LEARNING UDI COMMUNITY

The Critical Link Between Cost, Quality, and Outcomes (CQO) and Unique Device Identification (UDI)

WHITE PAPER

AHRMM
Advancing Health Care through
Supply Chain Excellence

COST QUALITY OUTCOMES

CQO:
The Health Care
Supply Chain

AHRMM.ORG/LUC

The Cost, Quality, and Outcomes Movement

The ever-changing economy, reduction in Medicare reimbursements, and the passage and upholding of the Patient Protection and Affordable Care Act (ACA) have brought sweeping changes to the health care field. Evolving reimbursement policies designed to reward value not volume require hospitals and health care systems to deliver quality care at an appropriate cost.

Historically, health care supply chain professionals have focused much of their efforts on negotiating with suppliers to achieve the lowest product acquisition price, in addition to managing the processes associated with the procure-to-pay cycle.

In this changing health care environment, with the shift from volume to value, hospitals and health care systems need to understand the total cost of ownership of supplies, procedures, and delivered care across the care continuum. Total costs are impacted by the quality of care. For example, infections and unplanned readmissions raise total costs, while lowering reimbursement levels.

Health care executives increasingly recognize that their organization's success relies on the performance and effectiveness of the supply chain. Therefore, the role of supply chain must transform into one that is much broader in scope and more closely aligned with the clinical side of hospital operations; it is at the intersection of *cost, quality,* and *outcomes* where supply chain can most effectively improve the quality and affordability of health care:

- **Cost** – all costs associated with caring for individuals and communities
- **Quality** – care aimed at achieving the best possible health
- **Outcomes** – financial results driven by exceptional patient outcomes

The AHRMM Cost, Quality, and Outcomes (CQO) Movement frames the critical role supply chain professionals play in driving high quality care, at a more affordable cost, to deliver greater value to patients.

The Critical Link Between CQO and UDI

In his book, "The Healthcare Supply Chain: Best Practices for Operating at the Intersection of Cost, Quality, and Outcomes," Christopher O'Connor, AHRMM Past Chair and President & Chief Executive Officer, Nexera and Acurity, states: "A strategic supply chain must be able to tie its data to clinical product use as the basis for making informed purchasing decisions that facilitate positive clinical outcomes and a high ROI based on current reimbursement models."

But health care has long struggled with disparate data sources and lack of data standardization, with each party to the supply chain – manufacturers, distributors, group purchasing organizations (GPOs), and providers – speaking their own language when it comes to product identification. As a result, it has been challenging – if not impossible – for health care organizations to leverage data for strategic sourcing initiatives or identify variations in clinical practice.

The FDA's AccessGUDID Web Portal
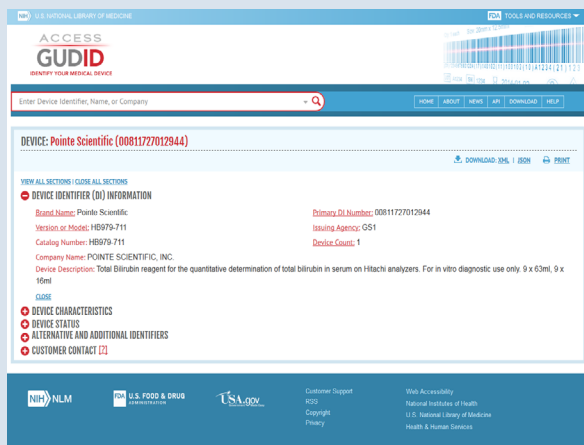
That's changing with the implementation of U.S. Food and Drug Administration's (FDA) unique device identifier (UDI) rule. The regulation requires medical device manufacturers to assign a unique identifier and apply it to the device label, packages and, in some cases, on the device itself in in both plain text and machine-readable formats.

