LEARNING UDI COMMUNITY

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

Beaver Dam Community Hospital
UDI Capture Work Group
Case Study

LEARNING UDI COMMUNITY CASE STUDY

WORK GROUP TITLE:

UDI Capture Work Group

CASE STUDY PARTICIPANTS

Jordan Noyes, Contract Operations Specialist at Beaver Dam Community Hospitals, Inc. (BDCH)

CASE STUDY ORGANIZATION

Beaver Dam Community Hospitals, Inc. (BDCH) is a non-profit, non-stock corporation serving the greater Dodge, Columbia and Fond du Lac County regions of Wisconsin. The new Beaver Dam Community Hospital opened for service on February 11, 2006. The 60-bed acute care hospital combines advanced medicine and technology with a state of-the-art facility to create a healing environment of care for patients and their families.

OPENING STATEMENT

Jordan Noyes, Contract Operations Specialist at BDCH, describes his organization's work to use device identifiers (DIs)[1] as a "visionary movement," noting how the 60-bed, acute-care rural hospital is tackling the same challenges around product data standardization similar to other leading health systems across the U.S.

Noyes says the main driver behind their data standardization project is preparedness for the Class I compliance date of September 24, 2018, which is the U.S. Food and Drug Administration's (FDA) deadline for medical devices to enumerate their products with unique device identifiers (UDIs) and submit standardized data to the Global Unique Device Identification Database (GUDID). Over 50 percent of medical devices are already required to be labeled with UDIs based upon the passing of medical device class go-live dates.

Noyes and his team are currently exploring how to leverage supplier DIs in the operating room (OR) to capture implants electronically via barcode scanning at the point of use for documentation in electronic health records (EHR). This will involve storing product DIs in the organization's enterprise resource planning (ERP) system and feeding them from the item master to their EHR system, both of which are McKesson Paragon products. Noyes said automating the product data capture process in this way should reduce the risk for human error, increase productivity and improve data accuracy in the EHR for greater patient safety.

Eventually, Noyes and his team would like to leverage DI capture in the procure-to-pay process, all the way through to patient billing.

DATE INITIATIVE WAS IMPLEMENTED

November 2016

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[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)

CHALLENGES TO IMPLEMENTING A UDI CAPTURE SOLUTION

Noyes and his team are currently in the process of identifying barriers to DI implementation and developing a plan to overcome them. So far the greatest barrier they've identified is their ERP system. The system has the capability to store DIs, which are the index keys to all records in AccessGUDID (https://accessgudid.nlm.nih.gov/). While the ERP system has the capability to store the DIs, it does not have the ability to transmit those DIs to the organization's EHR system allowing a link between the scan at the point of care and the ERP system. If the ERP system does not have these capabilities, the BDCH IT team will need to implement an intermediary software to serve as an interface between the ERP, EHR, and scanning systems for DI capture and transmission.

The other challenge Noyes identifies is the need for change management to show how DIs can facilitate process improvement in the OR workflow. He notes that because DI implementation will impact how product data is captured at the point of use, there has been some resistance to change among frontline users. BDCH recently hired a new director of surgery, whom Noyes and his team are working with to show the value of DIs for improving the workflow that comes with product data standardization and process automation.

STAKEHOLDERS INVOLVED

- Supply Chain is driving the UDI initiative
- Chief Medical Officer (CMO)
- Chief Financial Officer (CFO)
- Surgical team
- IT department

SOLUTION

BDCH is currently in the "information gathering" stage of DI implementation. Noyes and his team are working to gain buy-in from various stakeholders across the organization (e.g. clinicians, IT) and put into place a plan to move forward.

According to Noyes, a recent Lean Rapid Improvement Event (RIE) related to inventory management paved the way for their DI implementation work. Through the cross-functional RIE event, the organization discovered it was overstocking product inventory for surgery. This presented an ideal opportunity to demonstrate how product data standardization and process automation could help with inventory management, particularly for implants.

Noyes and his team plan to start DI implementation with BDCH's primary implant supplier (Zimmer). Once they have configured their ERP system to store DIs in the item master and feed them into the EHR system, they will download the DIs for the implants they use in surgical procedures from GUDID to provide one source of information and avoid the need for ongoing downloads from the manufacturer. If they have concerns with the Zimmer data in GUDID, they will contact Zimmer to identify issues. As mentioned above, the supply chain team is currently working with the IT team to get the necessary technology in place.

