LEARNING UDI COMMUNITY

AHRMM
Advancing Health Care through
Supply Chain Excellence

Unique Device Identifier (UDI-DI) Communication Change Process Report

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UDI-DI COMMUNICATION CHANGE PROCESS REPORT

VISION:

The vision of having one consistent unique identifier assigned to a specific manufacturer and medical device model/version combination, allowing the device to be tracked from the point of creation through its journey across the supply chain and into a patient's health record, was what drove the creation of the Unique Device Identifier (UDI) regulations. The UDI was designed to have two components; the Device Identifier (UDI-DI), a mandatory, fixed portion of the UDI that identifies the labeler and the specific version or model of the device, and the Unique Device Identifier Production Identifier (UDI-PI). The UDI-PI -- a conditional, variable portion of the UDI -- identifies one or more of the following when included on the label of the device: lot or batch number, serial number, expiration date, manufactured date, or distinct identification code as required for human cell, tissue, or cellular and tissue-based products.

The UDI was expected to improve patient and device safety by enhancing key patient safety systems, like the product recall and adverse event reporting processes and improve device evaluation by supporting research to determine the clinical effectiveness of specific devices within defined patient populations. Additionally, the UDI would streamline and improve the efficiency of the health care supply chain by requiring manufacturers to submit the data associated with the UDI-DI to the Global UDI Data Base (GUDID) and make this information available to all stakeholders at no cost through AccessGUDID. The regulations that were developed to support the creation and adoption of the UDI System were initially harmonized in an International Medical Device Regulators Forum (IMDRF) work group and informed by a broad cross section of representatives from health care provider organizations, manufacturers, government agencies and standards organizations.

CHALLENGE:

Previously, the steering committee for the Association for Health Care Resource & Materials Management (AHRMM) Learning UDI Community (LUC) had chartered a work group to investigate issues surrounding the situation where a manufacturer assigns more than one UDI-DI to what health care providers and U.S. regulators consider the same medical device (https://www.ahrmm.org/sites/default/files/ahrmm/multiple-device-identifier-work-group-report-031919.pdf). One of the outcomes of that study was the recommendation that a second work group be formed to analyze and make recommendations around the UDI-DI Change Communication Process. Specifically, the work group was challenged to:

1. Understand the factors that led to multiple and somewhat contradictory interpretations of when a new UDI-DI should be assigned for a given product.
2. Understand the processes manufacturers used to inform distributors and health care providers when changes were made to the UDI-DI.
3. Identify the process and IT system implications for distributors and health care providers when changes were made to the UDI-DI.
4. Gain a more in-depth understanding of the capabilities and limitations for Enterprise Resource Planning (ERP), Electronic Health Record (EHR), inventory management and any other relevant information systems' ability to store multiple UDI-DIs per manufacturer per unit of measure and track changes to the UDI-DI.

PROCESS:

A sub-group of approximately 60 representatives from various manufacturers, distributors, health care providers, U.S. FDA, GS1 U.S., Health Industry Business Communication Council (HIBCC), health care information technology providers and field consultants worked together to clarify and address the issues outlined above. The group worked to identify the change requirement scenarios, implications of changing the UDI-DIs and mitigation efforts. This is not an all-inclusive list but a good representation of the state of the health care field. The sub-group focused primarily on the use of GS1 as the standards body for assigning the UDI-DI (GS1 GTIN) since it is the organization used by most manufacturers and providers. However, they also received input from HIBCC for assigning the UDI-DI (HIBCC's Universal Product Number (UPN)).

CURRENT SITUATION:

As the work group members began analyzing the currect situation, they formed a series of questions that helped frame the situation and highlighted knowledge gaps between the various stakeholder groups. The following section outlines those questions as well as what was discovered.

Why does a UDI-DI Change?

