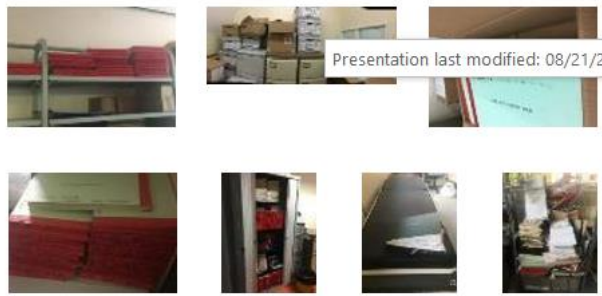
Key Themes:

- Visionary Leaders
- Systems Integration
- Effective Implementation

Benefits - Product Recall




Presentation last modified: 08/21/2023



194 Books in this slide
800 records per book
Over 155,000 potential records

Recall 1




10:15 - MHRA Notification Confirmed in Trust

10:28 – Confirmed we have the product in the Trust and that there will be no use of these products in the coming days

11:42 – Confirmation to Medical Director -Operations that all respective products have been removed from the clinical area and are under the control of the appropriate Inventory Manager.

Recall 2





Company informed us of a potential reaction to a lens. Consultant requested that we identify patients that had had these lenses.

In previous recalls this would have taken at least 6 days of a Band 7 time. This work would have had to be spread over a number of weeks.

Identified and reported demographics and NHS Number of **over 500** patients in **less than 40 minutes**.

Within six weeks all 500 patients were reviewed and proved clear of adverse outcome.

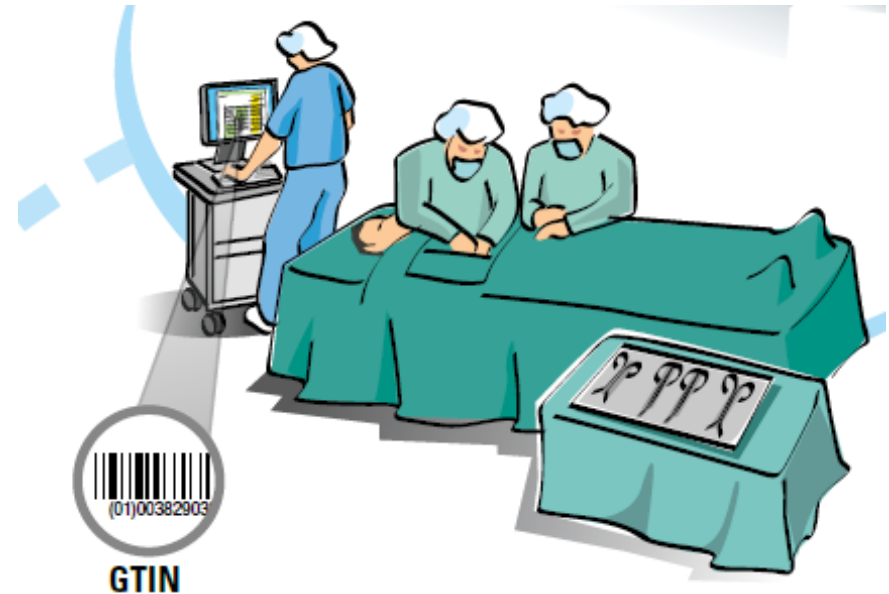


Use of UDI by Healthcare Providers: Traceability of Products

Which products do hospitals want to track?

Traceability Goals Include:

- Prevent incorrect product from being utilized
- Mitigate risk of outdated or recalled products
- Track all products used on all patients
- Enable Comparative Effectiveness Research programs
- Prevent specimen collection errors
- Maximize reimbursement and billing opportunities



Use of UDI by Healthcare Providers: Traceability of Products

Leading Healthcare Systems are able to scan UDI labels and store the information in their EHRs.

