

PREMIER RESEARCH INSTITUTE

Unique Device Identifier: Implementation Guide

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In addition, we would like to recognize the numerous organizations that provided valuable information for case studies, strategies and recommendations. Although all of these organizations have been involved in the implementation guide's development, they do not necessarily endorse the guide's recommendations or conclusions.

Organizations

Baptist Health South Florida
Miami, FL

Carolinas HealthCare System
Charlotte, NC

Franciscan Ministries of Our Lady Health System
Baton Rouge, LA

Geisinger Health System
Danville, PA

Kaiser Permanente
Oakland, CA

Mayo Clinic
Rochester, MN

Mercy Health
St. Louis, MO

Brigham and Women's Hospital
Boston, MA

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Executive Summary

The Food and Drug Administration's (FDA's) unique device identifier (UDI) system will help hospitals generate supply chain efficiencies, improve patient care, and reduce costs once it is incorporated and adopted into the electronic databases used to purchase and track medical devices, including surgical, wound care, patient monitoring and implanted products.

This new tool, which will assign each medical device with a unique code corresponding to its make and model, will replace the use of catalog numbers and other device nomenclature systems to provide a standard, unambiguous product identifier across supply chain, clinical and administrative departments within hospitals.

By adopting UDI for all devices into their supply chain management systems, hospitals will benefit from better cash flow, reduced labor costs, simplified supply chain management, efficient payment and reporting processes, and enhanced inventory management.

For some devices—particularly implanted products—UDI adoption should also extend into the clinical suite, electronic health records (EHRs) and claims to facilitate easier recalls when devices malfunction. This will also encourage comparative effectiveness research on device performance, allow more accurate reporting of device failures, prevent medical errors, and reduce manual and unstandardized methods of device data entry.

As the highest risk devices obtained UDIs in 2014, hospitals must now begin to adopt this tool and achieve the benefits envisioned by FDA and articulated in the Brookings Institution's *UDI Roadmap for Effective Implementation*, which was developed by materials management, clinical and administrative experts from hospitals and health systems.

This guide provides hands-on advice from healthcare organizations already adopting UDI in their electronic databases, demonstrating that the envisioned benefits of this new tool can become a reality by reducing costs while improving care. Each section of this guide identifies the key benefits of UDI adoption, as well as workflow and technology changes needed to improve device tracking.

While healthcare organizations are not required to use UDI, the benefits of preparing for and adopting this new tool greatly outweigh the costs of implementation by increasing supply chain efficiency, enhancing the revenue cycle, increasing the quality of care and improving patient safety.

What is a Unique Device Identifier?

Over the last few years, the FDA has worked to improve data collection on medical devices, envisioning a new postmarketing surveillance system that would: [1, 2]

- Communicate timely, accurate, systematic, and prioritized assessments of the benefits and risks of medical devices throughout their marketed life using high-quality, standardized, structured electronic health-related data;
- Identify potential safety signals in near real time from a variety of privacy-protected data sources;
- Reduce the burden and cost of medical device postmarket surveillance; and
- Facilitate the clearance and approval of new devices, or new uses of existing devices.

The creation of the unique device identifier (UDI) presents an opportunity for healthcare systems to improve their patient care while reducing costs.

A UDI is a code assigned to each medical device that consists of two parts. [3] The first part is a device identifier (DI) that contains the manufacturer name along with the version or model of the device. The second portion of a UDI is a production identifier (PI) and includes the current production information for that specific device, such as the lot or batch number, the serial number and expiration date. While every device will have a DI, some devices may not have PIs or will only have certain portions of a PI—such as just the expiration date but not a serial number. All UDIs must be readable by both a human and through automated technology, such as bar coding. Exhibit 1 provides an example of UDI numbers in the GS1 format. Appendix A provides additional examples.

Exhibit 1: Example of Device Identifier with Production Identifier in GS1 Format [4]

Global Trade Item Number (GTIN) with Expiration Date, Lot & Serial encoded in a GS1-128 Barcode¹



FDA regulations allow for three acceptable UDI formats created by GS1, Health Industry Business Communications Council (HIBCC) or the International Council for Commonality in Blood Bank Automation (ICCBBA), which is used exclusively for blood, tissue, and organ products. For clarity, this paper will use the GS1 format as an example, but the information is generally applicable to other UDI formats. UDI numbers do not change based on what organization is receiving the device, but they do change under limited circumstances if there is a significant change in the device such as its specifications (i.e., new models or versions), performance, size, composition, package quantity, package dimensions, or if distributed by a re-labeler.

¹ A GTIN is one of the options for the DI portion of the UDI.

Where Are Unique Device Identifiers Found?

There is a different UDI at each level of packaging (see Exhibit 2).[4] Barcodes are shown on the package in a location that allows ready access for a scanner to be used when the device is stored or stacked on shelves. The human readable portion of the barcode is placed so that it can be read in the same way as other labeling information, i.e. on the portion of the label most likely to be facing out on the shelf.²

Exhibit 2: Packaging Level UDIs* [4]



*UDI in GS1 standard format displaying a DI (GTIN) without PI information

Why Have a Unique Device Identifier?

Hospitals, physicians, patients and health plans can achieve several benefits from the UDI system once it's adopted.

- ✓ It is often difficult to locate all recalled devices, whether they are on hospital shelves or implanted in patients. The UDI system will provide devices with a consistent, standardized, and explicit identifier so devices can be tracked from manufacture through to use in a patient. In turn, this device identification system will help locate products by searching inventory databases, patients' health records and other information sources for the UDI of recalled products.
- ✓ There are often challenges documenting the devices used in care because there is no standard system for identifying products. The UDI system will standardize how devices are identified, thereby creating operational and clinical efficiencies to free up additional time for direct patient care.[5]
- ✓ The UDI system is expected to replace unstandardized catalog number ordering, thus creating procurement and inventory management efficiencies. This system can then help hospitals reduce inventory on hand, ensure product utilization prior to expiration, and otherwise better manage inventory.

² Those devices reused and reprocessed between each use will have the UDI imprinted directly onto the device. This guide will not address the unique issues associated with these devices.

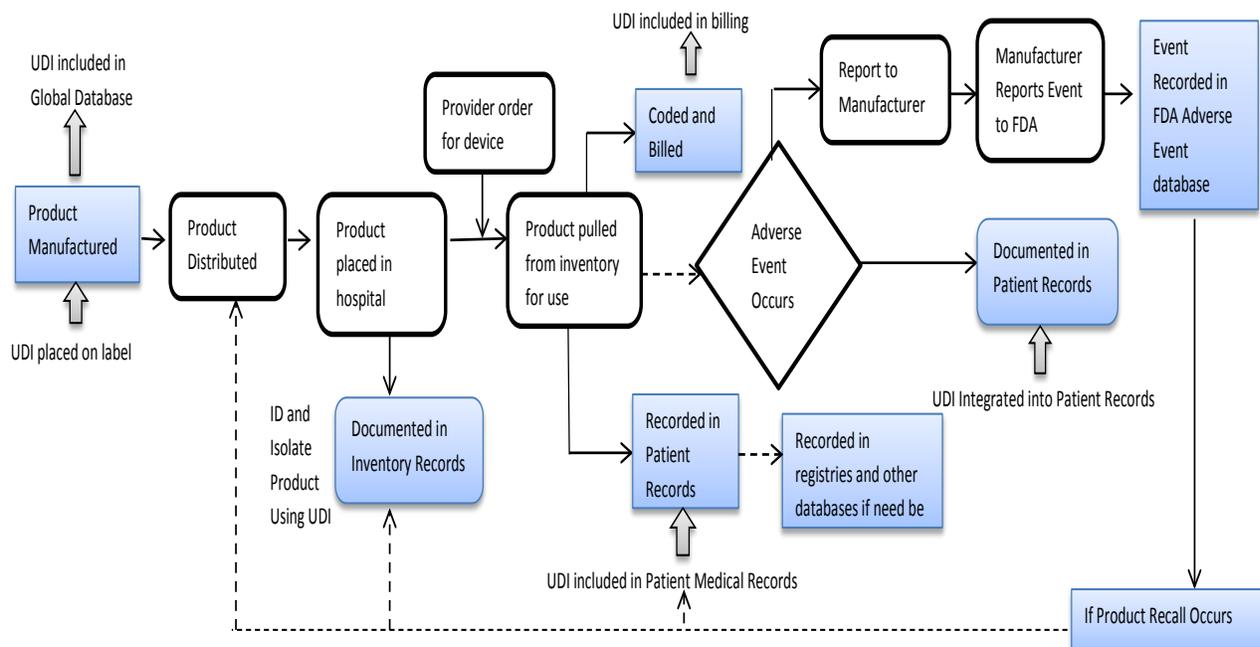
- ✓ It is difficult for providers, patients, and manufacturers to understand the long-term risks and effectiveness of medical devices because of challenges tracking long-term outcomes associated with devices. Through more precise device identification with UDI, researchers, health systems, and health plans will have the necessary information to conduct long-term outcomes analyses and compare the performance of different products.