- There are multiple factors that manufacturers consider as they determine when a UDI-DI change is necessary including:
    - Government regulations
    - Issuing Agency Standards and Guidelines
    - Mergers and Acquisitions
    - Manufacturers' internal policies and IT system configurations

Manufacturers must follow Government regulations for complying with the UDI rules. These regulations take precedent over issuing agency standards and guidelines. Until recently, the majority of the LUC's focus has been on the United States' rules for when the UDI-DI must change. Recently many countries have begun developing and implementing UDI regulations. Varying and sometimes conflicting Government requirements are adding complexity to the situation. The U.S. has been an active participant in the IMDRF and its work groups. The goal of this group is to encourage harmonization and learn from countries, such as the U.S., who have experience implementing UDI regulations. IMDRF has developed recommended guidelines for situations that warrant a change to the UDI-DI (commonly referred to as UDI-DI triggers). A list of their recommendations can be found at:

http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-udi-sag.pdf
http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-190321-udide-n53-annex.xlsx
http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-190321-sr-udi.pdf

- The U.S. and other Governments authorize existing data standards organizations

(including GS1, HIBCC, and ICCBBA) as the issuing agencies for the UDI, and manufacturers take into consideration the issuing agency standards and guidelines when determining when to change the UDI-DI.

- Manufacturers have differing interpretations and practices related to implementation of issuing agency guidelines, which leads to variation in determining when to change the UDI-DI. For example, one manufacturer indicated they have a 64-item check list they review to determine if a UDI-DI change is required.
- Many manufacturers have global packaging and sell the same products in multiple countries. The Government requirements for changing the UDI-DI vary and therefore a UDI-DI change requirement in other countries can impact products sold in the U.S.
- Some manufacturers assign multiple UDI-DIs for the same unit of measure to an internal reference number (e.g., catalog number) resulting in multiple UDI-DIs for what the health care provider considers the same product. This practice is driven by a variety of things including the design of the manufacturer's internal supply chain systems and the application of issuing agency standards and guidelines that were implemented prior to introduction of the UDI and associated regulations. They may "change" the UDI-DI by adding UDI-DIs without any change to their reference number.
- If a company acquires a portion of another company and does not license and acquire the rights to that company's prefix, then new UDI-DIs are required.

What are the implications of non-U.S. jurisdiction-specific UDI regulations on the UDI-DI Change Communication process for U.S. health care providers and distributors?

It may further increase the number of UDI-DIs for a product with the same specifications.

- Manufacturers are increasingly using global standards to manufacture product that can be sold in multiple countries. This reduces costs, avoids a fragmented supply chain and improves inventory management. It also increases the likelihood that regulations outside the U.S. will impact U.S. customers.
- Manufacturers may need to adjust their UDI-DIs to align with jurisdiction-specific (e.g., European Union) regulatory requirements which in turn could increase the volume of UDI-DI changes. Some of the UDI-DI changes that are required by other jurisdictions may not be perceived as important or relevant to health care providers in all markets. This underscores the criticality of having clear and consistent UDI-DI change communication practices in place.
- Given the increase in the volume of DI triggers, some manufacturers will continue to create a one-to-one relationship between the reference number and the UDI-DI, and some will choose to assign multiple UDI-DIs to a single reference number. Regardless of the choice, health care providers and distributors will still need to know the cause for the change and whether it has clinical and/or inventory management implications.

How do manufacturers currently notify distributors and health care providers when the UDI-DI Changes?

- According to health care providers, most manufactures do not have a formal process to

notify customers when or why UDI-DIs change.

- Manufacturers that maintain a one-to-one relationship between reference number and the UDI-DI may consider a change to the UDI-DI the same as new product release. The communication process designed for new product releases frequently does not address whether the "new" device is a clinically equivalent replacement for an existing product or if it is something distinct from existing devices. This distinction is important to health care providers to differentiate between a change which causes them to substitute one item for another (impacting inventory management systems) and a totally new product which may need review and approval by a value analysis team and require training.
- Currently there are not agreed upon guidelines to determine what constitutes a "clinically equivalent" device. Some situations like UDI-DI change due to change in package size or addition of CE mark clearly don't impact the functionality of the device but other situations are less clear.

How is the UDI-DI used by distributors and health care providers?

Electronic Transaction Sets (Purchase orders, advance shipment notices, invoices, etc.)

- Small but growing number of trading partners using UDI-DI instead of internal reference numbers for transactions.
- The vision is to eliminate the confusion caused by mapping provider, distributor and manufacturer internal numbers by moving all transaction sets to the UDI-DI.
- Distributors typically capture the UDI-DI in their item master as an attribute.
- A survey of providers indicated an intention to expand use of UDI-DI in transaction sets within the next year.

