



**LEARNING UDI
COMMUNITY**



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Resource & Materials Management

Advancing the Healthcare Supply Chain

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American Hospital Association

University Health Network UDI Capture Work Group Case Study



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WORK GROUP TITLE:

UDI Capture Work Group

CASE STUDY PARTICIPANTS

Wendy Watson, OR Supply Chain Manager at University Health Network

CASE STUDY ORGANIZATION

University Health Network (UHN) serves the residents of Toronto, Ontario, Canada's largest city, and the surrounding communities. UHN is comprised of 10 program areas spread across four hospitals and eight sites. It has \$2B in revenues, 1,200 patient beds and its surgeons perform 24,000 surgical procedures each year.

Affiliated with the University of Toronto, UHN has the largest hospital-based research program in Canada, with major research in cardiology, transplantation, neurosciences, oncology, surgical innovation, infectious diseases, genomic medicine, and rehabilitation medicine. The scope of research and complexity of cases at UHN has made it a national and international source for discovery, education, and patient care.

OPENING STATEMENT

UHN initiated a supply chain technology transformation project throughout its 40 operating rooms (ORs) and two sites with a goal to achieve clinical time efficiencies, patient safety and surgeon cost data for improved decision making and savings. The system provides surgeons with their real-time procedure cost data for all surgical supplies used per patient, per procedure. This real time data captures the intraoperative supplies, as well as the pick and returns from the sterile processing department (SPD), which is used to update procedure cards.

In the background, the system automates clinical patient charting. When the nurse vends an item or scans an implant serial number in the Pyxis OR point of use (POU) inventory system, the patient chart is populated via the interface with the item manufacturer part number, the hospital proprietary number, the description, expiration date, and serial or lot number. This solution reduces the time and steps required for the nurse to select inventory and manually chart the information. It moves the nurse closer to the patient and away from managing supplies, thereby improving patient care quality and safety.

The background technology is an automated supply chain foundation, with item master, orders interface, implant tracking, and analytics. This level of integration enables the enterprise resource planning (ERP) system, the POU, the ORSOS clinical charting system, and the electronic patient record (EPR) to all talk to one another. UHN has conducted three Lean events to measure the transformation from manual to automated processes. The organization has realized \$14M in both hard and soft dollar savings over five years.

According to Wendy Watson, OR Supply Chain Manager at UHN, her organization's interest in implementing unique device identifiers (UDIs) is driven by its desire to continue enhancing patient safety.

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She notes that unlike proprietary product identifiers, the UDI device identifier (DI¹) is a meaningful number in the patient chart that serves as a “universal language” so that if that patient travels, other healthcare provider organizations will know what products were used in that patient’s treatment. This is particularly important in the case of implantable devices. Although UHN currently captures the UDI production identifier (PI) this is seen as the next step in patient safety.

Watson and her team are in the process of conducting a UDI implementation trial, which involves:

1. Evaluating adoption feasibility from a systems and data perspective within the existing integrated technology framework.
2. Assessing the scalability for all class items, with minimal cost or clinical workflow impacts.
3. Implementing a test set of items in the live environment to identify successes and challenges.

UHN’s group purchasing organization (GPO) maintains a translation table that cross-references the enterprise resource planning (ERP) system item number to an identifier of UHN’s choosing. This gives UHN the ability to use the DI for product identification in the patient’s chart. UHN is currently testing this concept with DIs from a heart valve vendor. The vision would be to phase in the DI for all item class codes with the end goal of capturing every DI used in the patient chart.

“We have contributed to this feasibility study to determine ease of UDI adoption,” said Watson. “We hope that some of the opportunities we have identified will provide visibility to the provider adoption perspective. We are committed to patient safety and see the value in the concept of one universal DI number and language.”

Although Health Canada has not yet announced a UDI adoption date, Watson sees the value of the ONCs Meaningful Use 3 requirement that the Common Clinical Data Set (CCDS) include the UDI, and CMS’ requirement that providers share the CCDS for implantables with one another. The go-live date for both of these requirements currently is January 2018. The long-term benefits include improved global adverse events tracking and recall, more timely real word evidence collection for quality evidence-based sourcing, timely feedback for enhanced performance design, and global access to information about the right item for the patient and provider over time and location. At this time the working groups in Canada have largely focused on assessing adoption at the GPO level. Participation in the U.S. study has provided Watson with shared learnings from U.S. sites, as well as a forum to contribute her findings.

DATE INITIATIVE WAS IMPLEMENTED

November 2016

¹ Each issuing agency has an alternative name (aka) for the DI of UDI. The aka name used by each issuing agency is listed below:

GS1 - Global Trade Identification Number (GTIN)

HIBCC - Universal Product Number (UPN)

ICCBBA – Processor Product Identification Code (PPIC)

² An FDA-accredited issuing agency (IA) is an organization that operates a system for assignment of UDIs according to the UDI Rule.