Key Themes:

- A standardized data structure amongst device manufacturers is essential
- System modifications are often required
- A UDI data system such as the regulator UDI Database is essential
- Disciplined scanning processes are necessary

1a Analysis

Tools: Edit Query, Edit Report

View Structure, Drill

Formula: =NameOf([Part Nbr])

Patient MRN Id	OR Procedure Name	Supply Item Type	EPIC Supply Item Name	Manuf Cd	Item Nbr	Part Nbr
E1402260637	APPENDECTOMY	Basin	BASIN SURGI-START SGL 31144333	TYCI	120234	31144333
E1402260637	APPENDECTOMY	Catheter	CATH FOLEY 16FR TRAY 900016A	CRBA	77894	900016A
E1402260637	APPENDECTOMY	Cautery	CAUT PENCIL HNDCTRL WHLSTR E2	TYCI	328	E2515H
E1402260637	APPENDECTOMY	Cautery	ELCTRD CAUTERY 4IN 0014A	MDYN	120194	0014A
E1402260637	APPENDECTOMY	Cautery	PAD GROUNDING E7507	TYCI	43204	E7507
E1402260637	APPENDECTOMY	Cautery	TIP CAUTERY TEFLON SHORT 0012	MDYN	24918	0012
E1402260637	APPENDECTOMY	Clip	APPLIER ENDO CLIP II 1-USE W/MED-L	TYCI	266114	176657
E1402260637	APPENDECTOMY	Dressing	DRSG BANDAID 0.75X3" 3065LF	TYCI	42376	3065LF
E1402260637	APPENDECTOMY	Dressing	DRSG GZE 4X4IN 10/PK 2539	TYCI	182350	2539
E1402260637	APPENDECTOMY	Glove	GLV SURG BIOGEL 6.5 30465	MOLN	13319	30465
E1402260637	APPENDECTOMY	Glove	GLV SURG BIOGEL 8.0 30480	MOLN	9928	30480
E1402260637	APPENDECTOMY	Gown	GOWN SURG ULTRA XLG 95121	KIMB	4140	95121
E1402260637	APPENDECTOMY	Lab	BACTISWAB AEROBIC C/S R723115	ATC	181335	B723115
E1402260637	APPENDECTOMY	Lab	CULTURETTE SPECIMEN ANAEROBIC	BECT	12906	00382902365006
E1402260637	APPENDECTOMY	Laparoscopic	ENDO CATCH 10MM 173050G	TYCI	259427	173050G
E1402260637	APPENDECTOMY	Laparoscopic	SPNG ENDO KITTNER 13300	VICN	207726	13300

Use of UDI by Healthcare Providers: Traceability of Products

Froedert Health (Wisconsin USA) publicly shared examples of their product tracking ability:

Key Themes:

- Industry collaboration was essential
- Achievements included use of UDI in various procurement processes.
- Implementation Team members included Froedert, W.L. Gore, and GHX

Implants					
Implant	* Qty Used	* Charge Used	Qty Wasted	Charge Wasted	* Inventory
SCREW 3.5MM 16MM LOCK 212.104 [0...	2	Yes	1	Yes	WMC OPERATING ROOM
SCREW 3.5MM 20MM LOCK 212.106 [0...	1	Yes			WMC OPERATING ROOM
SCREW CORTX 3.5MM 12MM 204.812 [...]	1	Yes			WMC OPERATING ROOM
SCREW CORTX 3.5MM 14MM 204.814 [...]	2	Yes			WMC OPERATING ROOM
SCREW CORTX 3.5MM 16MM 204.816 [...]	1	Yes	1	Yes	WMC OPERATING ROOM
SCREW CORTX 3.5MM 18MM 204.818 [...]	1	Yes			WMC OPERATING ROOM
SCREW CANCELS 4MM 16MM 206.016 ...	1	Yes	1	Yes	WMC OPERATING ROOM
7HOLE1/3LCPPLATE 241.371 [0005270]i	1	Yes			WMC OPERATING ROOM
ARTICUL/EZE BALL 28 +1.5 GR [13651...	1	Yes			WMC TRUNK STOCK FOR OR

+ X		* Surgeon	Ebrahimpour,Prouskeh B
Device Identifier	10603295033066	* Procedure	ORIF Ankle Fracture
Manufacturer	DEPUY ORTHO		
Lot Number	D22054105		
Batch Number			
Catalog Number	136511000		
Serial Number			
Size			
Site			
Solution Lot Number			
Solution Prep By			
Cultured			
Donation ID Number			
Manufactured Date			
Expiration Date	06/30/27		
Comment			

Billing Information	
Charge Code	02014384
Cost	
Charge	

Device (Brand Name)	
ARTICUL/EZE	

Use of UDI by Healthcare Providers: Outcomes Analysis

Leading Hospital System is tracking devices utilized by physician for specific surgeries

Clinical Integration of UDI:

- Tracking of medical devices in the operating room
- Comparison of cost per case
- Identification of recalled products
- Using medical device consumption data to drive clinical and supply chain decisions

Top joint replacement surgeons (based on number of procedures)					
Surgeon	Procedures	Total charges	Total CM	Managed care \$	Managed care % charges
Physician A	454	21,949,714	3,103,262	11,845,145	53.96%
Physician B	312	14,095,663	1,909,697	7,035,619	49.91%
Physician C	309	12,723,689	2,077,133	5,605,814	44.06%
Physician D	271	12,317,684	1,695,163	6,070,290	49.28%
Physician E	214	9,364,168	1,801,043	5,394,784	57.61%
Physician F	190	8,076,907	1,799,611	4,583,034	56.74%
Physician G	156	6,641,098	1,177,892	3,321,180	50.01%
Physician H	118	8,831,643	1,400,327	3,961,820	44.86%
Physician I	108	5,352,669	627,952	1,693,068	31.63%
Physician J	106	5,772,591	271,041	1,413,958	24.49%
Physician K	106	5,671,339	343,111	1,842,893	32.49%
Physician L	86	4,848,215	444,629	1,316,483	27.15%
Physician M	81	4,517,735	162,091	584,620	12.94%
Physician N	77	3,207,773	409,337	1,140,820	35.56%
Physician O	77	4,748,732	50,058	1,758,174	37.02%
Physician P	75	7,153,480	513,791	1,778,643	24.86%

Physicians names redacted for anonymity.

Use of UDI by Healthcare Providers: Outcomes Analysis

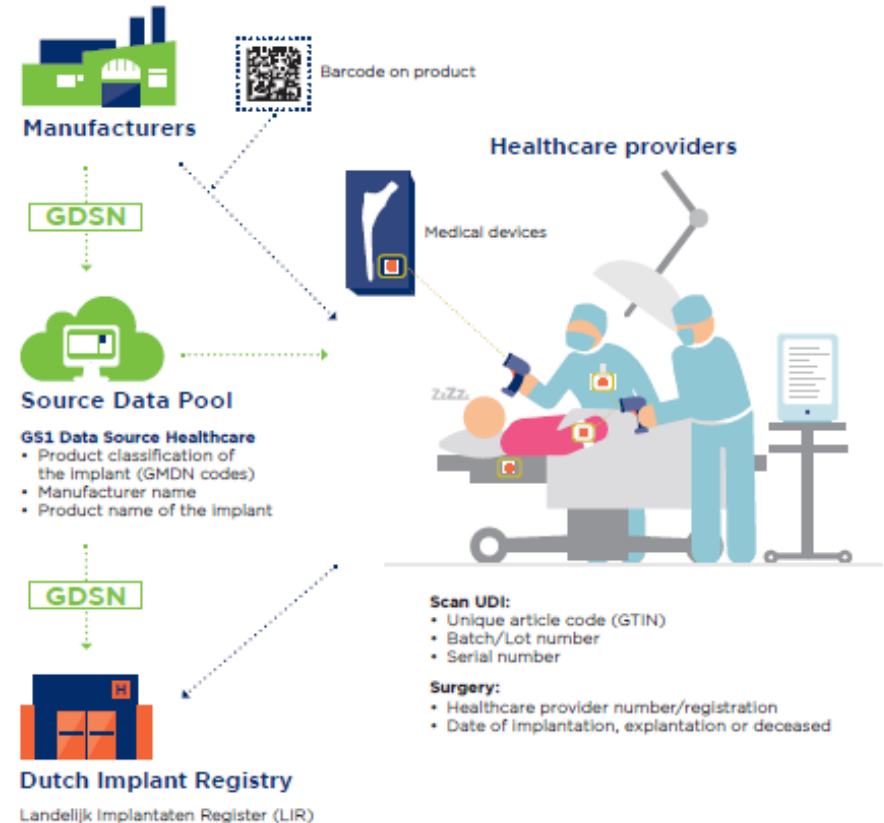
The Dutch National Implant Registry in the Netherlands:

UDI in an Implant Registry:

- Specific high-risk implants which are implanted in patients in the Netherlands must be registered
 - UDI is utilized to identify devices
 - GDSN is used to share data
 - Requirements are aligned with the MDR Regulation (Article 27. Health institutions shall store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to class III implantable devices.)
- [Registratie van implantaten | Medische hulpmiddelen en technologie | Rijksoverheid.nl](https://www.gs1.nl/en/knowledge-base/legislation-in-healthcare/dutch-implant-registry-for-healthcare-providers/)
 - <https://www.gs1.nl/en/knowledge-base/legislation-in-healthcare/dutch-implant-registry-for-healthcare-providers/>

Dutch Implant Registry

All products which are implanted in patients in the Netherlands must be registered in the Dutch National Implant Registry. It's about high risk medical devices (Class III), deadline January 1st 2019. UDI and GDSN are used as agreed by the Dutch market (ADC).