Inventory Management

- Current ERP systems utilize only the UDI-DI for inventory management purposes. Therefore, some providers implement specialized inventory management systems that track medical device UDI-DI and UDI-PI. These systems track the device from receipt to use thus providing full track and traceability of the device. Examples would include Tissue and Implant management systems.

Clinical Documentation

- EHR vendors are required by ONC to meet 2015 ONC regulations that require them to be able to record the UDI-DI and UDI-PI of a patient's implantable device. Providers are then required by CMS to document both components of the UDI for implantable devices, if available, in a patient's electronic health record.
- Other required data elements include Description (GMDN or SNOMED), Brand Name, Version or Model number, Company Name, MRI safety information contained on the label and whether the device is required to be labeled as containing natural rubber latex or dry natural rubber.

- The UDI is also included in U.S. Core Data for Interoperability (USCDI), standardized set of health data classes and constituent data elements to support nationwide, interoperable health information exchange as required in various ONC and CMS regulations.
- To facilitate accurate capture of this information a growing number of providers are using barcode scanning and RFID to capture the UDI at the point of care and then pulling additional data elements from the GUDID via AccessGUDID into the EHR.

Recall Management

- A growing number of providers are attempting to utilize the UDI to increase accuracy and speed up the recall process.
- Currently patient safety is compromised by the limited ability to link a specific medical device to a specific patient. This makes notifying patients who have received a recalled implant exceedingly difficult.
- There is currently a LUC work group focused on incorporating the UDI throughout the recall process and transitioning the process from paper to an electronic format.

Why do health care providers, researchers and the FDA want to track changes to the UDI-DI?

Health care providers want to know whether a change to the UDI-DI has clinical implications. They need to know if the change has implications on their purchasing and inventory management process and whether it will impact their ability to scan the product at the point of care.

Researchers frequently need to be able to group devices and therefore want to understand if the device with a new UDI-DI is clinically equivalent to the previous device.

The FDA wants to be able to track changes due to mergers and acquisitions so they can improve their adverse event analysis by identifying a device that is being reported under multiple names.

What are the implications of UDI-DI changes on information systems?

ERP systems are used by health care systems in the U.S. to manage purchasing, inventory management and payment functions. The ERP system is considered the "source of truth" for data related to medical devices (e.g., UDI-DI, descriptions, price, etc.).

- None of the major ERP systems currently being used by health care providers can accommodate multiple UDI-DIs per manufacturer per device, per unit of measure without special customization.
- ERP systems have no ability to track UDI-DI changes.

EHR systems are used by health care providers for clinical documentation and patient billing. This includes documenting specific medical device utilization. Generally, the UDI-DI (when available) is passed from the ERP system into the EHR system. When the medical device is utilized, the EHR matches the UDI-DI portion to the record it received from the ERP system and adds the UDI-PI. Some health care providers use third party inventory management systems that are also part of this workflow.

- Although the EHR systems can accommodate multiple UDI-DIs, the limitations of the ERP systems make it difficult to keep these systems synchronized.
- Patient perioperative records are routinely audited to ensure accurate documentation and charge capture of medical device consumption. The presence of the UDI-DI improves the efficiency of this process and reduces the burden on nursing staff.

Many health care providers and distributors augment their ERP systems with specialized inventory or warehouse management systems.

- Most IT systems continue to rely on the reference (e.g., catalog/model version) number changes to track when an item is being replaced and changes to inventory management practices must be made to prevent stockouts. Most distributors track the UDI-DI in their item masters as an attribute but do not include it in their warehouse management systems.
- As the field expands use of the UDI-DI in transaction sets (e.g. purchase orders) it will become increasingly important to track UDI-DI changes. This is especially important in situations where a manufacturer assigns multiple UDI-DIs to the same reference number.

Are there software solutions available to augment current system limitations?