Using the UDI in the supply chain will improve efficiencies, reduce errors, and result in cost savings. More importantly, UDIs raise the possibility of increasing patient safety by giving providers better information about the devices, enabling postmarket surveillance, and reducing medical errors.[5-10]

Who Uses a Unique Device Identifier?

The UDI is structured as a universal code that can be used throughout the entire supply chain from the manufacturer to the patient, and potentially to other users such as the Food and Drug Administration (FDA) and payers. To understand why the FDA is implementing a UDI system, Exhibit 3 shows where the UDI can be incorporated into the patient care experience and how it would work if an adverse event happened with a device.

Exhibit 3: Unique Device Identifier in Use[11]



When Will the Unique Device Identifier Start Being in Use?

With the introduction of the UDI final rule in September 2013, implementation for high-risk devices began in September 2014. [3] UDIs on other devices are mandated to be phased in over seven years, but

you may see the UDIs before that as manufacturers sell off non-identified devices and implement UDI across all their devices before the deadlines. (See Appendix B for full implementation schedule.)

How Does an Organization Implement Unique Device Identifiers?

You will need to address the following areas during UDI adoption:

- Supply chain management systems
- Clinical suite software and electronic health records (EHRs)
- Claims and billing

Please note that this is not a definitive guide to UDI implementation. Each organization will have different challenges on this journey and will need to create its own unique solutions to those challenges.

Supply Chain Management System

Benefits: The UDI allows you to more efficiently and effectively manage your supply chain in a number of ways including:

- ✓ Better cash flow: Using UDI simplifies your chargeback and rebate processing, thereby decreasing the amount of money your organization has in unresolved sales accounts.
- ✓ Reduced labor costs: Adopting UDI reduces the amount of time staff spend building and maintaining tables in different systems to track all your proprietary account numbers.
- ✓ Simplified supply chain management: Using a common number (UDI) facilitates information exchange between various supply chain partners.
- ✓ Efficient payment and reporting processes: Using UDIs allows sales to be automatically reported to providers with fewer errors, thereby improving electronic data interchange (EDI) and e-business dealings.
- ✓ Enhanced inventory management: UDIs provide a consistent way of identifying items. This means receivers are better able to correctly identify the items for distribution and use by reducing the number of items sent in error, thereby supporting efficient replacement of these items throughout the organization.

Workflow: Before implementing any project, it is necessary to know where you are right now. This helps you identify any processes or workflows that need to be changed to enable adoption of UDI into your organization. While your supply chain may be functional, there may be redundant activities, out-of-sync processes, or organizational disconnects that reduce efficiency. You need to ask yourself: “are we getting the right item to the right place at the right time to meet the needs of the patient at the *right* cost?”

For organizations with multiple hospitals within a single supply chain, it is important to do an assessment within and between hospital sites. By aligning your supply chain and revenue cycle between

sites, you may be able to achieve greater standardization and increased economies of scale so that the costs and benefits of streamlining the supply chain are financially feasible.

Changes: After completing an assessment, you will need to measure differences in hospital workflows, both across institutions and within hospitals. The goal is to align the systems so that UDI can be adopted effectively and efficiently. Using a standardized approach to workflow changes will help you understand what the barriers are, what the improvement goal is, how to change the status quo and how to measure improvement. Things to consider when looking at workflow changes are:

- How items are entered into your Enterprise Resource Planning (ERP) systems, which are used to manage and track inventory received from vendors. ERP systems are populated based on how products enter the hospital—from a supplier or directly from a manufacturer, for example—and contain information based on whether the hospital purchases products individually or as part of larger cases. As shown in Exhibit 2, there can be multiple levels of UDI information depending upon the level of packaging. The point at which your organization will perform the initial scan upon receipt from the vendor is dependent upon how your system is currently organized and how your ordering system is structured. If there are multiple levels of packaging, the UDI may be entered into the ERP multiple times. Many manufacturers accept orders only at the case level, but you may need to maintain inventory at the inner pack or item level for inventory management and billing purposes. It is recommended that organizations enter UDI information for each level of packaging.
- As part of the workflow changes you may want to consider how your procedure and operating rooms are stocked with inventory. Some organizations use a replenishment model, where units contain standard stock that is re-ordered when it is removed for use in a patient. In this model it is easier to have the UDI entered when the item is removed from the unit level inventory. Other organizations use a physician preference model, where between each patient the room is set up according to physician preference. This approach allows an organization to tailor the supplies to the procedure and the physician. In this model it is better to enter the UDI while the items are being collected before being placed in the room. Then only unexpected items need to be scanned during the procedure.
- You will need to make decisions about where and who will be responsible for scanning. Some organizations have personnel from the supply chain do all the scanning, from receiving through to the procedure and operating rooms. Some organizations have other staff, such as a technician or nurse, responsible for scanning items in the procedure rooms.

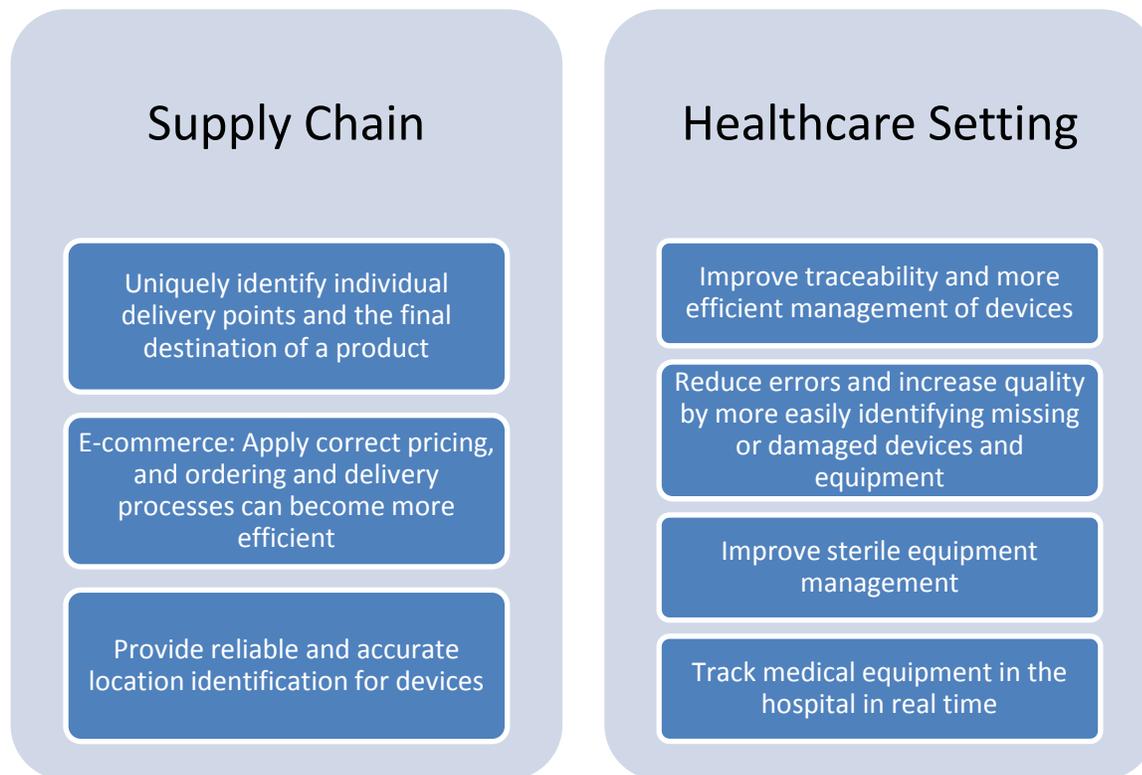
Technology: As part of UDI adoption, you will also want to ensure that locations within your facility can be unambiguously identified through the use of a standard, unique code assigned to each supply chain location. The Global Location Number (GLN), a 13-digit number that identifies supply chain parties