The AHRMM Learning UDI Community (LUC)

The manufacturer must also submit the UDI-DI (device identifier portion of UDI), along with certain device attributes, to the FDA's Global Unique Device Identifier Database (GUDID). GUDID data is accessible to the public through the FDA's web portal AccessGUDID.

Now that manufacturers have populated the GUDID with their product data, the big question is – *how can health care supply chain professionals and clinicians leverage UDI data to improve cost, quality, and outcomes for their organizations and the health care ecosystem as a whole?*

The U.S. FDA in its 2018-2020 Strategic Priorities acknowledged that engaging in collaborative communities improves patient and device safety by allowing stakeholders in the medical device ecosystem, including CDRH, to proactively work together to solve both shared problems and problems unique to others. FDA identified the Association for Health Care Resource & Materials Management's (AHRMM) *Learning UDI Community (LUC) as an example of a coordinated, action-oriented early adopter collaborative community.*

Michael Schiller, CMRP, AHRMM Senior Director states: "The LUC, as a health care collaborative effort, is designed to address issues impacting the implementation and use of unique device identifiers by developing a common understanding and approach to UDI adoption within the health care setting."

Members of the LUC have and continue to engage in a wide range of cross-functional work groups to develop recommended practices and resources that can accelerate UDI adoption. These recommendations and resources are open to all those who are interested in advancing UDI adoption within the health care field and are designed to benefit the health care ecosystem by providing more consistent, consensus-based processes to support UDI adoption.

As part of this work, they have identified data quality issues limiting the value of the data within the GUDID to meet the needs of the various stakeholders attempting to use it. Each of the five LUC work groups focused on data quality have proposed their recommended practices to address these challenges.

What is UDI?

1. Regulation
2. Requirements on the package label
3. Global UDI Database (GUDID)

In an effort to capture broader insights on UDI adoption from across the health care field, AHRMM, with participation by the FDA, held LUC Data Quality Workshops during four conferences in 2017: the AHRMM17 Conference, GHX Health care Supply Chain Summit, Health care Manufacturers Management Council (HMMC) Spring Executive Conference, and the UDI Conference. During these workshops, conference attendees had the opportunity to voice their opinions on the state of UDI data quality, hurdles to UDI adoption and what recommended practices are necessary for providers and suppliers to effectively capture the UDI and use it in meaningful ways.

A clear message has emerged from health care stakeholders – the only way to drive greater UDI adoption across the health care field is for the individuals and groups engaged in UDI efforts to collaborate, share their experiences, and learn from each other. In this paper, the first in

"We now have a much better medical record. You can tell not only what was used but also 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."

- Fran Sercer, MSN RN, Associate Director of Interventional Services, Eskenazi Health

a two-part series on CQO and UDI, we leverage these collective insights to present challenges faced by providers and manufacturers today with regards to UDI adoption, and highlight potential solutions that have emerged from the work of the LUC and other health care business segment participants.

UDI in the Real World: Challenges to Implementation

When we examine the many attempts of end users to leverage the data in the GUDID to meet their various needs, we get a clear picture of its limitations. In reviewing the feedback from health care providers taking part in the 2017 LUC Data Quality Workshops and LUC Work groups, and those that have documented their experiences in individual LUC case studies, a number of common themes have emerged.

Inability to Access UDI Data

Across the board, one of the greatest challenges faced by provider organizations wanting to leverage UDIs for cost, quality, and outcomes initiatives is the inability to access consistent data. End users have stated that they cannot find all of the UDI data they need in the GUDID, and that the data may be inconsistent or incomplete to support user needs.

Some have attempted to use the GS1 Global Data Synchronization Network (GDSN) to access GS1 Global Trade Item Numbers (GTINs), others have obtained UDI data from manufacturer websites or reached out directly to their suppliers, while still others leverage third-party content management services.

