LEARNING UDI
COMMUNITY

AHRMM
Association for Healthcare
Resource & Materials Management
Advancing the Healthcare Supply Chain
A personal membership group of the
American Hospital Association

University of Tennessee Medical Center UDI Capture Work Group Case Study

LEARNING UDI COMMUNITY CASE STUDY

WORK GROUP TITLE:

UDI Capture Work Group

CASE STUDY PARTICIPANTS

Becky Ashin, Vice President, Advanced Orthopaedic Center, University of Tennessee Medical Center

Beth Kaylor, RN Clinical Director, Innovation, DeRoyal Industries

CASE STUDY ORGANIZATION

The University of Tennessee Medical Center (UTMC) is a 609 bed, academic medical center. It is the regions only Level 1 Trauma Center and Magnet recognized hospital. There are six Centers of Excellence, Brain & Spine, Cancer, Emergency & Trauma, Heart Lung Vascular, Orthopaedics & Women's & Infants. The medical center recently opened the Pat Summitt Clinic for Alzheimer's Care, became the 1st hospital in Tennessee to receive the Advanced Certification for Total Hip and Total Knee Replacement, earned The Tennessee Center for Performance Excellence, and recognized by *U.S. New & World Report* as a "Best Hospital."

OPENING STATEMENT

Physician preference cards contain a list of supplies that hospital staff member's think a surgeon may use during a procedure. They are used to guide what supplies are pulled into a surgical case, are often used as the foundation for the surgical case consumption screen, and are used for resource forecasting.

But in many cases, the supplies listed on a physician preference card are inaccurate. At UTMC, on average, 50 - 70 percent of items pulled for a case are returned to stock. This leads to excess inventory, manual labor wasted on picking unnecessary supplies and then returning them unused after a case, and inaccurate charge capture. The movement of unused items in and out of the operating room (OR) can also put patients at greater risk for infection.

UTMC partnered with DeRoyal, one of its medical-surgical product suppliers, on an initiative to develop the "perfect physician preference card." Utilizing the Orthopaedic OR's, they developed a "smart trash can" featuring software that reads radio-frequency identification (RFID) tags on product packaging as it is disposed of into the Safe, captures the information on the tag and transmits it to UTMC's OR software system, which serves as the hospital's patient medical record, and helps determine supply charges generated for each surgical case. The next phase will include an interface to UTMC's Lawson enterprise resource planning (ERP) system.

UTMC has used the data collected from the Safe to determine which supplies are actually being used during a procedure verses what is already populated on the consumptions screen. With this information they have improved the accuracy of physician preference cards for greater efficiency, more effective inventory management, lower costs, more accurate charge capture, and improved patient safety. Most recently, they have worked with their medical-surgical supplier to incorporate unique device identifiers (UDI) into the RFID solution. This further improves the accuracy of product data capture for even greater patient safety and operational effectiveness.

LEARNING UDI COMMUNITY CASE STUDY

PHOTO: *Expired Items Identified During Solution Development*

DATE INITIATIVE WAS IMPLEMENTED

2014-2017

CHALLENGES TO IMPLEMENTING A UDI CAPTURE SOLUTION

According to Becky Ashin, Vice President, Advanced Orthopaedic Center, University of Tennessee Medical Center (UTMC), one of the greatest challenges has been gaining the cooperation of suppliers to tag their products with RFID tags containing device identifiers (DIs)[1,2].

They have also discovered a variety of nuances around automated RFID scanning. During development of the RFID Safe, efforts were made to control the distance the Safe could read. In the prototype the Safe could read items several yards away. At one point it inadvertently read tags inside a passing delivery truck. It has since been shielded to only read items that are tossed into the mouth of the container.

STAKEHOLDERS INVOLVED

- Supply Chain Management
- Vice President of Orthopaedics
- CEO
- DeRoyal
- IT staff
- OR staff, including surgical techs and OR circulating nurses

SOLUTION

UTMC's RFID solution features three components:

- **The Safe**, which is used to track supply use by case within the ORs.

- **The Link**, which are antennas that will be placed in the ceilings of UTMC's sterile core areas and OR rooms where supplies are stored – this can continually read all supplies for inventory and supply chain purposes.

---

[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.

- **The Vault**, which will be used to track high-cost supplies (e.g. implants) in a locked storage areas. Once Link antennas are installed in the ceiling of these rooms, UTMC will be able to track both the supplies and people that enter and exit it through key entry access.

PHOTO: Safe in Use

Today, UTMC has finalized testing, product data capture, and software integration of the Safe into its endovascular suites. In early June, the Safes will be deployed in all 36 operating rooms. Because most of UTMC's suppliers do not RFID tag their products, the hospital relies on its distributor to do most of the tagging, and the supply chain and OR staff does the rest.