FDA has accredited three issuing agencies – GS1, HIBCC and ICCBBA.

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CHALLENGES TO IMPLEMENTING A UDI CAPTURE SOLUTION

UDI access. UHN's GPO is in the very early stages of using the Global Data Synchronization Network (GDSN) to access GS1² Global Trade Item Numbers (GTINs), so to obtain the DI numbers for the implant trial the UHN team searched directly on vendor websites. A quick search identified that not all vendors have their websites populated with UDI information. To conduct the first test case of UDIs within their technology infrastructure (heart valves), Watson secured the product DIs directly from the vendor. Although manufacturers populate their DI records in the FDA's Global UDI Database (GUDID), Watson explains that when they searched the database the DIs did not match the numbers provided directly from the vendor.

Watson also checked the GDSN for this vendor's DIs but the information contained within this database did not match what was contained within the GUDID. Furthermore, the GDSN contained only one of the two DIs registered for this vendor's product.

The GDSN and GUDID are repositories that hospitals can use to access vendor DIs, but in Watson's experience the information contained within these databases is inconsistent and/or incomplete. Therefore, beyond the study sample size of data, the collection and validation of data for UHN's 9,000 unique items would require a more strategic method.

Furthermore, in Canada, there is no single source for DIs because the GDSN contains only GS1 GTINs, and the GUDID does not contain complete information for medical devices sold in Canada. One challenge is that a supplier's target market often determines which country's database they will populate with their DIs. These "target market DIs" are often based on the regulatory agency that approved the device. For example, a supplier that secured approval for a product from the U.S. FDA would populate the FDA's GUDID with its DIs, but if Health Canada approved the product then the supplier would not populate the product's DIs in the GUDID, unless the device was also sold in the U.S. For medical devices that also contain a pharmaceutical element, the supplier's target market might also be based on the product's packaging language. For example, Canada is a French and English speaking country so some packaging and DIs may differ for this reason.

UDI Format

Another challenge that Watson and her team have faced during the heart valve trial is the issue of leading zeros. UHN's ERP system would drop the leading zero in a DI because of an existing interface rule. The hospital IT team and the clinical charting system engineer modified the interface so that it would retain the leading zero and UHN configured all integrated systems (POU, clinical charting system) so that the leading zeros would flow all the way through to the patient chart.

Multiple Barcodes

Products featuring multiple barcodes or various barcode formats make it challenging for clinicians to know which barcode to scan. Watson notes that ideally all vendors would label their products with the same barcode format for UDIs and there would not be so much variation in the number of barcodes. In the meantime, to overcome this challenge, Watson's team has identified to clinicians the correct barcode to scan on a product by marking it with a small red dot sticker.

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Multiple Countries of Origin

A major challenge to widespread UDI implementation is the issue of multiple countries of origin for the same product size and description. When Watson and her team secured DIs from their heart valve vendor, they discovered that the same product could have different DIs based on its country of origin. Having multiple DIs for one item based on county of origin prevents clinical system adoption, as the exact product DI used must be documented in the patient record. The integrated clinical systems' item master and workflow require one DI per unit of measure be associated to one unique item.

“Using the device identifier in the place of the ERP system item number is a challenge at this point in time because of the multiple countries of origin, manufacturers using the DI as part of their inventory control processes, and other factors that we are currently uncovering as we proceed down the path to adoption,” said Watson. “It is an issue that requires further discussion among the FDA, hospitals and the vendor community to allow for easy adoption. This working group with AHRMM and the FDA, as a participating member, is a great opportunity to address these early bumps in the road that UHN and other hospitals have encountered.”

System Implementation Workload

UHN's GPO can only associate one item number to a description in the cross-reference table. When the new item is sent across the interface, it must be immediately set up in the downstream systems so that orders do not fail. The POU and clinical charting systems both require that the new DI numbers be flagged for class code, and lot, serial and expiration capture. The items then have to be physically unloaded and reloaded in POU stations with the new DI, and the lot and serial barcodes must be scanned in and associated to the new DI.

Because of this challenge, Watson said UHN will need to take a “slow-phased in” approach to using DIs in place of the hospital proprietary numbers. She notes how collaboration between UHN and its GPO is necessary to understand the downstream system implementation workload. To ensure a smooth transition, they will need to work together to changeover small batches of items at a time. This will also ensure additional full time employees (FTEs) are not required for implementation, and all orders will flow through the interface so that patient safety is not compromised.