Even when manufacturers have populated the GUDID in a complete and compliant manner, the information provided isn't necessarily the information needed by

> "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. Suppliers need to make their DI data in GUDID as a source of truth to various populations."
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> *- Jim Booker, Manager of Master Data Management, Supply Chain, Stanford Health Care*

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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] 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)

the end users – or in the format in which they need it. For example, the GUDID contains inconsistent clinically relevant device attributes related to device size and composition. These attributes are necessary to assess device performance. In addition to clinically relevant size, device categorization hierarchy used for devices in the GUDID – the Global Medical Device Nomenclature (GMDN) – is not particularly useful for users searching for a product's real-world clinical applications (see Device Categorization Work group information on page 10 of this paper).

packaging. This may be the result of legacy products identifiers in the supply chain or may be lack of compliance with UDI regulations. Either way, the lack of PIs prevents a clinician from recording complete UDI data at the point of use.

- **Data errors and inconsistency:** Providers have reported that some of the barcodes when scanned pull different information than what is printed on the label – explicitly the dates. They have also found inconsistency among barcode labels for the same products, with some barcodes generating the necessary product data and others generating nothing.

UDI Label Requirements

Problems with Labeling and Barcodes

Health care provider organizations have also experienced a variety of challenges in attempting to capture UDI data from a product label at the point of use. Obstacles include:

- **Multiple barcodes:** Some product packaging contains multiple barcodes, and each barcode can contain different information. Clinicians and others find it challenging to determine which barcode to scan in order to capture the product's UDI data.

- **Incomplete UDIs:** Providers have encountered products that do not contain production identifier (PI) information on the unit of use

"If there are many barcodes on the package then the nurse doesn't know which one to scan. If the barcodes are too close together on the package the nurse will literally have to put a finger over one of them so that he/she can scan one at a time. If we could get everything in one 2D barcode that would be so much easier because a nurse would just scan that one little box and the data would populate all of the required fields."

- Sandi Michel, MPMP, ITIL, CLSSBB, Director of Supply Chain Systems and Quality, the Office of Data Standards & Interoperability for Franciscan Missionaries of Our Lady Health System (FMOLHS)

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[3] Production Identifier (PI): A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
- the lot or batch number within which a device was manufactured;
- the serial number of a specific device;
- the expiration date of a specific device;
- the date a specific device was manufactured;
- the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

The State of UDI: Moving From Compliance to Value

Since the FDA published its final UDI rule on September 24, 2013, manufacturers have been working to assign UDIs to their products, apply UDIs to product labels and packages, and publish the UDIs and required device attributes to the GUDID.

Manufacturers have had to allocate significant time, labor, and financial resources toward their UDI compliance efforts. Furthermore, some manufacturers initially believed that meeting the UDI regulatory requirements would be completed as a one-time project rather than a program requiring continuous process of maintaining and updating current data in the GUDID, assigning UDIs to new products as they are introduced to the market, and adding this new product data to the GUDID. Some companies have used the UDI regulation to build master data management processes a manufacturer to address product data changes that occur as a result of new and discontinued products, mergers and acquisitions (M&As), and other business factors.

During the 2017 LUC Data Quality Workshops, manufacturers voiced some of the challenges they face, particularly those related to submitting data to the GUDID and subsequently managing that data. These challenges include:

Lack of flexibility: The current GUDID structure is too rigid and manufacturers have a tough time updating their data. Many said there is no easy way to make minor edits to existing data, and some updates required communication with the FDA. They voiced the need for:

- A batch update capability through which they can update only those fields that need editing, rather than having to update all of a record's content
- A "drop down menu" through which they can make minor corrections without having to contact the FDA
- The ability to "unpublish/republish" when they find an error they need to correct

Lack of an audit trail: Another common complaint made by manufacturers is that the GUDID does not offer the ability to easily track changes made to records. They voiced the need for:

> "There are many ways that a GUDID data field update impacts manufacturer processes in terms of system validation, procedures, soft validation. I would prefer to complete (updates) a fewer number of times. It would be better to have UDI updates that occur all at once."
>
> *- Manufacturer attendee, of 2017 LUC Data Quality Workshops*

