LEARNING UDI
COMMUNITY

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

Eskenazi UDI Capture Case Study

LEARNING UDI COMMUNITY CASE STUDY

WORK GROUP TITLE:

UDI Capture Work Group

CASE STUDY PARTICIPANTS

Lawrence Gossman, AVP, Supply Chain, Fran Sercer, MSN RN, Associate Director of Interventional Services, Anita Sears, Director of Supply Chain, Eskenazi Health

CASE STUDY ORGANIZATION

For nearly 160 years, Eskenazi Health has provided high-quality, cost-effective, patient-centered healthcare to the residents of Marion County and Central Indiana. Accredited by The Joint Commission, nationally recognized programs include a Level I trauma center, regional burn center, comprehensive senior care program, women's and children's services, teen and adolescent care programs, Eskenazi Health Midtown Community Mental Health, and a network of primary care sites located throughout the neighborhoods of Indianapolis known as Eskenazi Health Center. In partnership with the Regenstrief Institute, Eskenazi Health conducts groundbreaking work that informs health information technology around the globe. Eskenazi Health also serves as the sponsoring hospital for Indianapolis Emergency Medical Services. As the public hospital division of the Health and Hospital Corporation of Marion County (HHC), Eskenazi Health partners with the Indiana University School of Medicine whose physicians provide a comprehensive range of primary and specialty care services. In December 2013, Eskenazi Health moved to its new main campus and opened the brand new Sidney & Lois Eskenazi Hospital. The new modern and efficient facility is Central Indiana's first Leadership in Energy and Environmental Design (LEED®) Gold healthcare campus and offers unique features like a one-of-a-kind sky farm and extensive art collection.

OPENING STATEMENT

Eskenazi Health's unique device identification (UDI) journey started many years ago when healthcare began discussing the use of GS1[1] Global Location Numbers (GLNs) for location identification and device identifiers (DIs)[2] for product identification, as well as barcode standards. At the time of the U.S. Food and Drug Administration's (FDA) unique device identification (UDI) final rule, the Eskenazi Health supply chain team had already established GLNs for its bill-to and ship-to locations, and loaded them into its SAP enterprise resource planning (ERP) system in anticipation of using them for future supplier transactions. The team had also contemplated using DIs for product identification.

When the Office of the National Coordinator (ONC) for Health Information Technology issued a final rule that required the integration of UDIs into electronic health records (EHRs) for compliance with Meaningful Use 3 requirements, the Eskenazi Health team quickly started a project to determine how they could leverage their existing data standards work to meet the ONC's deadlines.

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[1] 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.

[2] A UDI consists of two parts: (1) a device identifier (DI), which is the mandatory, fixed portion of a UDI that corresponds to the model or version of a device; and (2) a production identifier (PI), which is the variable portion of a UDI that identifies one or more of the following when included on the label of a device: lot/batch number, serial number, expiration date, manufacturing date, and donor identification number.

In 2015, during implementation of their Epic EHR system, the team decided its ERP supply database would be the sole source of truth for product related information, including UDIs, units of measure (UOM), and pricing. At that point, they began developing the required infrastructure to use barcode scanning to capture product UDIs at the point of use in minimally invasive procedural (MIPS) areas.

"We started immediately with these areas because we knew most of the UDI requirements were hitting implant devices first, with regular general commodity supplies happening later," said Gossman. "Our goal was to be able to scan implant and tissue barcodes and have it populate the patient record and drop a charge. We did not set out to replace the ERP item numbers with DIs, but to create a cross-reference in the ERP and EHR."

Expectations among clinical leadership with regards to UDI implementation went far beyond compliance with Meaningful Use 3 requirements, they anticipated better charge capture, more specific item detail captured in the patient medical record, electronic implant recording for improved query and find, and improved workflow for the clinical team.