and/or locations, can serve as that code to uniquely identify your organization across the entire supply chain with all suppliers and group purchasing organizations. [12]

Although GLN took effect in 2010, many healthcare organizations have not implemented or only partially implemented GLNs because of the commitment involved in making the transition from proprietary account numbers. This section will discuss preparing your ERP, creating a GLN hierarchy, and testing it within your system.

Why create a GLN hierarchy: While creating a GLN hierarchy within your organization is not a requirement for adopting UDI, using these two systems in tandem will greatly improve the ability to accurately track products in the supply chain by unambiguously identifying devices and their locations.

Exhibit 4: Benefits of GLN Implementation [13]



Preparing your ERP for UDI: There are a few items that all organizations will need to complete before you can start UDI adoption. Things to consider when preparing your ERP:

- Talk with your ERP provider. Many of the ERP providers, such as Lawson and PeopleSoft, have incorporated the UDI requirements into their systems. Your ERP provider will be able to help you determine if your system is currently set up for UDI and other fields, whether these fields are autopopulated when you scan the UDI, or whether you will need to add in the fields. Fields

you may want to consider are manufacturer, manufacturer code, lot number, catalog number, model number, UDI, serial number, and expiration date (if applicable).

- It is important to assign GLNs to various supply chain locations in your organization to precisely identify these locations for business communications and transactions. Your GPO can provide your password for the GLN registry.³[13] Participating GPOs include: Amerinet, Ascension Health, HealthTrust, MedAssets, Novation, Premier, and Sisters of Mercy/ROi. If your GPO is not listed here, please contact them. If you are not a member of a GPO, you can register directly with GS1 US at <http://www.glnregistry.org/>.⁴
- You will need to know what technology upgrades, if any, are necessary. Does your organization already use scanning technology or are people responsible for entering the information by hand? While there is an immediate cost to install scanning technology, there is the potential for a good return on investment since it helps maintain better control over inventory management, ordering, accounts receivable, and accounts payable. As part of the scanning technology, you will need to ensure that the scanning software can support both linear barcodes (i.e., traditional barcodes) and other formats where a full barcode cannot be used (such as small packages and devices). The scanning technology will also need to be able to differentiate the UDI issuing agency based on the UDI format. Given the length of the UDI, manual entry increases the risk of data entry errors, so scanning technology is more efficient.
- It is important to know that UDIs can vary in length, so the UDI field should be a text field no less than 150 characters in length and justified either to the right or left. Creating this field as a text field will preserve any leading zeroes that may be present in the UDI so that the entirety of the identifier will be preserved and can be searched. In addition, as the UDI can be formatted differently based on the issuing agency, the entire string will indicate the format of the UDI. The UDI may also include the product additional information, such as the product expiration date or lot number, which some healthcare organizations may wish to parse out separately.[14]

Creating GLN hierarchy: The next step is to update or create your GLN hierarchy. If you belong to a GPO, they will already have created a GLN hierarchy for your organization based on their list of rostered locations. In such cases, it is still important to ‘synchronize’ the hierarchy to ensure that all of your current *Ship To* locations have GLNs.

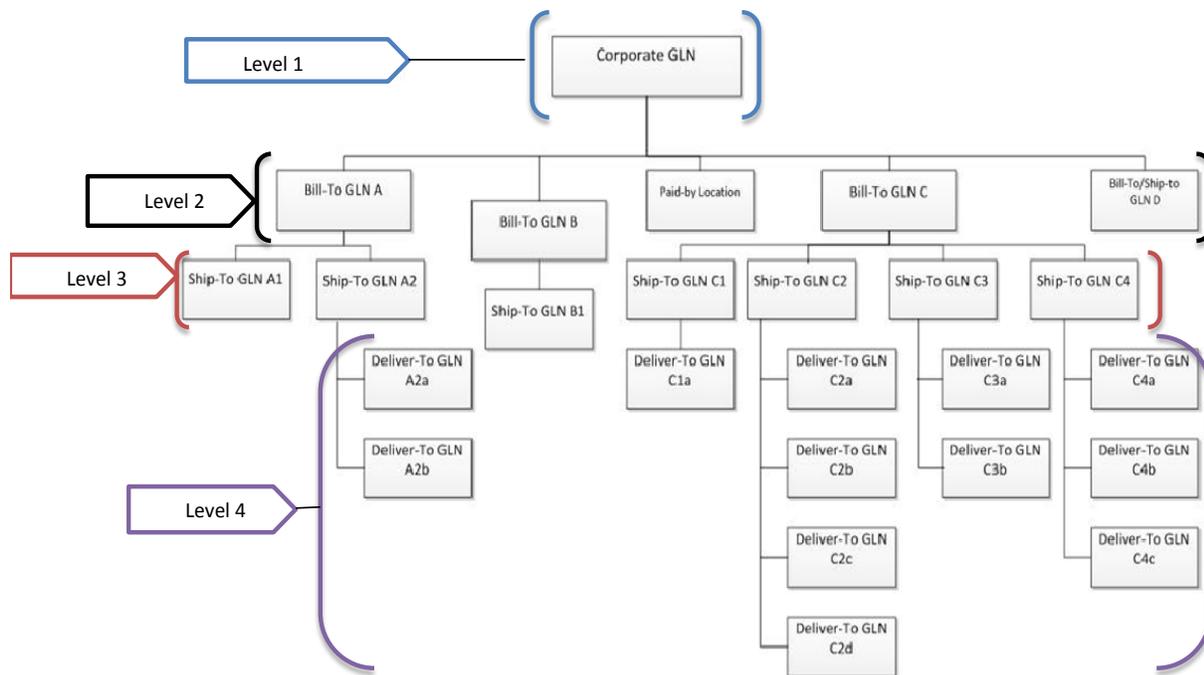
If you do not have a GPO-created GLN hierarchy or you would like to update the GPO-generated hierarchy, how you structure your GLN depends on how your supply chain is organized. You will need to identify the level of depth (i.e., packaging level) that your UDI numbering system will need to accommodate to support operations. For example, if you have multiple hospitals, you can assign one GLN to the corporate headquarters or one GLN per hospital.

³ Please note that manufacturers using HIBCC or ICCBBA standards will probably not have GLNs.

⁴ To register directly, an annual fee tied to revenues is required by GS1 US.

Business considerations of the parent organization and the business model (i.e., just-in-time [JIT] or central delivery) can affect the number of GLNs required for an individual organization. For organizations using a centralized distribution system, you will need a GLN for the central location. You may also want a GLN for each hospital and within each hospital you may also opt to assign GLNs to specific locations in each hospital, such as the cardiac catheterization procedure rooms or surgical suites. This approach allows you track delivery from the vendor, through to the final distribution point. Systems using a JIT inventory system may not need as many levels of GLNs, but they will need at least two levels: one for the hospital and one for the site within the hospital. (See Exhibit 5 for an example of a hypothetical GLN hierarchy.)