TECHNOLOGY USED OR IMPLEMENTED AS A RESULT OF THIS INITIATIVE

- McKesson Paragon ERP system

- McKesson Paragon EHR system with barcode scanning capability. BDCH utilizes other applications in certain departments, such as MedHost for the emergency department (ED), but they all filter up to Paragon.

- A software interface that will facilitate the feed of DIs from the ERP system to the EHR system.

SUCCESS FACTORS

According to Noyes, support from executive leadership is critical:

"Everyone understands there will be an outlay of capital on the front-end to get it done; our analysis shows we will make it up on the back end in automation and labor savings. The first thing we did was take it to the executive team to secure buy in, because you are talking about changing procedures across the organization."

LESSONS LEARNED

Noyes feels he and his team should have engaged the IT team earlier in the process because the initiative will require a great deal of work on their part.

NEXT STEPS

Noyes and his team will continue to work with IT to determine what technology is needed to capture product DIs in the ERP system, transmit them to the EHR system and facilitate barcode scanning of products at the point of use. Next they will develop a new process in conjunction with their clinicians. Noyes fully understands successful implementation and ongoing compliance hinges on securing clinician buy-in from the outset. Once these two steps are completed, they will implement the ERP/EHR software interface, secure Issuing Agencies[2] DIs from Zimmer and run trials to determine the effectiveness of their work.

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[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.

APPENDIX 1: GS1 UDI Label Example

UDI Components

UDI =

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

•GTIN – Global Trade Item Number®

•Lot Number

•Serial Number

•Expiry Date

*Another Production Identifier is Manufacture Date

APPENDIX 2: HIBCC UDI Label Example

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)

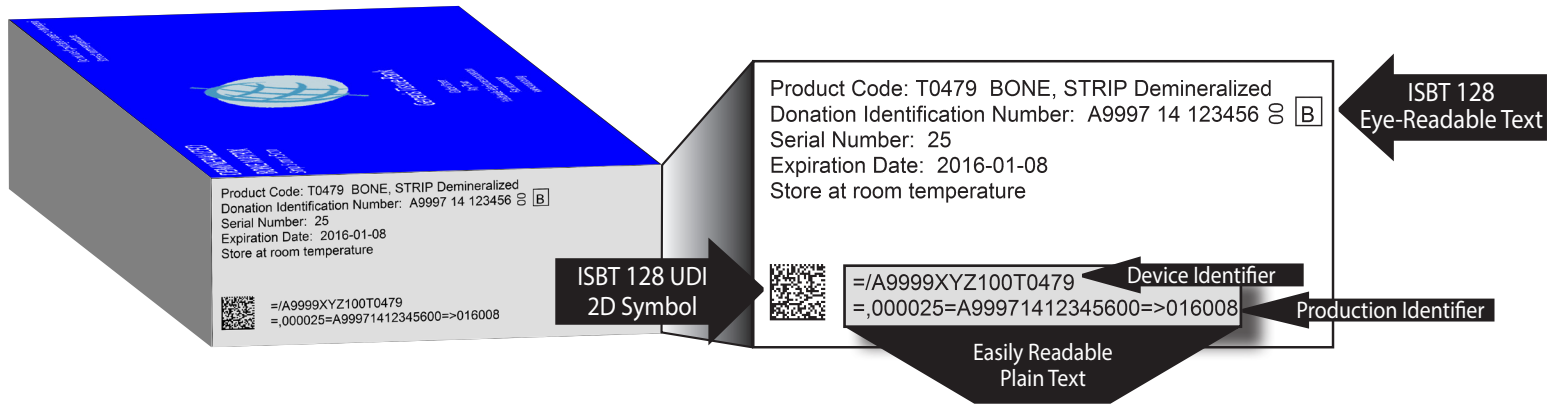**APPENDIX 3:** ICCBBA UDI Label Example

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 ← ISBT 128 Eye-Readable Text
Serial Number: 25
Expiration Date: 2016-01-08
Store at room temperature

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 UDI 2D Symbol →

=/A9999XYZ100T0479
=,000025=A99971412345600=>016008

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.