DATE INITIATIVE WAS IMPLEMENTED

October 1, 2016

CHALLENGES TO IMPLEMENTING A UDI CAPTURE SOLUTION

Merging supply chain and clinical processes and systems

While the Eskenazi Health supply chain team began UDI implementation with a solid understanding around the use of DIs in supply chain processes, they still had much to learn about the UDI rule and how it impacted clinical processes. As Gossman explains, the GS1 Global Trade Item Number (GTIN[3]) contains only the first 14 characters of the 66-character field of the UDI. The UDI contains not only the part number, but within the production identifier (PI), the serial number, lot number, expiration date, manufacture date, etc. They also faced the challenge of integrating operational (ERP) and clinical (EHR) systems to facilitate the flow of the device identifier DI portion of the UDI from the supply database to the patient record.

"Our experience of preparing our ERP (MMIS) system to sync with our new EHR system was a very difficult process." said Gossman. "It was an IT lead project driven by the need to meet the requirements of Meaningful Use 3 by a specific date. So the EPIC team came in with a set of assumptions that did not match our technology infrastructure and business processes."

"One of those assumptions was that our supply chain and revenue cycle (CDM) teams were already synced and interfaced," he added. "The reality was that we operated in a vacuum with two separate systems that did not talk to each other. Our ERP system was to be the one source of truth about the supplies, and revenue cycle was in the process of converting during the EPIC conversion."

[3] An Each issuing agency has an alternative name for the DI of UDI. The 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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STAKEHOLDERS INVOLVED

- Supply chain team
- ERP/IT (SAP) support team
- Cath Lab, IR, Neuro IR, and EP Clinical Informatics team
- Epic implementation team
- Charge capture team (CDM)

SOLUTION

With the help of their GPO, the Eskenazi Health team cleansed its existing supply database master data for improved accuracy and completeness. Next, they developed an interface between their ERP and EHR systems so that the supply database could populate the most current information into the EHR, including DI data, pricing, and vendor information. Currently, the supply database feeds updated data to the EHR system on an hourly basis.

"You are marrying together your supply, clinical, and charge capture systems so if something is incorrect in one system then it won't be right in another," said Fran Sercer, MSN RN, associate director of Interventional Services, Eskenazi Health. "We have to ensure there is integrity across all of them."

In order to capture UDIs for products currently in Eskenazi Health's inventory, the team walked through storage areas, scanned every product UDI they could find and loaded the DIs into the supply database. For non-inventory items where the DIs are not contained within Eskenazi Health's EHR system, such as specialty inventory otherwise known as "trunk stock", the team put into place a process by which to capture the DIs. The clinical team loads the items in the EHR as a one-time supply during the case for the integrity of the medical record. Then a ticket is created to formalize that item into the ERP and EHR. At the latest report, Eskenazi Health had loaded 10,790 GTINs into its supply database, which represents 33 percent of its item file.

"Trunk stock can be an issue if it is entered into the EHR on the fly and not entered into the ERP," said Gossman. "Then the ERP is no longer your single source of truth. So MIPS creates a ticket for each of those items when it is used and we enter them into the ERP system so they are there for the future."

At the point of use in the MIPS areas, a clinician scans a product's barcode to call up its DI information in the EHR, and also capture its PI data. Through this process the complete UDI – DI and PI – are captured within the patient's electronic medical record. The scan also drops the charge.

"My radiology techs on the front end audit every single case on the next business day," said Sercer. "They print a Revenue and Usage report out of Epic and validate that everything used in that case is correct and correctly captured. Next they give me any outliers and I submit tickets to get them fixed."

Because of regulatory requirements, Eskenazi Health's interventional radiology and cardiology laboratories must enter implantable items into its MacLab and Cardio Lab systems in real-time as they are used on patients. As a result, some double scanning/data entry is required. Cases are not posted for charging until after Eskenazi Health's review and usage report is audited against the MacLab system in the Cath Lab and CardioLab in the Electrophysiology (EP) Lab.

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"During go-live, if an item did not scan it would generate a ticket, which initiated a very complex manual process to resolve the issue in order to be able to enter a charge," said Gossman. "But after a few intense months, tickets reduced from about 50 a day to an average of six a day."