Exhibit 5: A Hypothetical GLN Hierarchy:[15]



It is important to know that your GLN registry needs to be maintained in real time.

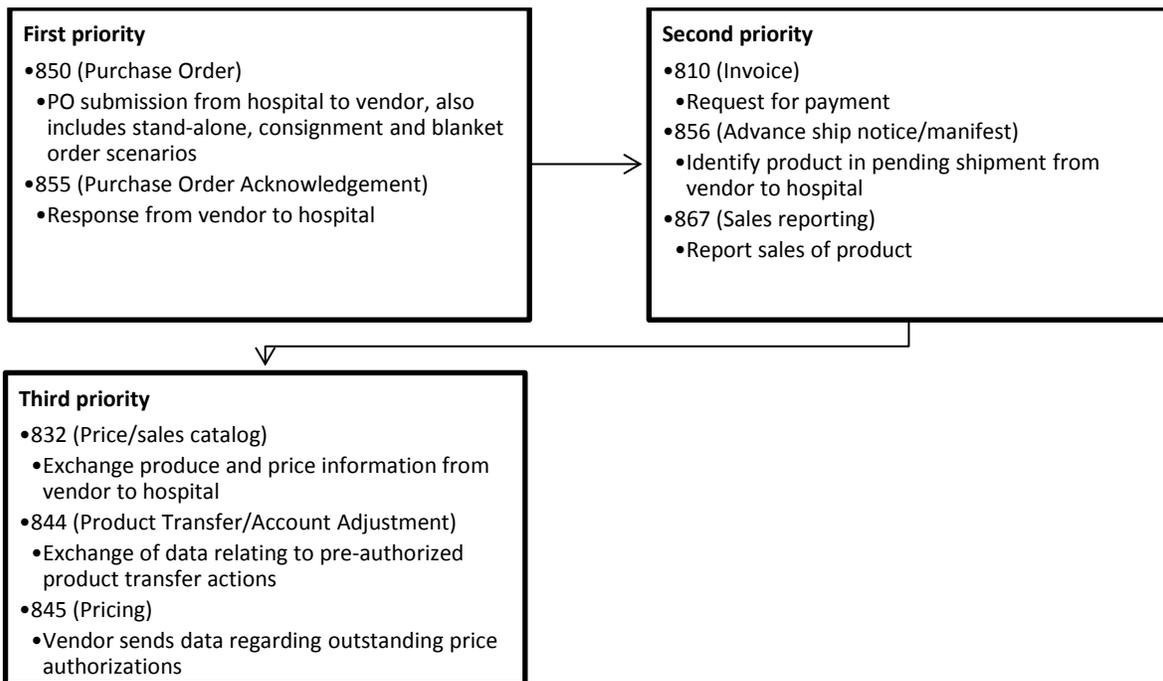
Testing GLN hierarchy: The next step in building your GLN hierarchy is to test it with your GPO, electronic data interchange (EDI), distributors, and manufacturers. This allows you to align existing account numbers to GLNs in preparation for EDI. Using GLNs in transactions (as the ship-to address) allows you to identify yourself and your business partners, thus replacing the use of proprietary account numbers. When going through this process, GS1 suggests you match in the following order[16]:

1. Start with your GPO ship-to locations and match those to your GLN hierarchy. This provides a current data feed to all vendors contracting through the GPO.

2. The next step is to work with your distributors to match proprietary account numbers to your GLNs.
3. Finally, work with any manufacturers where you have proprietary account numbers and match the account numbers with your GLNs.

Once the GLN hierarchy is in place and you have matched your proprietary account numbers to your GLN with your GPO, distributors, and manufacturers, the next step is to test your GLNs in your electronic and EDI transactions. GS1 recommends prioritizing your transactions in the following manner:[16]

Exhibit 6: X12 Electronic Data Interchange (EDI) Business Transaction Priorities



Once you have completed the GLN implementation in your electronic and EDI ordering processes, you can transition your paper-based transactions to electronic as vendors implement the technology on their end.

Getting UDIs into the item master: While preparing your ERP for the GLN, you can also work with vendors and your GPO to load UDIs into your item master. The hospital item master is constructed to support item replenishment and includes limited information such as a short item description, vendor name, available units of measure, and physician preference items. The item master provides the item-level information for your ERP system.

To ensure you have all the necessary UDIs for the products used/purchased for your organization, you will need to contact your GPO, manufacturers, distributors, and other suppliers for the UDIs for

each item they supply to you. You will load the UDI information into your item master using the same process as you would for any update procedure.

Storing UDIs: Specific tables or databases in your ERP where the UDI should be located include: item master, purchasing, replenishment, inventory management, rebates/chargebacks and classification. Eventually you will want to include UDI in other areas such as billing/claims systems and patient records. These areas will be discussed in the following sections.

It is important to have an item master update strategy in place before the initial upload of UDIs into the item master file. If your organization manually updates the item master, you may want to consider going to a more automated process to reduce errors and personnel time. If your ERP system can autopopulate updates, the information is available from a number of sources, such as your GPO, suppliers or other third-party vendors. You will need to determine the most efficient way to obtain new data. UDI information will also be available free of charge through the FDA Global Unique Device Identification Database (GUDID). GPOs and vendors will likely send regular updates for their UDIs.

To ensure you capture all UDIs that come through your organization, you need to create a system that allows you to identify new UDIs when they first enter your system. For example, when items are initially scanned into the system, ERP vendors could create an alert that will identify if the UDI is not currently in your system. The item(s) will then be put aside while someone confirms with the shipper the new UDI information.

Pilot testing the supply chain: The next step is to pilot test your organization's supply chain to ensure your systems can efficiently capture and use UDI. It is recommended that you test any new workflow changes before starting this step. This allows you to identify any bugs in the process and test new approaches that were part of the workflow redesign.

For ease of adoption it is advisable to start the pilot test with a **single vendor** in one part of your organization, such as a cardiac catheterization lab or operating room. If you have multiple hospitals in your system, you may need to decide whether to pilot test in all hospitals or just one hospital. Over the past few years a number of suppliers have been actively working with organizations that have been on the forefront of UDI adoption. When selecting a vendor for pilot testing, make sure that you have a good working relationship with them and they have experience in this area.

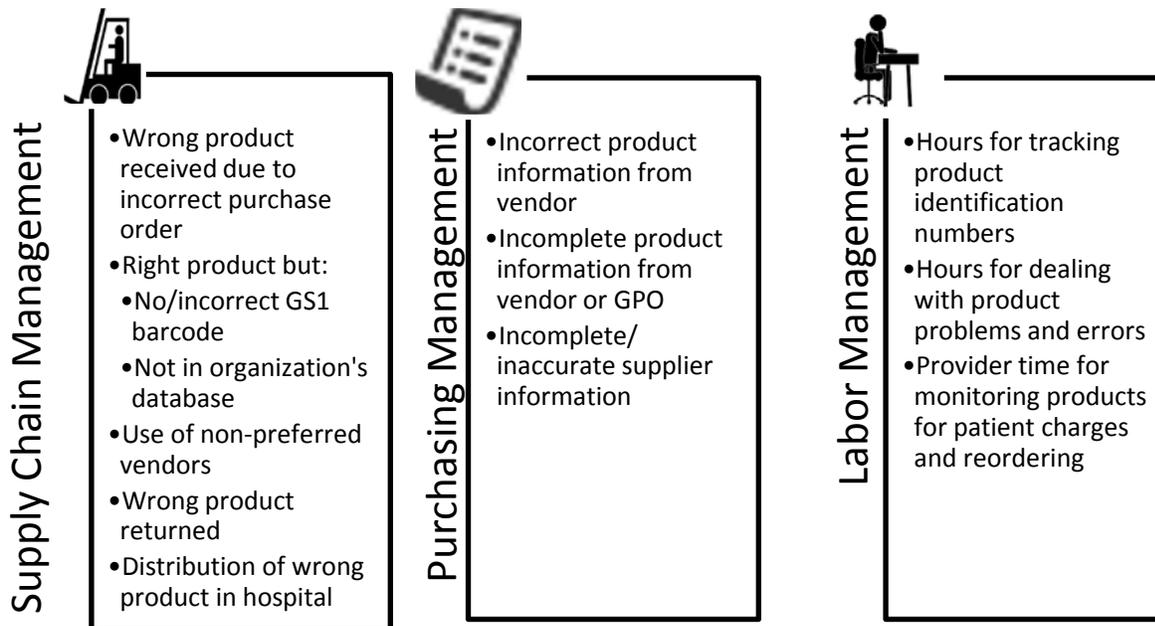
An essential part of this process is to ensure your staff has sufficient training to be able to pilot test the supply chain, but also to identify problems occurring during testing and provide potential solutions for the problems.