Observations on Successful UDI Implementation Efforts

Observations on Successful UDI Implementation Efforts

Common Themes:

- The hospital knows which specific UDI-related problem they are solving
- Visionary leader(s)
- Funding
- IT/Systems Infrastructure
- An Implementation Roadmap

Implementation efforts tied to: Regulations, laws, accreditation, reimbursement, or other requirements will succeed.

Medical Devices: Evidence and Research Dovepress
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ORIGINAL RESEARCH

Advancing Patient Safety Surrounding Medical Devices: A Health System Roadmap to Implement Unique Device Identification at the Point of Care

Open Access Full Text Article
Medical Devices: Evidence and Research downloaded from <https://www.dovepress.com/> by 70.176.22.84 on 30-Nov-2021
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Natalia A Wilson¹
James E T Cheng²
Jove Graham³
Joseph P Drozda Jr⁴

¹College of Health Solutions, Arizona State University, Phoenix, AZ, USA;
²Duke University School of Medicine and Health System, Durham, NC, USA;
³Center for Pharmacy Innovation and Outcomes, Galsinger, Danville, PA, USA;
⁴Outcomes Research, Marcy, Chesterfield, MO, USA

Background: The US Food and Drug Administration's Unique Device Identification System Rule of 2013 mandated manufacturers to assign unique device identifiers (UDIs) to their medical devices. Most high-risk (Class III), moderate-risk (Class II) and implantable devices now have UDIs. To achieve the necessary next step for a comprehensive UDI-enabled system for patient safety, UDIs must be electronically documented during patient care, a process not routinely done. The purpose of this research was to study the implementation experiences of diverse health systems in order to develop a roadmap for UDI implementation at the point of care.

Methods: Semi-structured interviews were conducted with personnel at health systems that had implemented UDI for implantable devices in their cardiac catheterization labs or operating rooms. Interviews were audio-recorded, transcribed, and analyzed using the framework methodology of Ritchie and Spencer. Data interpretation involved development of a conceptual model and detailed recommendations for UDI implementation. An expert panel evaluated and provided input on the roadmap.

Results: Twenty-four interviews at ten health systems were conducted by phone. Participants described implementation steps, factors and barriers impacting implementation. Findings populated a UDI implementation roadmap, that includes Foundational Themes, Key Components, Key Steps, UDI Use, and Outcomes.

Conclusions and Implications: The UDI implementation roadmap provides a framework for health systems to address the necessary steps and unmet factors that underpin UDI implementation at the point of care. It is intended to guide and advance routine electronic documentation of UDIs for devices used during clinical care, the critical next step for a comprehensive UDI-enabled system to enhance medical device safety and effectiveness for patients.

Keywords: unique device identifiers, implants, implementation framework, UDI-enabled system, implantable devices

Introduction
The Unique Device Identification System Rule¹ of 2013 was a significant regulatory effort by the US Food and Drug Administration (FDA) to advance patient safety surrounding medical devices. The Rule mandated that manufacturers assign unique device identifiers (UDIs) to their medical devices.² A UDI is a unique code that is required on the label and packaging of a medical device in both human and machine-readable forms. The UDI consists of the Device Identifier (DI) which identifies the device manufacturer and model and the Production Identifier (PI)

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Correspondence: Natalia A Wilson
College of Health Solutions, Arizona State University, 500 N. 3rd St., Phoenix, AZ, 85004, USA
Email: natalia.wilson@asu.edu

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Healthcare Providers have expressed interest in UDI Implementation Support:

- Device Manufacturers
- Industry Associations
- Distributors
- Regulators



We should expect healthcare providers to continue to request support and collaboration as they implement UDI.

Thank you!

Dennis Black

UDI Program Director

Becton Dickinson (BD)

Dennis.Black@bd.com