For those suppliers that have barcodes on their packaging, the team scans this data (e.g. manufacturer, product ID, lot number, expiration date) into the UTMC item file and uses it to encode UHF passive RFID tags containing the data, which they affix to the product packaging. If the barcode contains a DI, this data too is captured on the RFID tag.

In the OR, as the products are unwrapped and used, the packaging materials with the RFID tags are disposed of into the Safe, which records all of the data on the tags. The Safe's software is interfaced with UTMC's OR system so that the product data flows into the medical record and consumption screen.

Ashin and her Orthopaedic team used this information to develop "perfect" physician preference cards based on true consumption data, rather than "hunch and past history." They conducted a study and found only 56 percent of the products on physician preference cards were being recorded in the Safes meaning staff was returning nearly half of the products picked for a case back to stocking locations.

"Picking all these supplies for a procedure and then returning them significantly increases costs - take a simple sponge that costs $1.50 and by the time it goes back and forth a couple of times that cost can easily rise to $8 with all of the extra labor," said Ashin.

Ashin and her team are also using the data derived from the Safes to improve consumption capture accuracy, which will improve its charge masters. They found that on an annual basis, an estimated $30k of chargeable supplies in one OR's Safes were not on their OR system's consumption screen – multiply that by 36 ORs across UTMC and the organization has potentially been missing millions of dollars in charge capture each year.

LEARNING UDI COMMUNITY CASE STUDY

The efficiency gained through automated data capture has reduced manual labor for OR staff, and freed up nurses time to focus on their primary responsibility, which is patient care. With regards to patient safety, capturing UDI data via RFID and transmitting it into the patient record will help with adverse event reporting and recall management. The Safes also alert OR staff to expired products so they are not used in patient care. Furthermore, the data can also be used to identify clinical variation and other opportunities to standardize care. Staff can also indicate supplies that were opened and not used to track wasted supplies as well.

PHOTO: Associating Supplies Via Barcode Scanner

Ashin and her team also assessed the infection prevention benefits that can come from improved supply management. When reviewing data on products picked but unused in a case, they found supply returns to be as high as 70 percent. When this new technology is in place throughout all of the ORs, UTMC will be able track the location of all supplies including the chain of custody for individual products - where they have been, how they have been transported, and how many times they have gone in and out of the OR - to help with infection control.
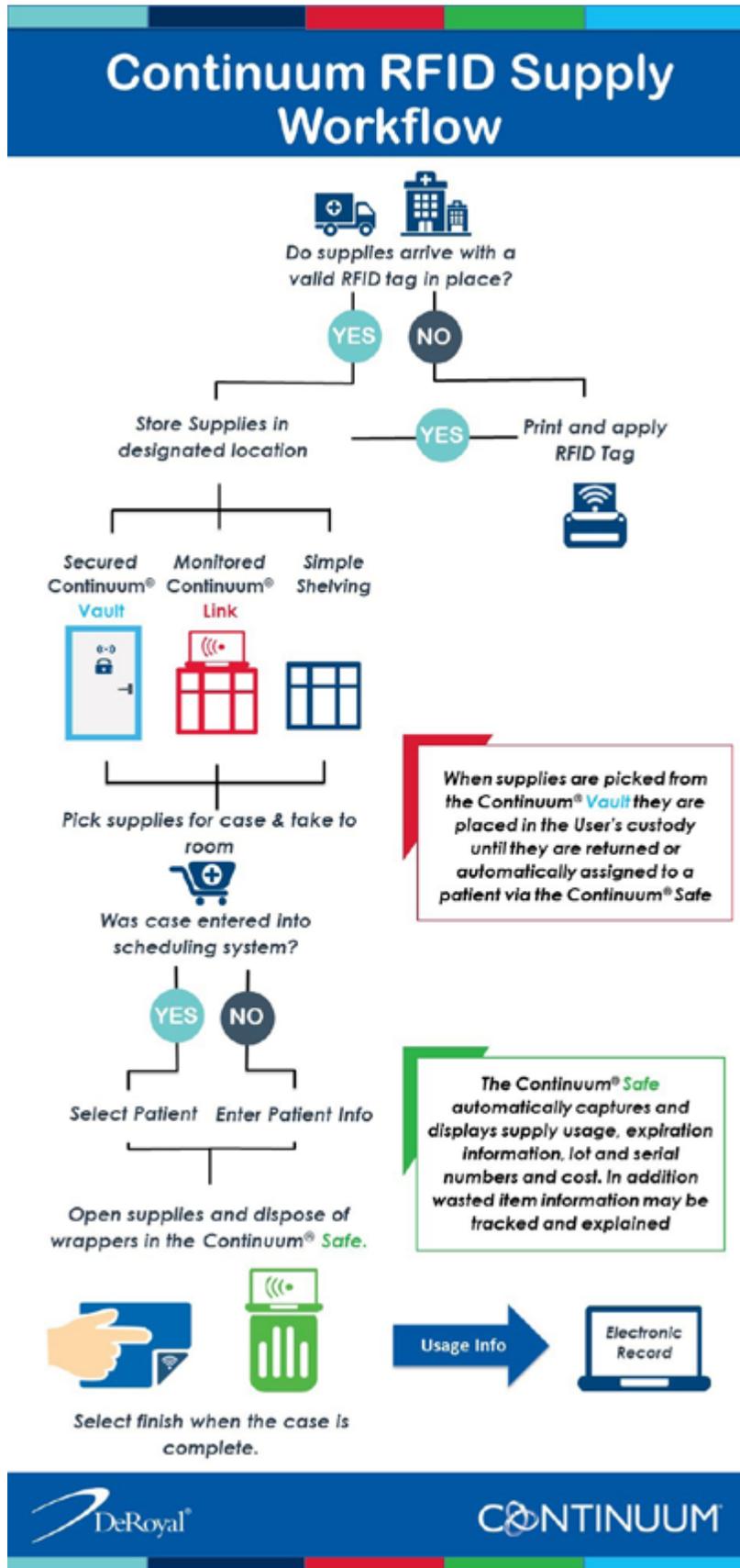