Generally you should select a specified period for testing (such as a week or less) and monitor all orders for errors and corrections. Once you are comfortable with the test results, you can move on to ordering without the monitoring. As you go through this process, some of the things you may want to test are:

- Are the shipping locations correct?
- Does the electronic data transmission work correctly between your hospital and the vendor? This includes purchase order, order acknowledgement, advance ship notices and invoices.
- Is the system correctly capturing rebate information?
- If there are errors, are the correspondents at each trading partner using the GLN and UDI in communication, or are they reverting to legacy account and part numbers?
- Has the staff developed work-arounds for scanning? What are they and why were they created?

Return on investment (ROI): Since the adoption of UDI can involve significant changes to the entire supply chain process, it is a better strategy to take a more holistic view when calculating ROI. That is, look at ROI across the supply chain and how changes before and after UDI adoption have filtered through areas that might not be considered part of a standard ROI. Some of the areas to consider while looking at ROI include staff time, resource use, and error rate.[17]

Exhibit 7: Areas of Consideration in Calculating Return on Investment



Some free useful resources for adopting UDI into your supply chain include:

- GS1 Healthcare US Implementation Guideline: Using the GS1 System for U.S. FDA Unique Device Identification (UDI) Requirements [18]
- GS1 Healthcare US: U.S. FDA Unique Device Identification (UDI) Rule Frequently Asked Questions (FAQs) [19]
- Medical Device Brand Owner GuideL Transitioning to GS1 Standards in the U.S. for UDI [20]
- GLN in Healthcare: Implementation Guide [13]
- GLN Roadmap in US Healthcare [16]
- GLN Implementation Workshop [21]
- Best Practice Guide: Building a GLN Hierarchy [15]
- GLN Quick Start Guide [22]
- GLN Implementation Activity for Healthcare Manufacturers and Distributors [23]
- GLN Implementation Activity for Healthcare Software Suppliers [24]
- GS1 Hospital Checklist for Software System Readiness [25]
- GS1 Global Data Synchronization Network™ (GDSN®) Data Integration Readiness Scorecard
- University of Arkansas Levels, Requirements, and Impacts Model (LRIM) for GS1 standards adoption [26]

Case studies:

- VA Supply Chain Transformation [27]
- Mayo Clinic/Cardinal Health GLN Implementation [28]

Clinical Suite Software and Electronic Health Records

While many of the issues related to adopting UDI into clinical suite software and the EHR are similar, such as adding new fields into the software, many hospitals still have separate systems and would adopt UDI into one before the other. In addition, some hospitals may choose to integrate the UDIs of some devices into just one of the two systems, while adopting UDI for other device types into both. To reflect differences in hospital operations, this section will discuss clinical suite software and EHRs separately, though many of the same principles apply to each. A number of innovative organizations, such as Mercy Health and Geisinger, are currently integrating UDI into their clinical systems and are benefiting from insights on how to overcome challenges.

Benefits: Including the UDI in your clinical suite software and EHRs can provide a number of possible benefits for your organization, including:

- ✓ Facilitating easier recalls when devices malfunction;
- ✓ Enabling clinicians and researchers—particularly at large health systems—to conduct analyses on device performance;
- ✓ Allowing more accurate reporting, reviewing and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly;

- ✓ Preventing medical errors by enabling healthcare professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device; and
- ✓ Reducing manual and non-standardized methods of data entry to record device use with an electronic system.

One of the major benefits of adopting UDI information into your organization’s clinical and EHR systems is the ability to track specific devices from manufacturer through use with the patient. From the hospital’s perspective, this will involve three primary areas: care coordination, postmarket device surveillance (including product recalls) and comparative effectiveness research. For example, currently when a product is recalled, hospitals have difficulty identifying affected patients because they lack information on the specific devices a patient received. At present, providers use multiple methods of identifying at-risk patients, with physicians and staff in a practice spending on average a combined 41 hours per year to identify these patients.[29] Adoption of UDI increases patient safety by allowing hospitals and physicians to quickly and efficiently identify those patients who received a recalled device, thereby reducing the risk of potential harm.

Hospitals can also use UDI to more efficiently conduct or support comparative effectiveness research. First, many hospitals, particularly those that participate in larger health systems; can review their patient data to better understand the quality of the services they provide. Integrating UDI data with clinical information, such as from the HER, can help these systems also evaluate the performance of devices used in their health system. For example, Mercy, a multi-state hospital system in the Midwest, demonstrated how it could use UDI and clinical data to evaluate how its physicians use different types of cardiac stents. Second, UDI adoption into EHRs can also help hospitals participate in registries that evaluate device performance. Transmitting UDI information directly from the clinical record—instead of requiring staff to manually enter device data—can help hospitals more efficiently submit data to registries.

As part of the process of adopting UDI into your organization beyond the supply chain, you will need to determine what types of UDIs are stored in the clinical suite software and what is stored in the EHR. For example, in a total knee joint replacement surgery, you would want the information about the joint device in the ERP, clinical suite software, and EHR. For the surgical drapes used in the procedure, you might only want the information stored in the ERP. While for sponges used, you might want to include the information in the ERP and the clinical suite software so you can ensure all sponges are removed from the patient.

Clinical suite software: Once testing is completed within the supply chain, the next phase is to bring UDI into the rest of your organization. Given the large number of data systems where UDI can be used and due to potential interoperability issues, it may be necessary to undertake a staged approach to adoption. We recommend that you start UDI adoption within your clinical suites, since those are the

areas where the class III devices are implanted into patients.⁵ Once UDI is fully implemented in the suites, the system can be rolled out to other areas.

Workflow: The amount of scanning done in a procedure room depends on the type of inventory stocking system your organization uses. As discussed earlier, hospitals use a combination of methods to stock procedure and operating rooms (e.g., replenishment and/or physician preference model). Using a replenishment approach means that every item used in the procedure will need to be scanned during or after the procedure. Since only those items used are scanned, there is no need to scan items back into inventory. When pilot testing this model, you will need to determine the most effective way of managing the inventory stored in the area and not just inventory used in the procedure. If your organization uses the physician preference approach, all the standard items for that physician will be scanned before they enter the room, so only ad hoc items will need to be scanned during the procedure. However, you will need to ensure scannable items not used in the procedure are re-scanned back into inventory.

There are a number of things to consider when dealing with the workflow needs of UDI adoption to improve efficiency and patient care. Based on how each hospital implements UDI, these workflow changes may affect the effort already undertaken by hospitals to track and maintain their inventory.