- "Versioning" records and an audit trail of corrections - the ability to store the original published data and history of edits
- An "edit status" that communicates what records are currently being updated
- An archive of "old records" to keep track of what corrections were made

Manufacturers were also faced with rolling compliance dates and, until recently, have been focused solely on compliance with the UDI rule and have not had the opportunity to consider the needs of those who want to use their data, including clinicians, supply chain professionals, value analysis committees, researchers, etc. Manufacturers have traditionally responded to FDA regulatory requirements by focusing on compliance. While the initial focus was to populate the GUDID in a way that is "compliant" with the rule, efforts by the AHRMM LUC, UDI demonstration projects and early adopters are identifying requirements that have the potential to make the UDI and GUDID more usable to end users. To achieve the vision of UDI to improve cost, quality, and outcomes manufacturers must increasingly go beyond compliance to understand and address the needs of UDI users when populating the GUDID.

In response to challenges with the GUDID submission process and the lack of an audit trail to track record changes, FDA incorporated manufacturer and user feedback into the latest releases of GUDID and AccessGUDID.

The objective was to reduce the barriers to the editing process to increase manufacturer control over

corrections and data quality improvements while, at the same time, increasing transparency to monitor DI record changes through version update fields (e.g. version date, version status, version record key).

FDA and manufacturers have a shared responsibility to improve product attributes required by the FDA. It would benefit the health care field as a whole if manufacturers took a step back and considered which optional attributes are useful to various end users. Because the GUDID features only a limited set of attributes, there are efforts underway to identify clinically relevant attributes for specific product types and to ask manufacturers to provide that data to supplemental databases that would complement the GUDID using the DI as the common thread. (See AUDI Work group on page 10 of this paper).

When considering the UDI regulation and the sharing of standardized product data throughout the health care field, manufacturers should also keep in mind the value they can derive from going beyond what the rule requires. If clinicians can use the data in the GUDID to generate real-world evidence for specific devices, then manufacturers can leverage this information in their research and development (R&D), marketing and sales efforts. Manufacturers could potentially also use this data to speed up approval of similar products, or the approval to use existing products for new or otherwise off-label, uses.

This holistic approach to the UDI rule and product data in general will bring about the benefits we all envision and expect the UDI to bring to the health care field.

UDI: Improved Care – Advanced Learning

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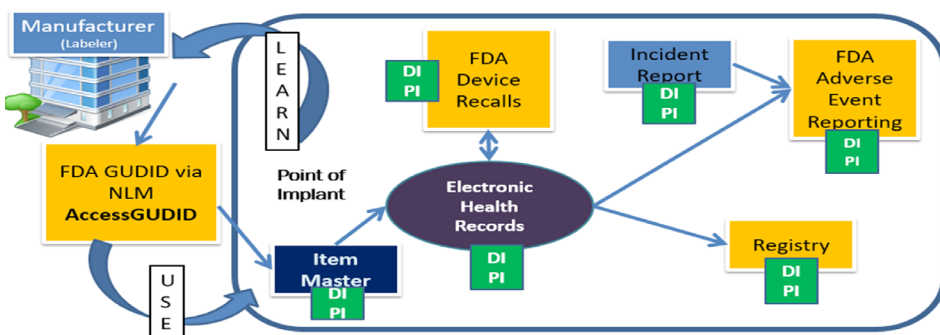
[4] Global Unique Device Identification Database (GUDID) User Manual – Unlocking Device Records for Editing Version 1.0; New data elements in AccessGUDID

Leveraging UDI for CQO: Current Efforts

There are currently a number of initiatives underway that are focused on leveraging UDI data to drive CQO benefits. Stakeholders from across the health care field are identifying issues and developing potential solutions that will allow end users to derive greater value from supplier data. They include efforts to supplement or augment the GUDID with clinically relevant data necessary for CQO.