STAKEHOLDERS INVOLVED

Cross Discipline Internal and External Teams, including:

- OR Supply Chain Manager and Site Supervisors
- Surgical Information Site Specialists
- Shared Information Management Services (SIMS) IT Engineer
- Group Purchasing Organization (GPO) or Operating Room Data Analyst
- Data Governance and Management
- BD Carefusion Pyxis Engineers

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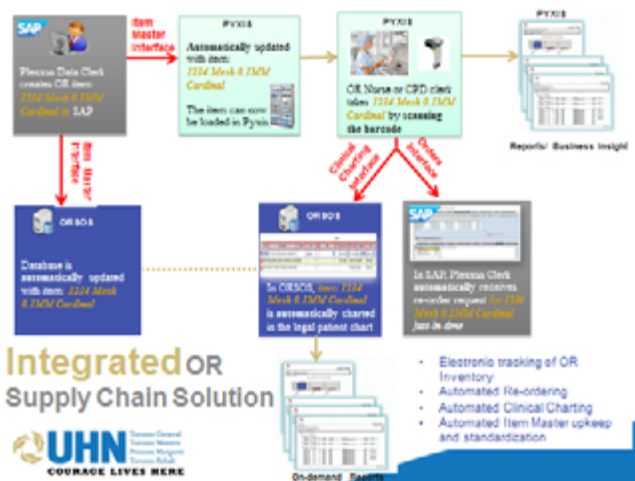
- ERP System IT Analyst
- McKesson ORSOS Technical Advisor

SOLUTION

Watson and her team are working to leverage their existing technology infrastructure to facilitate the capture of DIs. The goal is to replace the hospital's ERP system item numbers with the manufacturers' DIs. The DI would flow through all of the integrated systems so that, at the point of care, the POU system would send the DIs for all products used in the procedure to the clinical charting system for documentation in the patient's chart.

Within the existing infrastructure, all items Class I, II and III are captured in the patient's chart as they are managed through the POU system. This also triggers product replenishment through the interface with the ERP system. As ERP system ID numbers are replaced with DIs, this information could be used in the requisitioning/replenishment process with vendors as well. Recognizing that DI numbers are also unique to the packaging unit of measure (UOM), this would work for implants that are ordered and used in a UOM of "one". All other items are used in the OR in a UOM of "each," however the ordering would need to be converted by the GPO system to the box DI.

SOLUTION PROCESS



TECHNOLOGY USED OR IMPLEMENTED AS A RESULT OF THIS INITIATIVE

- SAP enterprise resource planning (ERP) system
- BD CareFusion OR Pyxis Supply Line system
- McKesson ORSOS clinical charting system

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SUCCESS FACTORS

- Existing infrastructure, roles and processes are in place and easy to build on
- Strong teamwork, commitment to patient safety
- High functioning team – quick delivery with minimal meeting time and no project leadership or executive escalation required

LESSONS LEARNED

Watson and her team believe it would be best to implement a phased approach to DI adoption, starting with those vendors that have correctly associated one DI to one product /unit of measure (not using country of origin) and that are accurately populating this data in the GDSN and GUDID repositories.

Watson says, “We are hopeful our findings can be reviewed with FDA and the vendor community to help hospitals with this important initiative for easy adoption.”

NEXT STEPS

“We will continue our work to embrace adoption with the goal of improving patient safety,” said Watson. “We look forward to engaging with the FDA and other members of the Learning UDI Community on our findings to date so that we can all work collaboratively to ease UDI adoption throughout the industry.”

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APPENDIX 1: GS1 UDI Label Example



UDI Components

UDI = Device Identifier (DI) + Production Identifiers (PI)
GTIN® + Application Identifiers (AI)



*Another Production Identifier is Manufacture Date

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APPENDIX 2: HIBCC UDI Label Example



Health Industry Business
Communications Council

2525 E. Arizona Biltmore Cir.
Suite 127
Phoenix, AZ 85016
602-381-1091
FAX 602-381-1093
www.hibcc.org



HIBCC UDI Label Example

DataMatrix

CompuHyper GlobalMed®
Ultra Implantable™
Fictitious Medical Device
2.25 mm x 8 mm

CAT 123ABC	USE BY: 2019-05-15	MANUFACTURED ON: 2015-10-01	SN 5678EDFG
LOT 1234AB			QTY: 1 EA
2 SINGLE USE	DO NOT USE IF PACKAGE IS DAMAGED	40°C UPPER LIMIT OF TEMPERATURE	KEEP DRY
Manufacturer			
CompuHyper GlobalMed® 123 Technology Dr Somewhere, XX 00000			
MedDevFront UK Somewhereshire XX12 3XX UK			
800.555.1234 (USA) 555.555.1234 (All Others) www.chgm.com		www.mdfco.uk	
X999123ABC0\$\$\$31905151234AB/S5678EDFG/16D20151001J			