- One tactic involves having someone from the procedure team, such as a technician, scan devices. While this does not increase the number of people in the room, there is a potential for additional costs because of inefficient use of personnel needed for the procedure. You also run the risk of physicians becoming dissatisfied with scanning if workflow is interrupted and procedures take longer.
- A second method is to have someone from outside of the clinical team, such as from inventory management, performing the scanning. This approach might cost more due to additional personnel and adds another person to the procedure room, but will not impinge on the procedure and it allows the staff to concentrate on the procedure.
- Another approach is to not do the scanning in the procedure room. Rather, the outer wrapping layer is saved for any UDI items used and these are scanned after the procedure is completed. This approach does not impact the actual procedure, but you will need a method to save the outer layer and you will have to have someone scanning post-procedure. One problem with this approach is that if the outer wrapping is damaged or missing, UDI capture could be incomplete.
- To avoid inventory errors, you will need to determine who is responsible for re-scanning devices back into inventory.

Technology: This discussion addresses only single-use consumable items used in procedure/operating rooms and does not address items that can be re-used, such as instruments.

⁵ Class III devices have UDIs on them starting in September 2014.

Just like for the ERP system, the clinical suite system will also need capabilities to store UDI, such as a text field. For standardization across your systems, the same technical specifications should be used for the clinical suite and EHR systems.

Pilot testing in a clinical area: As part of the team assembled for UDI implementation, a physician leader with an interest in UDI adoption should be included. For adoption to be successful beyond the supply chain, it is essential that your clinicians and other staff are onboard and see benefits for themselves and their patients.

When preparing for the pilot test, an essential part of the process is to ensure the staff has sufficient training to be able to test the workflow changes and the clinical suite software, but also to identify problems occurring during testing and provide potential solutions for the problems.

Once the clinical area is selected for testing, the first step is to ensure that UDI information can be transmitted from your ERP into the clinical suite software.⁶ Many organizations use separate software for the procedure and operating rooms that may or may not be integrated into the organization's EHR system. If you have a separate software system for the pilot unit, talk with the software vendor supporting your pilot unit. Many programs are already structured to accept barcode scanning so they are in a position to accept UDI information.

As part of the workflow analysis and redesign that occurred during the planning process, you will have worked through how, who and when the UDI will be entered into the system. At this point in your testing is when you ensure that the redesigned processes work and determine whether the UDI is being regularly scanned into the system. As you work through this pilot test, a few things you should look for include:

- Is the UDI being consistently captured via scanning?
- How often do people manually enter UDI information and why is this happening? The more frequently this happens, the more likely you will have errors.
- Does the workflow designed work? Do you need to make further adjustments?
- Are UDIs being scanned multiple times? That is, are they being scanned in both the inventory and procedure areas? This will cause an imbalance in the inventory and potentially overcharges to the patient.
- Is the software in the procedure room updating your ERP to ensure the item is being removed from inventory?

Case studies for UDI adoption in procedure/operating rooms:

⁶ This software can track, for example, the relevant devices used in the operating room and vital signs of patients while undergoing procedures, and manage anesthesia and other real-time information.

- A Case Study Analysis of Inventory Cost and Practices for Operating Room Medical/Surgical Items [30]
- Omnicell OptiFlex SS System Dramatically Improves Inventory Management and Financials in the Operating Room [31]

Electronic health records: To maximize the benefit to the patient, provider, and other stakeholders, it is important to integrate the UDI into the EHR. Although the FDA cannot require UDI incorporation into EHRs, the Office of the National Coordinator for Health Information Technology (ONC) can establish EHR certification criteria, which set baseline capabilities for the functions needed in patients' health records. ONC has indicated in public statements that there are many public health and patient safety benefits—including better recall compliance and care coordination—from including UDI in EHRs. While physicians will use many devices—often hundreds—while caring for a patient, implanted products should be the first focus for incorporation into patients' EHRs.

Workflow: There are several different workflow scenarios for UDI inclusion in EHRs.

- For many hospitals it will be most straightforward if UDIs are transmitted to EHRs from clinical suite systems. In this scenario, the relevant device UDIs would be transmitted electronically from the clinical suite software to the EHR. Given that the benefits of UDI capture for implants is well established, transmitting the UDIs of these products into patients' health records should be the first step for hospitals and EHR vendors.
- Some hospitals may need to scan the UDI of implanted devices directly into the EHR instead of using the clinical suite system. In these situations, the hospital staff should make sure to only scan UDIs that are needed in the EHR. Those products will include implanted devices, such as stents and artificial hips, and not surgical drapes or bandages, for example.
- Some health systems may wish to scan the UDI of non-implanted devices into the EHRs. For this to occur, EHR vendors will need to support a structured field in the EHR for non-implanted devices, and health systems will need to establish what non-implanted product UDIs should be in the EHR. Potential devices could include the UDIs for diagnostics or multi-use products, such as infusion pumps.

Hospitals will also need to decide when and who will scan UDIs. As discussed in the clinical suite section, there are many different potential workflows and considerations for capturing this information.

Technology: Currently, there are some challenges to adopting UDI into the EHR. Many EHR systems currently lack a dedicated field for UDI. EHR vendors will likely develop that field either in response to their customers' demands or certification criteria from ONC. All EHR systems are customized generally to meet the needs of specific organizations, so although at least one EHR vendor has created fields in their EHR to house UDI information, not all hospitals may elect to activate any or all of the UDI fields.[32] Until the UDI fields are included as a standard part of the EHR, you will need to talk with your vendor to determine if the required fields are available as part of your regular software update or can be

added as an upgrade/module. Since all the EHR vendors are familiar with the UDI requirement and they have been working with national innovators, they are working on incorporating UDI fields into their system.

Second, the UDI must be populated into the EHR. This can occur either through direct scanning or via interoperability from another system, such as the technology used in the clinical suite. Scanning of the UDI directly into the patients' health record requires that the EHR support barcoding and other automatic identification and data capture (AIDC) capabilities. Barcode readers also must be programmed to collect the UDI from the product packaging. The other way to populate the EHR is through direct input from the clinical suite or ERP software, which requires interoperability among these systems. If an organization has the same vendor for all clinical systems, everything should be interoperable between clinical systems.

Hospitals may also have various vendors for different areas in the hospital; as a result, hospitals must establish processes for those systems to communicate UDI information. In some cases organizations and vendors have been able to make the two systems communicate with each other by creating an interface or add-in program for the EHR software. [32, 33] If you do not yet have an interface among these systems, work with your EHR vendor to create a communication patch between the ERP, clinical suite system and EHR. The primary benefit of using a patch is that you will only need to maintain one database in the ERP. The downside is that establishing interoperability may be costly.

Another approach is that your organization can maintain a database within the EHR that will mirror information available in the ERP. This database would be independent from the ERP system, and populated with information on products that the hospital purchases. This separate list of devices purchased would not require the EHR to sync with the ERP, thus alleviating the need for interoperability. However, under this approach, hospitals will need to ensure that this separate inventory list is regularly updated.

Beyond interoperability, another issue is how the data might be exported from the EHR to registries, billing systems or ERP systems. Specified data standards for UDI information have not yet been standardized, but given that the Health Level Seven International (HL7) is the preferred standard for summarizing patient data, HL7 is working to create a UDI implementation guide.[33]

Finally, many EHR systems may have additional data elements associated with the UDI. For example, EHRs may list the name or model of the device, or whether the device is MRI-compatible. As the UDI is just an alphanumeric string of characters, displaying the name of the device, for example, can provide physicians at the point of care with clear information on the products implanted in the patient without requiring them to look up the UDI in a separate database. Similarly, if a physician orders an MRI, clearly indicating whether an implanted device is MRI-compatible can save providers time and resources by not requiring them to look up this information. To populate this information into the EHR, software vendors may need to link their systems with external databases that house detailed device data. These external

databases may include the FDA’s Global Unique Device Identification Database (GUDID) or systems built by private third-party vendors.

When talking with your EHR vendor, some of the things you should consider include:

- Is your vendor planning to incorporate UDI as part of their EHR or clinical suite system, regardless of whether this capability will become a federal requirement?
- How will the EHR interface with other electronic systems, both inside and outside the hospital?
- What fields will the EHR have related to UDI, and how will these fields be populated? Fields that you may want include manufacturer, manufacturer code, lot number, catalog number, model number, UDI, serial number, and expiration date (if applicable).