Through their work, the Eskenazi Health team has successfully delivered on the expectations that clinical leadership had at the start of this project. These include:

- Better charge capture: per case charge has increased by an average of $3,000 per case.

- More specific item detail captured in medical record: a catheter is no longer just another catheter. Eskenazi Health captures the entire UDI.

- Electronic implant record for improved query and find: brand, make, model, serial number, and lot number.

- Improved workflow for clinical team: the team no longer has to leave the room to look up and chart information.

"We now have a much better medical record," said Sercer. "You can tell not only what was used but what time it was used and who used it. It also creates an electronic implant log, which meets regulatory requirements. We have also improved charge capture. We are not charging just for a 'stent' – we are charging for the exact stent that we used."

TECHNOLOGY USED OR IMPLEMENTED AS A RESULT OF THIS INITIATIVE

- SAP enterprise resource planning (ERP) system, implemented in January 2001

- Epic electronic health record (EHR) system, implemented October 2016

- Resource Central ticket resolution process

- Charge master (CDM), converted to Med Assets/nThrive during Epic conversion

- Motorola MC55A0 Barcode scanners

SUCCESS FACTORS

Collaboration is critical

Healthcare organizations should start with a good plan and have all of their stakeholders involved from the beginning because everyone will have some work to do.

"One of the biggest things we learned from this initiative was that we couldn't do it on our own," said Gossman. "There had to be collaboration among all of the different units. When we started this process Epic called everything 'supply chain,' even finance and patient charging. We in supply chain were left scratching our heads and thinking we don't do that. So we had to bring others to the table where we all stayed for the duration of the project."

Leadership support

"The organizational leaders and the C-suite very quickly pulled together high level folks from different areas – we needed resources quickly and we got them," said Sercer. "No one person knew all of the answers so we had to get the right people together to contribute to the initiative. The culture helps too – the idea that it isn't my problem or your problem – it is everybody's problem."

Investment in information technology (IT) infrastructure:

- A healthcare organization's supply database system must handle whatever data characteristic a product's DI provides. While the GTIN is 14 characters, other issuing agencies can exceed that (e.g. HIBCC is 23-character).

- An organization's EHR system must meet Meaningful Use 3 requirements.

- Barcode technology is required for point of use scanning – preferably a wireless handheld scanner.

Other success factors include:

- The ability to keep up with regulatory timeframes.

- Leveraging relationships with trade partners.

- Capturing supplier DIs in the supply database as the "source of truth."

"The Meaningful Use 3 requirements for the EHR are very stringent," said Gossman. "I know our IT team had several people assigned to working on this starting in 2015, for a go-live in October 2016. It's more than just passing the DI or accepting the UDI bar code."

"Keeping your supply database updated with current UDI data as the regulatory timeframes approach requires much greater visibility and control than in the past," Gossman added. "Obtaining the DI data from your trade partners in a usable format is not as straightforward as it might seem. You just have to keep working at it. It's best to have someone focus on it rather than spreading it around to multiple staff. At this stage, I would focus on building the DIs in your database as a cross-reference to your existing item numbers – not replacing them."

LESSONS LEARNED

Engage in a pilot

Pilot with a department and a vendor to test that your organization has completed all of the necessary pre-work.

"We didn't have the opportunity to pilot – we got thrown into it – I call it the 'big bang theory' – go do it and get it done by this date," said Gossman. "But if you have the time, I would recommend that you pilot."

Clean the supply database data

Reviewing and cleaning your supply database is extremely important. Validate the supply items used. Walk storage spaces in all areas and check PAR and inventory locations searching for supplies that may not be in your supply database.

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Every item used in patient care needs to be identified. Missing items will bring documentation to a halt in the EHR at the point of use.

"You have to go through a supply database cleanup for many reasons," said Gossman. "The big reason is you are trying to merge things from one system to another, and you will have disparate data and duplicates. So you need to standardize your data."