PHOTO: Supplies Returned to Stock

TECHNOLOGY USED OR IMPLEMENTED AS A RESULT OF THIS INITIATIVE:

- Continuum™ Safes (smart trashcans), Link and Vault

- GE OR system

- RAIN UHF RFID tags

- Passive RFID tags

- Barcode Scanners to scan product data into the RFID Tag Print Application

- Lawson enterprise resource planning (ERP) system

SOLUTION PROCESS/TRAINING DOCUMENT

Continuum RFID Supply Workflow

Do supplies arrive with a valid RFID tag in place?

YES → Store Supplies in designated location

NO → **YES** → Print and apply RFID Tag

Store Supplies in designated location:
- Secured Continuum® **Vault**
- Monitored Continuum® **Link**
- Simple Shelving

Pick supplies for case & take to room

When supplies are picked from the Continuum® Vault they are placed in the User's custody until they are returned or automatically assigned to a patient via the Continuum® Safe

Was case entered into scheduling system?

YES → Select Patient

NO → Enter Patient Info

Open supplies and dispose of wrappers in the Continuum® Safe.

The Continuum® Safe automatically captures and displays supply usage, expiration information, lot and serial numbers and cost. In addition wasted item information may be tracked and explained

Usage Info → Electronic Record

Select finish when the case is complete.

DeRoyal   CONTINUUM

LEARNING UDI COMMUNITY CASE STUDY

SUCCESS FACTORS

Ashin points out that staff support has been critical to the success of the initiative. Also crucial is having the resources to implement it. She states:

"While the technology is simple to use there has been a paradigm shift but the staff has been very supportive," she says. "Sometimes you have to spend money to make money – this will save us a lot of money in the long run. The main cost to the hospital has been in running wiring for electrical power and network connections where the Safes are located in the OR's. Ongoing costs are tagging supplies."

LESSONS LEARNED

Ashin notes while labeling products with RFID tags and capturing the data with the Safes seems simple on the surface, it has taken several years to develop and implement the technology (2014-2017). She points out how the integration of computer systems has been the greatest challenge to overcome. The second challenge has been the lack of suppliers that tag their products RFID.

NEXT STEPS

Ashin and her team are also working to deploy RFID scanning technology through the Link that will enable them to capture product data within UTMC's sterile cores. The technology will have the capability to identify what is on the shelves for ordering purposes, what items have been removed from the core, and which are close to expiring so that staff can prioritize their use and reduce product obsolescence.

PHOTO: Sterile Core

Another area where UTMC plans to use a similar technology is in a supply Vault that houses very costly supplies. This requires a storage area with a door. Ashin notes they currently have a room where orthopedic implants are kept that has door and how this storage room will be accessible via a key fob and equipped with RFID scanning so that UTMC will know who entered the room, which supplies they exited with and which supplies they returned to the room. For instance, they will be able to track staff or others who enter, take implants, and either use them and/or return them to the storage room.