The UDI Ecosystem
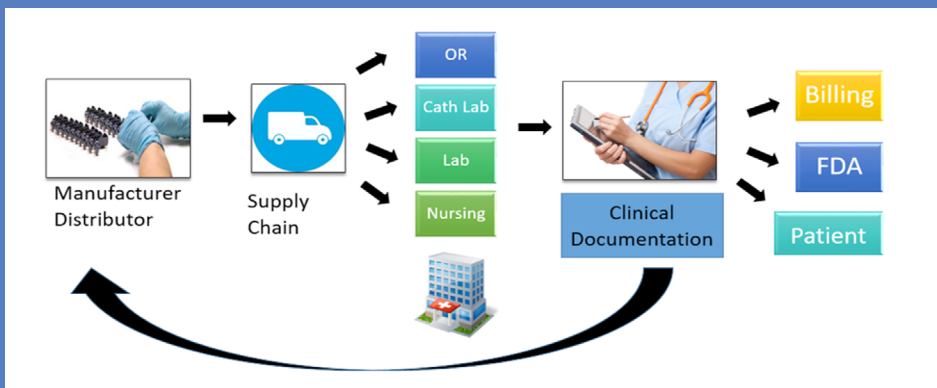
A brief description of some of these initiatives follows. In the second paper of this series, we will delve deeper into these efforts and provide insights from the individuals who are leading them.

The MDEpinet Augmented Unique Device Identifier (AUDI) Data Work Group

The mission of the Augmented UDI (AUDI) Work Group is to provide the framework for best practices in expanding the UDI-associated device system to manage clinically significant attributes not currently found in the GUDID, such as product composition, and risk for cyberterrorism. The AUDI Work group report is available at www.ahrmm.org/LUC.

AHRMM LUC UDI Capture Case Studies

In addition to these work groups, there are a number of individual health care organizations that are collaborating with suppliers on initiatives to improve the access and usability of GUDID data in order to drive CQO initiatives within their organizations. They are finding solutions to overcome issues related to data quality and accessibility, barcode scanning, and system interoperability. These case studies can be found in the UDI Capture section of the LUC Resource Center at www.ahrmm.org/LUC.

CQO UDI WHITE PAPER

The AHRMM LUC Clinically Relevant Size (CRS) Work Group

The clinically relevant size of products in the GUDID is an important attribute required for clinical device use, surveillance, and research purposes (e.g. comparative effectiveness). The AHRMM LUC Clinically Relevant Size (CRS) Work Group is engaged in an effort with manufacturers to correct existing device size data in the GUDID so that it is clinically relevant, and to standardize accurate capture of device size data for new entries into the GUDID. The full CRS Work Group report can be found on the AHRMM website at www.ahrmm.org/LUC. The learnings from this report are currently being used to inform the development of standards list of values by device type. For example, Medical Device Epidemiology Network Registry Assessment of Peripheral Interventional Devices (MDEpiNET RAPID) Informatics UDI Work Group has developed a consensus based set of size dimensions for stents, artherectomy devices, and other PIDs that will be incorporated into GUDID as structured fields.

Device Categorization: GMDN/SNOMED Terminologies LUC Community Work Group

Devices within the GUDID are categorized according to Global Medical Device Nomenclature (GMDN), which is the terminology most commonly used by manufacturers and regulators. But when documenting devices for clinical purposes, health care providers most often use the Systematized Nomenclature of Medical & Clinical Terminology (SNOMED CT) terms. This work group is reviewing the pros and cons of both terminologies and also using the RAPID Project to determine if the categorized hierarchy for device data currently within the GUDID can be leveraged for clinical and research purposes, most notably to obtain real-world evidence on the performance and safety of devices in patients. The Device Categorization Work Group summary statement is available at www.ahrmm.org/LUC.