Claims and Billing Systems

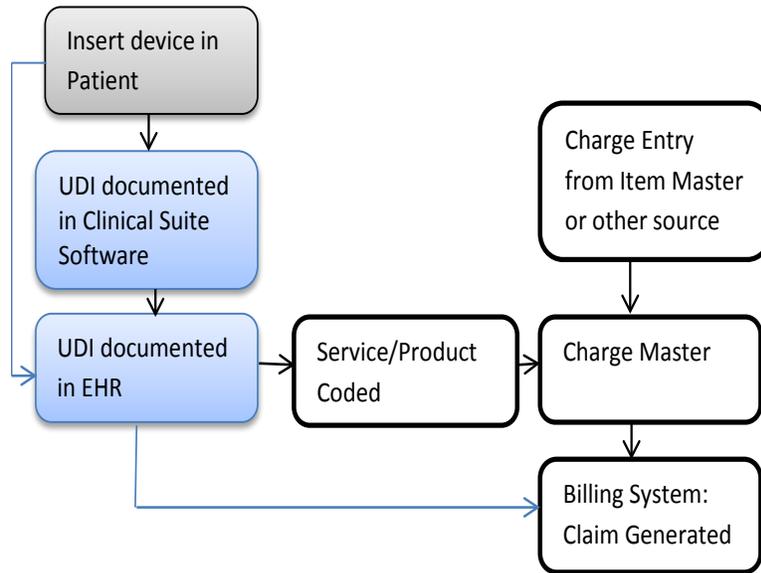
Currently, claims do not include information on the devices used, but adding that level of granularity for high-risk devices is expected to provide many benefits. There is no space in the current electronic claim transaction standard—developed by the Accredited Standards Committee (ASC) X12— to include UDI information. ASC X12 could, as part of a future update to the claim, add a field for UDI. UDI incorporation in claims would not be required for every device; instead, this new field would primarily be used for high-risk implanted products.

Claims are electronically created based on data pulled from the patient record, coded, and then—where appropriate—linked to codes in the chargemaster.⁷ (See Exhibit 8. Black lines show the current status.) If the UDI is approved to be added to the claim form, your organization will need to determine the most efficient way to include the UDI on the claim. If pricing information is not required for the device, the UDI may be taken directly from the EHR or item master, for example, and would not need to be included in the chargemaster. (See Exhibit 8. Blue lines show alternative methods.)

Another option is to have a one-to-one correlation between products in the item and chargemasters, or have the UDI linked to the appropriate code in the chargemaster if pricing information is needed in the claim. Every hospital will need to determine how to incorporate UDI into claims, and whether—based on the uses and workflow—the chargemaster will need to link to UDI.

⁷ The chargemaster is a master file built within hospital information systems, and designed to communicate (interface) with other software applications or systems to support government-mandated standard billing requirements. It contains data elements such as charge descriptions, billing codes, pricing, and other necessary data elements.

Exhibit 8: Hospital Billing Schema



This section provides areas that you will need to think about as the UDI migrates into the claims and billing systems.

Benefits: Including UDI in your billing and claims systems can potentially help your hospital in the following ways:

- ✓ The UDI allows payers to automatically validate coverage and reimbursement for contracted devices since no additional information is required. This will decrease the time between claim submission and payment in the revenue cycle.
- ✓ There are many other public health and health system-wide benefits for UDI capture in claims. For more information please see The Brookings Institute UDI Roadmap for Effective Implementation. [34]
- ✓ Claims data are regularly used by health plans, the FDA and registries to evaluate the safety and quality of drugs and procedures. Including UDI in claims will support those same types of analyses on devices. That information on device performance –once provided to hospitals–will help clinicians to improve care and quality for their patients.

Workflow: If UDI will be incorporated into claims, hospitals will need to make workflow changes based on how they intend to populate the claim.

If UDI information is pulled from EHRs, hospitals will need to establish the necessary flags for when specific UDIs must be sent to the claims and billing system. As the EHR may contain the UDIs of devices that are not intended for the claim, establishing these flags should limit the transmission of UDI to only those situations when it is required.

If UDI data is pulled from the chargemaster, it is essential to maintain the chargemaster so it accurately reflects prices and is in compliance with Medicare billing guidelines. Given the complexity of the chargemaster, most organizations update it on an annual basis with ad hoc updates done throughout the year. If your organization is manually updating the chargemaster, you should consider realigning the workflow to automate as much of the process as possible. There are software products that can update the chargemaster regularly, thus reducing the probability of having a claim rejected.

When redesigning the workflow, these are a few things you may want to consider:

- How does your organization want to populate the claim—from the EHR or another system, or via the chargemaster?
- Does your organization want to conduct a one-time synchronization between the item master and chargemaster? This creates a clean and conditioned data file that removes inaccurate, outdated, and incorrect information, thus creating an accurate file for improved revenue capture and more accurate reimbursement. Then your organization is only responsible for updating the chargemaster, rather than cleaning it.
- Does your organization update the chargemaster annually? If your organization updates the chargemaster on an annual basis or less frequently, you are missing the opportunity for price updates and additional revenue capture.
- Does your organization manually update the chargemaster? This situation presents the prospect for data entry errors and updates that are not timely, resulting in the potential for rejection of claims and lost revenue.

Technology: As with UDI adoption into EHRs, there are barriers beyond keeping the chargemaster current, including interoperability and information storage.

- The necessary electronic links between the EHR, claim and—if necessary—chargemaster must be established for interoperable transmission of UDI among systems.
- Claims processing systems must be updated to accommodate a new field for UDI. Given that the new claims form will be updated to address many changes, your technology vendor should also incorporate the addition of UDI to the claim.
- If your facility chooses to incorporate UDI in the chargemaster, then your software and data elements would need to be updated accordingly.

What about the future?

As the highest risk devices started using UDIs in September 2014, medical device tracking is on the verge of evolution that can improve the efficiency of the supply chain while improving costs and patient outcomes. For a healthcare organization's supply chain, this means you will be facing unprecedented opportunity in the next few years to leverage this new tool as more devices have UDIs and the need to capture UDI information grows. Your organization's clinicians can also use this new tool—as part of EHRs

and clinical suite systems—to better coordinate care and track which devices are implanted in patients. Last, the health system as a whole may leverage UDI as part of administrative claims to obtain better information on the devices used—data that can help your physicians improve the care they provide.

Currently, there is no mandatory requirement or payment penalty associated with UDI adoption in healthcare organizations. However, the benefits of preparing for and adopting a UDI system can increase efficiency in your supply chain (thereby reducing costs), enhance your revenue cycle, increase your organization’s quality of care, and improve quality and patient safety.

The FDA and manufacturers have taken the first step by creating and implementing a UDI system. It’s now up to you to use this new tool to make your business more efficient and, more importantly, enhance the care you provide.