HIBCC DI
(Fixed Product Data)

HIBCC PI
(Variable Production Data)

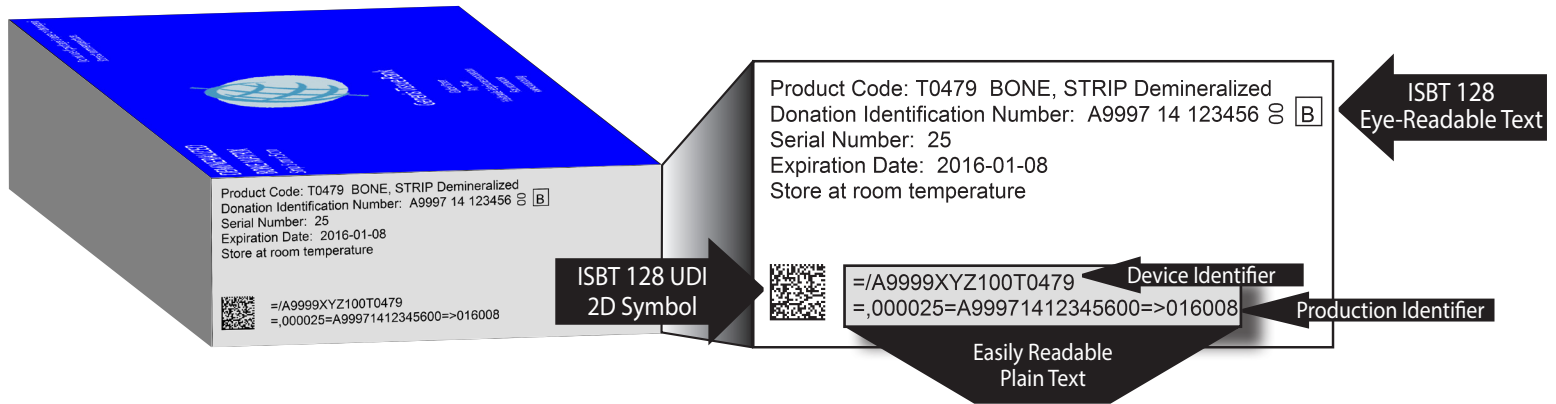
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APPENDIX 3: ICCBBA UDI Label Example

USING ISBT 128 UNIQUE DEVICE IDENTIFIER ON MEDICAL DEVICES THAT CONTAIN HUMAN TISSUE



Medical devices containing Human Cells, Tissues, or Cellular and Tissue-Based Products (HCT/P) labeled using ISBT 128 will provide UDI information, including the Donation Identification Number, in a standardized electronically-readable format and in eye-readable text. These illustrations show examples of how the information may be presented. The two-dimensional symbol contains the critical tracking information. Receiving systems should be programmed to scan and interpret this symbol to provide optimal efficiency and accuracy.



Item	Recommended Abbreviation(s)	What it Identifies
Donation Identification Number	DIN	This identifier links the product to its donor (the Distinct Identification Code as required by 21 CFR 1271.290(c)).
Product Code	Prod Code or PC	This code identifies the type of product (e.g., bone powder or a pre-sutured tendon).
Pack Number or Serial Number	Pack or SN	This code uniquely identifies a specific product for a given DIN and Product Code.
Expiration Date	Exp or Exp Date	The date on which the product should no longer be used.
Manufacturing or Production Date	Mnf Date or Prod Date	The date on which the product was made.
Lot Number	Lot No. or LN	This identifier links to a production record of the process or the tissue.
Device Identifier	DI	The FDA UDI Device Identifier (identifies the specific version or model of a device and the labeler of the device).
Production Identifier	PI	The FDA UDI Production Identifier (information that more precisely identifies the device).

The illustration shows a blue box for a medical device. The top left corner contains the text: "DEMINERALIZED BONE MATRIX Strip 5 cm x 5 cm". The top right corner contains the instruction: "Do not use if package is open or damaged. Store at room temperature." The center of the box features a globe logo and the text "Generis Tissue Bank". Below the logo, the address is listed: "Global Street, Any Town, Worldwide Telephone: xxxxxxxxxx, Fax: xxxxxxxxxx, www.xxxxxxx.org".

On the bottom right of the box is the ISBT 128 UDI 2D Symbol. A callout box points to this symbol, containing the following information:

- PC: T0479 BONE, STRIP Demineralized
- DIN: A9997 14 123456 [B]
- SN: 25
- Exp Date: 2016-01-08
- Store at room temperature

Below the callout box is the 2D symbol itself, with the following information printed below it:

- Device Identifier: =/A9999XYZ100T0479
- Production Identifier: =,000025=A99971412345600=>016008