Request supplier DIs

Request every DI from suppliers via a spreadsheet and then load the data into your ERP system. Consider making this a requirement in your suppliers' contract terms and conditions.

Consider unit of measure

Eskenazi Health's ERP system can only store one DI per item. They have converted all items in their item master for Epic to the lowest unit of measure (LUOM) and enter the single DI regardless of how it was shipped.

"Remember, the DI is specific to the packaging," said Gossman. "So the same item will have different DIs depending on the purchase unit of measure. Multiple units of measure could cause issues in your supply database."

ERP space limitations

Eskenazi Health's ERP system has only enough room to store the DI portion of the UDI, but not necessarily the entire UDI (DI and PI portions). To overcome this challenge, they scanned every item from the minimally invasive procedural area shelves into the EHR system to capture the PI information.

Have a robust workflow

Have a robust workflow to fix any/all issues related to scanning post implementation, such as missed items, charge coding errors, and supplies as implants and implants as supplies.

"We do have a single charge code for each unique item, however, our revenue cycle team chose to tie each item to the specific cost center, which requires that a catalog be built in Epic to point the items to the cost center," said Gossman. "If you can avoid this, I highly recommend it. When something crashes at the point of use, it takes a lot of work to fix it, and you will find yourself reconciling the same issue over again for multiple departments."

Track progress

Keep a log to track progress for as long as you feel necessary.

Staff appropriately

Anticipate staffing resources for this workflow.

NEXT STEPS

The Eskenazi Health team is now circling back to implement the solution in its Main Operating Room and Burn Center Operating Room.

APPENDIX 1: GS1 UDI Label Example

UDI Components

$$UDI = \text{Device Identifier (DI)} + \text{Production Identifiers (PI)}$$
$$\text{GTIN}^® + \text{Application Identifiers (AI)}$$

(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
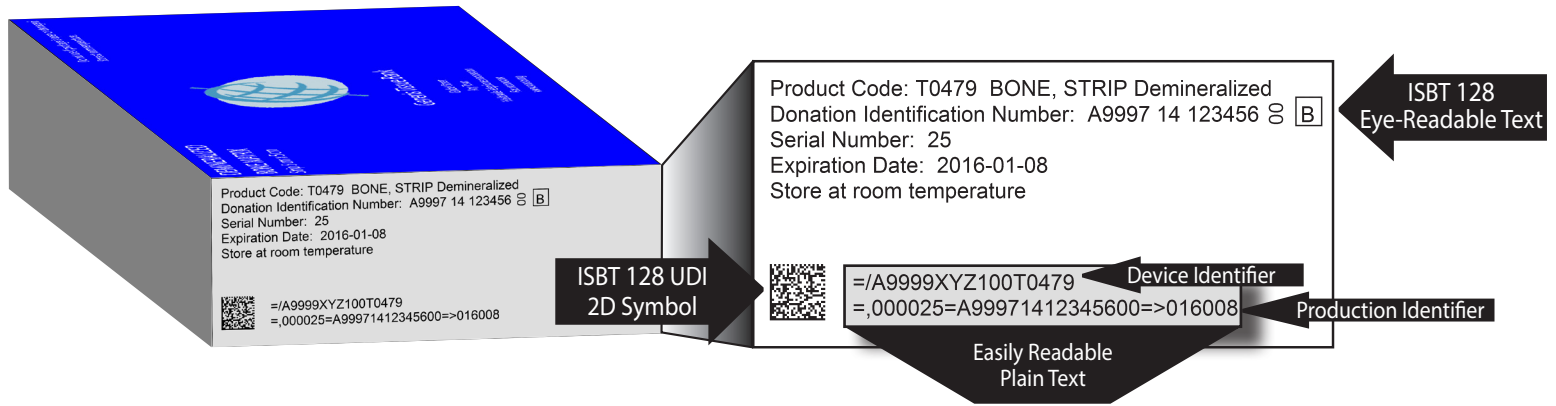(Fixed Product Data)

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

=/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.