LEARNING UDI COMMUNITY CASE STUDY

With the implementation of the Safes, the Link and the Vault, UTMC will be able to track all supplies, volumes and replenishment needs. It will also be easier for staff members to locate items since they will know exactly where they are.

The data that UTMC collects will help it achieve more effective/proactive inventory management, including the real-time management of accurate par levels, replenishment, and obsolescence.

PHOTO: Location of the Vault

UDI Components

UDI = Device Identifier (DI)   +   Production Identifiers (PI)

GTIN®   +   Application Identifiers (AI)

(01) 1 0304040 12345 1 (17) 091231 (10) A1345B (21) 1234

- GTIN – Global Trade Item Number®
- Expiry Date
- Lot Number
- Serial Number

*Another Production Identifier is Manufacture Date

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

LOT 1234AB

USE BY:
2019-05-15

MANUFACTURED ON:
2015-10-01

SN 5678EDFG

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

800.555.1234 (USA)
555.555.1234 (All Others)
www.chgm.com

MedDevFront UK
Somewhereshire
XX12 3XX UK

www.mdfco.uk

+X999123ABC0/$$31905151234AB/S5678EDFG/16D20151001J

HIBCC DI
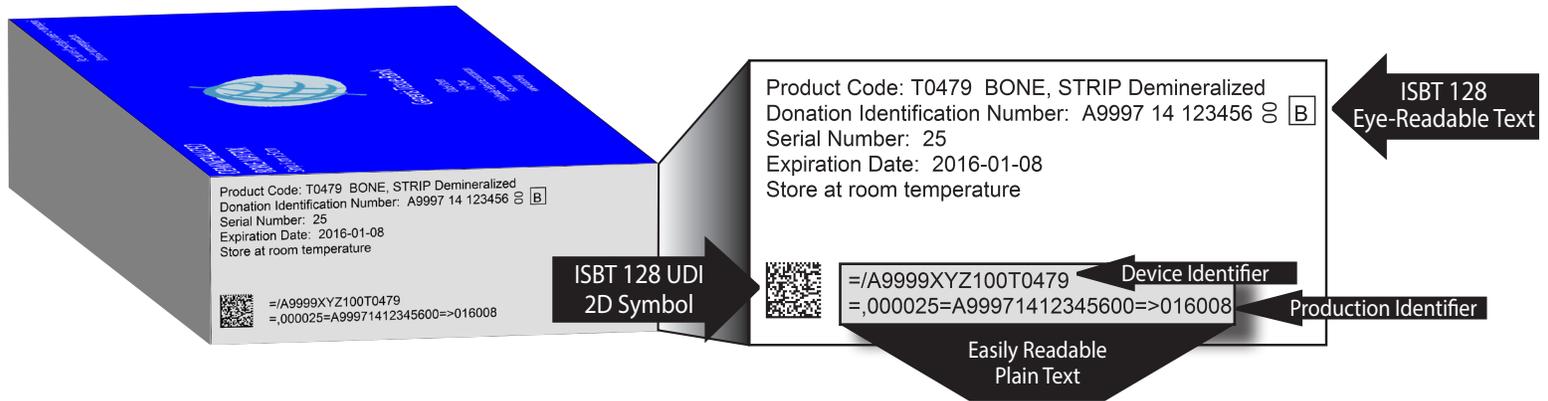(Fixed Product Data)

HIBCC PI
(Variable Production Data)

APPENDIX 3: ICCBBA UDI Label Example

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

ISBT 128
More than Identification

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.

Product Code: T0479 BONE, STRIP Demineralized
Donation Identification Number: A9997 14 123456 B
Serial Number: 25
Expiration Date: 2016-01-08
Store at room temperature

ISBT 128 Eye-Readable Text

Product Code: T0479 BONE, STRIP Demineralized
Donation Identification Number: A9997 14 123456 B
Serial Number: 25
Expiration Date: 2016-01-08
Store at room temperature

=/A9999XYZ100T0479
=,000025=A99971412345600=>016008

ISBT 128 UDI 2D Symbol

Device Identifier

Production Identifier

Easily Readable Plain Text

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).

DEMINERALIZED
BONE MATRIX
Strip 5 cm x 5 cm

Do not use if package is open or damaged.
Store at room temperature.

Generis Tissue Bank

Global Street
Any Town
Worldwide Telephone: xxxxxxxxxx
Fax: xxxxxxxxxx
www.xxxxxx.org

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

=/A9999XYZ100T0479
=,000025=A99971412345600=>016008

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

=/A9999XYZ100T0479
=,000025=A99971412345600=>016008

GS1 and ICCBBA Joint Guidance recommends use of ISBT 128 on medical devices containing HCT/P.