- Third party software application systems have developed solutions that map multiple UDI-DIs to a single reference number and thereby facilitate barcode scanning at the point of care.
- Third party software application providers are also developing products that track UDI-DI changes and communicate those changes to their customers.
- The GUDID has a field for Previous DI, which was originally added in 2017 and limited to DI changes resulting from mergers and acquisitions. In 2019, FDA expanded the definition to: "Device Identifier that was assigned to a given version/model of a medical device before the same version/model of the device was assigned a new or substitute device identifier for reasons other than changes to the device physical specifications or new indications for use that change the version or model."
- GS1 offers the Global Data Synchronization Network (GDSN), which is an interconnected network of interoperable data pools governed by GS1 standards. It is a paid subscription service between information providers (Publishers) and trading partners (Subscribers) and regulators. This service exchanges real-time product data and messaging status to achieve end-to-end synchronization using standardized data formatting. Currently, it has limited use in health care but could be a partial solution to communicate changes to the UDI-DI given wider adoption. It is not, however, a global solution as it is limited to those able to pay for the service and it does not include medical devices using HIBCC and ICCBBA standards.
- Current ERP solution providers are evaluating the implications of expanding their capability to maintain more than one active UDI-DI per device per unit of measure while maintaining a cross reference to all previously assigned UDI-DIs.

RECOMMENDED PRACTICES TO IMPROVE UDI ADOPTION AND UTILIZATION:

As the work group studied the issues related to the UDI-DI change communication process, it became evident that there were broader issues negatively impacting the adoption and utilization of the UDI that were having a ripple effect on the UDI-DI change communication process. If the field is going to reap the patient safety and supply chain efficiency benefits of the UDI and maximize the return on the dollars that have been invested, then it must renew its focus on expanding utilization. Joint advocacy efforts that highlight the benefits to stakeholders across the field are essential.

What is the fastest way to expand utilization of the UDI?

- The UDI final rule makes changes to certain parts of 21 CFR governing FDA's existing regulatory systems and processes to integrate UDIs and device identifiers. These changes, known as the conforming amendments, affect part 803 (Medical Device Reporting), part 806 (Medical Devices; Reports of Corrections and Removals), part 814 (Premarket Approval of Medical Devices), part 820 (Quality System Regulation), part 821 (Medical Device Tracking Requirements), and part 822 (Postmarket Surveillance). The FDA should require the inclusion of the UDI-DI and UDI-PI consistently in all the FDA medical device databases specified in the UDI conforming amendments and should not redact the UDI-DI in public-facing databases and datasets[1].
- CMS should clarify that its "if available" caveat related to documenting the UDI for implantable devices only applies to non-sterile devices. All sterile devices are required by the FDA to have a UDI and should therefore be documented in the patient's EHR.
- The ONC should devote resources to highlighting the UDI requirements as part of their implementation efforts.
- Reinvigorate global harmonization efforts to increase understanding and minimize the negative impacts that UDI regulations from other countries have on the U.S. market.
- The FDA could also support further adoption of the UDI by using it the "primary key" between FDA databases. Leveraging the information in GUDID to auto populate other FDA forms could reduce the burden on manufacturers and ecourage them to keep the information in GUDID accurate. It is also critical they ensure proper funding to support enhancements to GUDID and enforce current UDI and GUDID requirements.

What could be done to further educate everyone on the uses and benefits of the UDI across the health care field and improve coordination among the various organizations providing UDI education?

- Collaboration among field organizations (AHRMM, AdvaMed, HIDA, etc.), standards issuing agencies, FDA, GPOs and any other interested stakeholders to review existing educational materials and identify opportunities to clarify and strengthen messaging to the field.

[1] https://www.hhs.gov/hipaa/for-professionals/faq/2071/can-device-identifier-di-portion-unique-device-identifier-udi-be-part-limited-or-de-identified/index.html

- Develop a plan to strengthen communication and ensure active participation of representatives from the FDA in all LUC activities. Enhancing bi-directional communication will improve the quality of educational materials produced and assist all stakeholders in clearly understanding the implications and benefits of maximizing UDI utilization.
- LUC collaboration with the AHRMM education committee to create ongoing educational opportunities for AHRMM members related to UDI adoption and utilization. Explore the opportunity to add questions testing UDI knowledge in the AHRMM certification exam.
- Develop and publish case studies of current best practices that promote education across the field such as health care provider vendor management policies that include required reading for sales representatives on the UDI and its relevance to hospitals.

RECOMMENDED PRACTICES SPECIFIC TO THE UDI-DI CHANGE COMMUNICATION PROCESS:

What can be done specifically to improve the UDI-DI change communication process?

Education:

Educate all stakeholders on the current and future role of the UDI-DI in electronic transaction sets, inventory management, clinical documentation and patient billing.

- Accreditation Standards Committee X-12, which is responsible for determining the data elements included on the claims form, has agreed there will be a space for the UDI-DI for high-risk implantable devices on the next form update.

