LEARNING UDI
COMMUNITY

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

Stanford Health Care UDI Capture Work Group Case Study

LEARNING UDI COMMUNITY CASE STUDY

WORK GROUP TITLE:

UDI Capture Work Group

CASE STUDY PARTICIPANTS

Jim Booker, Manager of Master Data Management, Supply Chain, Stanford Health Care

CASE STUDY ORGANIZATION

Based in Stanford, Calif., Stanford Health Care is part of Stanford Medicine, a leading academic health system that includes the Stanford University School of Medicine, Stanford Health Care, and Stanford Children's Health, with Lucile Packard Children's Hospital. Stanford Medicine is renowned for breakthroughs in treating cancer, heart disease, brain disorders, and surgical and medical conditions. Stanford Health Care has 613 licensed beds, 49 operating rooms and over 15,000 staff members and volunteers.

OPENING STATEMENT

Health Care, clinicians use various query tools to manually identify and document items used in a procedure within the organization's EPIC electronic health record (EHR) system. Because most items do not feature barcodes, clinicians must manually search for them in the EHR system using product descriptions. As a result, there is the distinct possibility that a clinician will document the wrong item in the patient record or miss an item completely, which presents patient safety and financial risks to the organization.

The supply chain team at Stanford Health Care has piloted a project whereby clinicians scan barcodes on product packaging to electronically capture product data standardized on the device identifier (DI[1]) portion of the UDI in the organization's EHR system. They have worked with their counterparts in the Stanford information technology (IT) department to integrate the organization's Infor Lawson enterprise resource planning (ERP) system with the EHR system so that product DIs are fed nightly into the EHR. This ensures the supply chain, clinical and financial departments are all using the same standardized product information for the DI -enumerated items.

DATE INITIATIVE WAS IMPLEMENTED

July 2016-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)

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CHALLENGES TO IMPLEMENTING A UDI CAPTURE SOLUTION

DI Access

According to Jim Booker, Manager of Master Data Management, Supply Chain, for Stanford Health Care, the greatest challenge to implementing a unique device identification (UDI) capture solution is gaining access to medical device suppliers' DIs.

To populate and enhance their item master, Booker and his team have attempted to use the U.S. Food and Drug Administration's (FDA) AccessGUDID website to find supplier DI information in the FDA's Global Unique Device Identification Database (GUDID) but have discovered the information they need cannot always be found.

"My biggest challenge is taking the 60k products in my item master, finding DI information for each product's unit of measure and getting the data into our item master so that when a clinician scans a barcode on a package, the information is correctly interpreted by the EHR system," said Booker.

Booker and his team have tried finding DIs on individual supplier websites, and contacting suppliers directly to request DIs for the products they use. He said while some suppliers have on their websites specific instructions to providers on how they can request/access their DIs, most do not have this type of resource.

"I've found several challenges and barriers to getting consistent data in a format where we can load it into systems without having to go to the package or perform one-off type research," said Booker. "Suppliers need to make their DI data more available and easier to access in GUDID or data based upon GUDID (e.g. GS1[2] GDSN, supplier websites) as a source of truth to various populations."

System Considerations

Another challenge that Booker and his team have faced is storing DIs within their ERP system. He explains how their system has separate subscreens and corresponding databases in which to store each of the issuing agency's DI portion of UDI, including two databases/subscreens for HIBCC Labeler Identification Codes (LICs), one for the GS1 GTINs, two for Universal Product Codes (UPCs) (UPN 1 and UPN 2), one for National Drug Codes (NDCs), and yet another for stock-keeping units (SKUs). Booker says it is unclear where they need to store HIBCC LICs, and plans to have a conversation with the ERP vendor to discuss this issue.

STAKEHOLDERS INVOLVED

- Supply Chain
- IT
- Clinicians

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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.

SOLUTION

The supply chain team at Stanford Health started with a select group of implant-related products already enumerated by the supplier with DIs and for which the packaging features barcodes containing the DI information. System configurations required collaboration between supply chain, and individuals within Stanford's IT group who support the ERP and EHR systems.

Stanford already had in place a nightly product data feed coming from its ERP system into its EHR, and the EHR system had a pre-configured field for DIs. The IT team created a separate database table to store the DI in its ERP system and an interface to pull the DIs from this table into the EHR system as part of the nightly product data feed.

Stanford's EHR system features a barcode scanning module so the IT team leveraged this for the DI barcode scanning. They trained clinicians on how to scan the barcodes on product packaging at the point of use to capture DI information into the EHR. If a clinician is closing out a case in the EHR and he/she scans a product barcode and doesn't find the DI data, he/she can manually look up the product number and get the required information to drop the charge and then manually enter the data into the EHR system.

The results of a pilot where clinicians used barcodes to electronically capture surgical mesh product data standardized on DIs showed automation of this kind reduces the clinician's time to capture and record the mesh in the EHR from *one-to-two minutes*, down to just *one-to-two seconds*. Booker and his team are in the process of documenting other benefits as well, such as improved accuracy in the product capture and billing process. They are also expanding this work to more item-intense implant procedures where they will document the time savings achieved from electronically capturing product information via barcode versus manually finding/recording it.