The AHRMM LUC Unit of Use (UOU) Work Group

Under the UDI rule, manufacturers are required to provide unique device identifiers at the "Unit of Use" (UOU). The original intent of this requirement was to provide a mechanism to track individual medical devices, but there is no common definition for UOU among health care stakeholders or what UOU means. Take for instance a box of sponges with individual packages that each contain two sponges – is the UOU the package or the individual sponges? The AHRMM LUC Unit of Use (UOU) Work Group was tasked with identifying issues related to UOU, developing recommendations for the proper disposition of UOU and use of the UOU in the GUDID and EHRs, identifying potential use cases for UOU, and developing potential solutions for these use cases. The UOU deliverables include a three-part report and webcast series which can be found on the AHRMM website at www.ahrmm.org/LUC.

The FDA UOU Explained (Webcast)
- Talking Points (PDF)

Clinical Recognition of the UOU (Webcast)
- Talking Points (PDF)

Potential UOU Examples (Webcast)
- Talking Points (PDF)

The AHRMM LUC Low Unit of Measure (LUM) UDI Single Device Work Group

Medical device distributors use low unit of measure (LUM) to better support health care provider needs for improved efficiencies and better patient care by optimizing inventory levels, allowing clinicians to focus less on inventory management and more on patient care, and reducing costs and waste. While the UDI rule requires manufacturers to identify devices through distribution and use, distributors engaged in LUM programs might remove a device from UDI compliant packaging in order to provide individual devices to providers. In these cases, providers may not be able to capture product data at the "each" level within clinical and business systems. The AHRMM LUC LUM UDI Single Device

Work Group has provided recommendations on how manufacturers and distributors can overcome this issue. The LUM Work group report can be found on the AHRMM website at www.ahrmm.org/LUC.

The AHRMM LUC Catalog Number Work Group

Health care providers have historically used manufacturer catalog numbers to identify medical devices within their systems for processes such as procurement, inventory management, recall management, spend analysis, item master management, and linkages to clinical and charge master systems. The GUDID currently does not contain catalog numbers as a required field, therefore provider organizations cannot use catalog numbers as a way to match data sets from their item master with the data the device identifier information within the GUDID. The AHRMM LUC Catalog Number Work Group is working with other data quality groups to address this issue and requesting that manufacturers and suppliers enter catalog numbers in all GUDID records moving forward. The Catalog Number Work Group report can be found on the AHRMM website at www.ahrmm.org/LUC.

Global UDI Harmonization: The International Device Regulators Forum (IMDRF)

Health care today is truly global, with medical device manufacturers selling their products throughout multiple countries, and health care providers procuring and using devices manufactured by companies across the world. Under the Global Harmonization Task Force (GHTF), regulatory agencies in Australia, Canada, Japan, the European Union, and the U.S. laid the foundation for harmonized regulatory guidance across these countries. Their work continues under the International Device Regulators Forum (IMDRF), which is a voluntary group of medical device regulators from around the world, who are working to accelerate international medical device regulatory harmonization and convergence, including UDI harmonization.

Conclusion

Under the FDA's UDI rule, manufacturers are making major strides in standardizing device identification and making this data available to the broader health care community. But in order for health care providers and others to effectively use the data to significantly impact cost, quality, and outcomes, manufacturers and providers must go beyond checking the compliance box and deliver information that meets the needs of their various data consumers.

With growing economic and regulatory pressures, the health care field has no choice but to evolve. If health care providers are to deliver improved clinical outcomes at an appropriate cost, they must have accurate and timely product data on which to make decisions. Manufacturers must continue take these needs into consideration when populating the GUDID, and work to deliver data that is consistent, accurate and complete.

There are a number of efforts underway where health care providers, manufacturers, regulatory authorities, and other stakeholders are coming together to address the current challenges with the integrity of the data in the UDI system so that the GUDID can provide value across the health care continuum. In next paper we will examine each of these efforts, offering insights from work group leaders, individual organizations, and health care thought leaders on how GUDID data can be successfully leveraged to improve clinical care.