Educate health care providers:

- When inaccurate or incomplete data is found in the Global UDI Database (GUDID) to report it to the manufacturer using the Customer Contact information populated in the GUDID. Inaccurate information can also be reported to the FDA help desk.
- Encourage utilization of software application providers as a source of best practices related to the UDI and the UDI-DI change communication process.
- The DI allocation rules of the Issuing Agencies.
- Implications of Global UDI requirements.

Educate manufacturers:

- Implications of UDI-DI changes on health care provider and distributor systems and processes.
- Importance of keeping data in GUDID updated and accurate.
- Benefits of providing ongoing education to sales representatives on the UDI, its functionalityw and its importance.
- On the updated definition and importance of populating the Previous DI field in the GUDID.

Educate software application providers and their supporting consultants:

- Importance of interoperability and the flow of the UDI between different IT systems
- Challenges being created by the gaps in the UDI-DI change communication process.
- Importance of their role in educating health care providers on the implications of configuration decisions on data management and the ability to maximize utilization of the UDI.
- Criticality of staying current on all regulatory requirements and changes.

Provide feedback to the FDA on the impact of the Previous DI field in GUDID has on the health care supply chain tracking of device information. Suggest options to improve the quality of the information contained in the Previous DI field by:

- Supplying training on the proper use of this field and the relationships between the records "connected" when this field is populated.
- Consider adding a "reason code" that would be required when the field was populated.

What can be done beyond education?

Process Improvements for:

Manufacturers assigning multiple UDI-DIs to a single reference number, or manufacturers including both GS1 and HIBCC barcodes on their packaging:

- Implement the recommendations contained in the LUC Multiple Device Identifier report (https://www.ahrmm.org/sites/default/files/ahrmm/multiple-device-identifier-work-group-report-031919.pdf) to eliminate or minimize this practice where applicable.
- Develop and share standard processes among third party software applications to implement software solutions that map multiple UDI-DIs to a single reference number. These solutions improve the accuracy and efficiency of barcode scanning at the point of care.
- Work with ERP solution providers on developing the ability to store multiple UDI-DIs per unit of measure.

Manufacturers treating UDI-DI changes as new product release or with no formal process to communicate changes:

- Collaborate with trading partners on ways to proactively communicate when and why a UDI-DI changes.

All manufacturers:

- Collaborate with software application providers to determine ways to track UDI-DI changes in a manner that will optimize inventory management and support EDI transaction sets as well as allow for improved analytics.
- Participate in field's efforts to define "clinical equivalent" and develop reason codes for UDI-DI changes.

- For users of GS1, pilot the use of GDSN as a means of communicating UDI-DI changes. Identify the cost/benefit of this type of solution and determine if there are ways to apply functionality to AccessGUDID.

Health care providers:

- Collaborate with manufacturers to develop a process to identify when a new UDI-DI signifies a new to market device or one with a clinically significant change (e.g., requires training or a change in behavior by clinical staff) versus when a new UDI-DI has no clinical relevance and is clinically equivalent to the current device being utilized.
- Collaborate with manufacturers and software application providers to develop systems to accommodate the assignment of multiple UDI-DI to a single reference number and to track changes and the associated reason for UDI-DI changes.

Software application providers:

- Implement enhancements that will automatically update changes to the UDI-DI and allow health care providers to differentiate between a new product UDI-DI and a new UDI-DI. This will include the ability to track reason codes for new UDI-DI.
- Implement enhancements to support tracking of multiple UDI-DI per manufacturer item / UOM combination to a single reference number.
- Make sure the provider and the manufacturer ERP systems can both use the UDI-DI for all transaction sets.
- Ensure that Inventory systems can scan the barcode containing the UDI and use the appropriate segments (e.g., UDI-DI and UDI-PI) to update inventory, rotate stock, reorder products and manage recalls.

FDA:

- Collaborate with the field advocacy groups to supply appropriate training on the use of Previous DI.
- Collaborate with a multi-stakeholder group to determine the implications of creating and housing reason codes related to UDI-DI changes in the GUDID.

By working together across the health care field, we can achieve the patient safety and supply chain efficiencies that were envisioned when the UDI was created.

APPENDIX

The following individuals comprised the UDI-DI Change Communication work group:

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