TECHNOLOGY USED OR IMPLEMENTED AS A RESULT OF THIS INITIATIVE

- Infor Lawson ERP system
- EPIC EHR system with barcode scanning module
- Data feed configured to pull DIs into EHR as part of nightly data feed from ERP system

SUCCESS FACTORS

- Access to clean, normalized data in a clear, readable format
- Access to data elements required by different stakeholders – those in supply chain need different data attributes than those in clinical areas
- Ability to access supplier DIs through GUDID
- A clear understanding of who within a supplier organization a provider needs to contact for questions regarding the company's DIs and the data in the GUDID
- A "UDI starter kit" for healthcare providers that includes instructions on how to access supplier DIs
- A correlation between supplier divisions and products, where a division's GLN aligns with its product GTINs so providers know which divisions produce which products

LESSONS LEARNED

- Supplier DIs are not readily available or easily accessible

- It is not always possible to find the product data required by supply chain within the AccessGUDID

- Within AccessGUDID, it is a challenge to find DIs for a specific unit of measure (UOM). While clinical staff members need DIs for a product "each," supply chain needs DIs for all UOM, for example, "case", "box" and "each"

- In some cases, when suppliers publish data to a GDSN-certified data pool, providers must pay a fee to access it

NEXT STEPS

Booker notes how clinicians have been very receptive to this pilot. He and the team are planning to expand it into the main operating room (OR) area with other DI-enumerated barcoded products as this data becomes available. The ability to exchange this data to support coordination of care would help Stanford Health Care meet meaningful use certification (MU3) requirements.

Furthermore, linking the DI to patient records and including data from GUDID in the EHR would benefit charge capture. Booker and his team are working to demonstrate a return on their investment (ROI) related to this.

"Our decision support team in finance wants to know the actual total cost of a procedure, all the way down to the sponges and sutures being used," said Booker. "Giving clinicians the ability to scan these products instead of having to translate and enter finite 14-digit numbers for them would go a long way in supporting this."

Once Stanford has the majority of its medical-surgical products enumerated with DIs, Booker says they would like to expand the use of standardized product data into other functional areas of the organization. He notes how capturing product DIs via barcode scanning in receiving could help Stanford with inventory management, as would using DIs to put unused items back into inventory following a procedure. Manufacturer's entry of the catalog number within the GUDID would provide significant benefits to providers, creating a crosswalk from the catalog number to the DI.

Additionally, Booker says the use of DIs in electronic data capture (EDI) transactions with distributors and manufacturers would drive greater accuracy and efficiency in the procure-to-pay process and help ensure products are available to clinicians when needed.

"Instead of having all of these different versions of catalog numbers where we send out a PO asking for a case and a manufacturer sends us a box – all of those errors that normally occur with EDI transactions – we can communicate and get exactly what we need," said Booker. "Once we have all of this data collected we can work on making this a more efficient process."

APPENDIX 1: GS1 UDI Label Example

UDI Components

$$UDI = \begin{array}{l} \text{Device Identifier (DI)} \quad + \quad \text{Production Identifiers (PI)} \\[1em] \text{GTIN}^{\circledR} \qquad\qquad\qquad + \quad \text{Application Identifiers (AI)} \end{array}$$

(01) 1 0304040 123451 (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

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

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
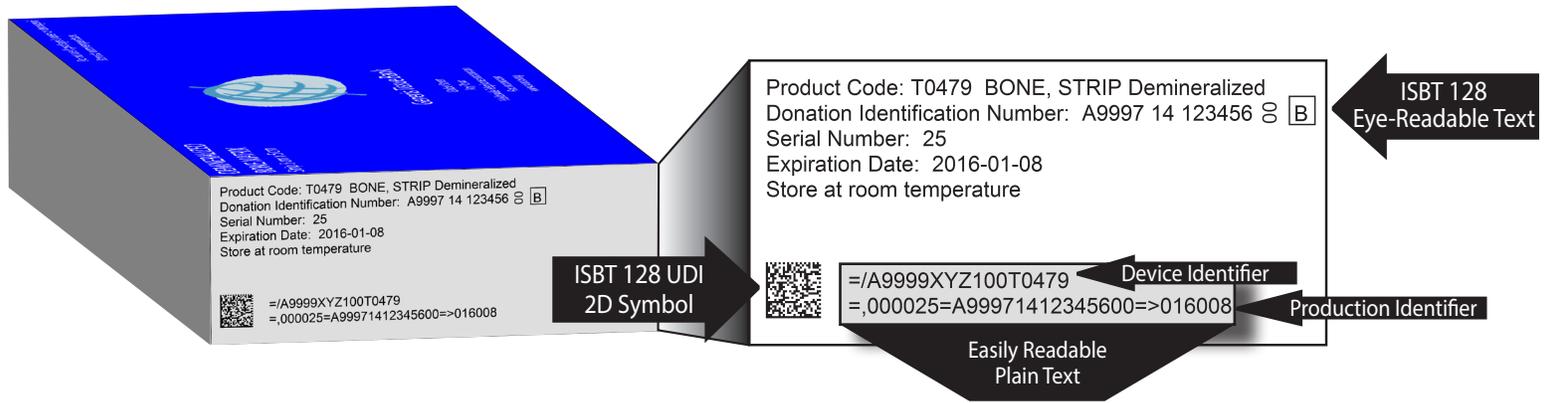(Fixed Product Data)

HIBCC PI
(Variable Production Data)

APPENDIX 3: ICCBBA UDI Label Example

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

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

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

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