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Appendix A: Examples of Unique Device Identifiers

Additional Examples of Unique Device Identifiers [4]

GTIN with Lot Number & Expiration Date encoded in a GS1-128 Barcode



GTIN with Lot Number encoded in a GS1-128 Barcode



GTIN



Lot/Batch

GTIN with Serial, Lot & Expiration Date encoded in a GS1 DataBar® (Stacked) & Composite



GTIN with Expiration Date and Serial Number encoded in a GS1 DataMatrix



Appendix B: UDI Implementation Schedule

September 24, 2014 – 1 Year after Issuance of Final Rule

- A unique device identifier (UDI) will be required on all Class III medical devices. Examples of Class III devices include implantable pacemaker, pulse generators, HIV diagnostic tests, automated external defibrillators, and orthopedic implants.
- UDI data should be submitted to the FDA Global Unique Device Identification Database (GUDID).
- A one-year extension can be requested at the latest by June 23, 2014.
- UDI must be provided by class III stand-alone software

September 24, 2015 – 2 Years after Issuance of Final Rule

- UDI must be present on Class II life-sustaining and supporting and implantable devices. Examples of Class II devices include acupuncture needles, powered wheelchairs, infusion pumps, surgical drapes and an implantable radio-frequency transponder system for patient identification and health information.
- For devices that are designed to be used more than once and/or require processing before every reuse, a permanent UDI marking on the devices themselves is required.
- UDI must be provided by Class III stand-alone software that is life-sustaining or life-supporting

September 24, 2016 – 3 Years after Issuance of Final Rule

- A permanent UDI marking on the devices themselves is required in the case of Class III devices that are designed to be used more than once and/or require processing before every reuse.
- A UDI must be present on the packages and labels of Class II medical devices. The UDI data should be submitted to the GUDID.
- UDI must be provided by Class II stand-alone software

September 24, 2018 – 5 Years after Issuance of Final Rule

- A permanent UDI marking on the devices themselves is required in the case of Class II devices that are designed to be used more than once and/or require processing before every reuse.
- A UDI must be present on the packages and labels of Class I medical devices.
- UDI must be provided by Class I stand-alone software. Examples include apps for cellular phones.
- UDI must also be present on devices not yet classified into Class I, Class II or Class III. The UDI data should be submitted to the GUDID.

September 24, 2020 – 7 Years after Issuance of Final Rule

- A permanent UDI marking on the devices themselves is required in the case of devices that have not been classified into Class I, Class II or Class III and are designed to be used more than once and/or require processing before every reuse.

PREMIER RESEARCH INSTITUTE

UNIQUE DEVICE IDENTIFIER: ENVIRONMENTAL SCAN

Author: Cheryl Fahlman, Ph.D.

Date: May 2014

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Currently, there is not a uniform method for tracking devices within and across the hospital systems and units. There have been previous attempts, such as the use of bar codes to track devices; however, nothing has gained traction in the industry to the point that we are able to easily locate a device after it is in the system. More recently, there has been a push by both industry leaders and Congress to implement a unique device identification (UDI) system. This program would create a unique identifier for each device and allow healthcare payers, providers, and device manufacturers to track each device from the manufacturer through the use by the patient. In addition, it would allow for easier recall in the instance that there was a malfunction with the device. Although, there is a general understanding of the potential return on investment that could be achieved with the UDI implementation, there is currently a paucity of information about how a UDI could be effectively implemented, and what the future benefits could be when the UDI is implemented. To that end, this study will try to elicit how more progressive health systems have implemented a UDI system, and help hospitals that do not have a system in place build the case for moving forward in their own systems to implement a method to capture the UDI.

As the first step in the process of developing a business case for health systems to implement a UDI system, we conducted an environmental scan to look at the current status of UDI programs within the United States.

Methodology: A literature review consists of three major tasks: (1) identifying relevant literature, (2) assessing the quality of or critically evaluating the literature, and (3) synthesizing the literature. Several sources are available for identifying relevant literature. For published literature, we relied on *PubMed*, the integrated text-based search and retrieval system at the National Library of Medicine for the major databases to access literature in the health and life sciences. Relevant materials that may be unpublished such as reports, proceedings, working papers, and committee reports -gray literature—was obtained from a broad search of the World Wide Web (WWW) using Google and Google Scholar, as well as a more narrowly focused search of selected organizational websites (such as the Food and Drug Administration). Excluding patients and using search terms such as “unique device identifier”, “UDI”, and “medical”.

Results:

Over the last few years, the FDA has worked to change the pre and post marketing processes for medical devices, envisioning a new medical device postmarketing surveillance system that would [1] [2]:

- Communicate timely, accurate, systematic, and prioritized assessments of the benefits and risks of medical devices throughout their marketed life using high quality, standardized, structured, electronic health-related data;
- Identify potential safety signals in near real-time from a variety of privacy-protected data sources;
- Reduce the burden and cost of medical device postmarket surveillance; and
- Facilitate the clearance and approval of new devices, or new uses of existing devices.

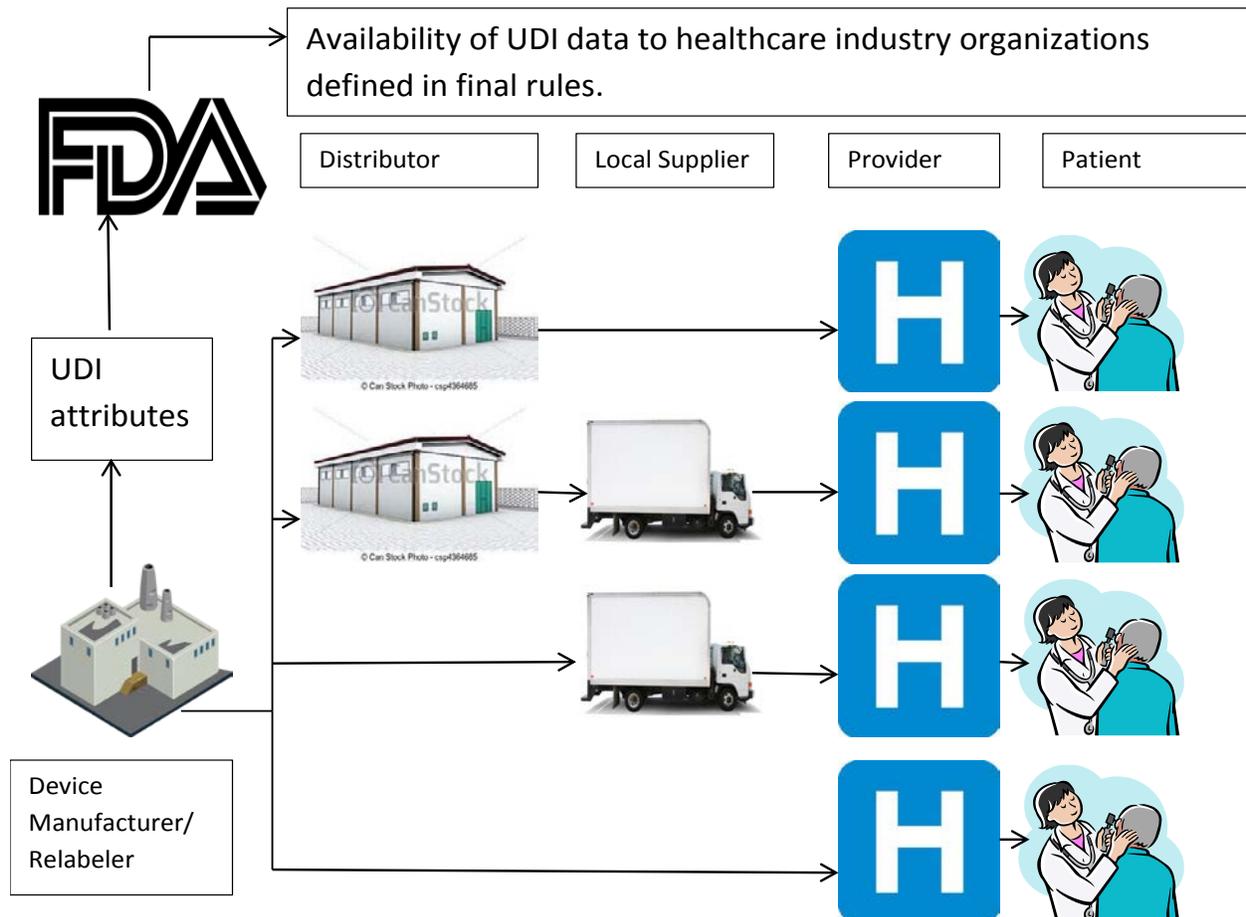
To achieve these goals the 2012 and 2013 FDA reports also outlined four strategies,[1-3] including:

- Establish a Unique Device Identification (UDI) system and promote its incorporation into electronic health information;
- Promote the development of national and international device registries for selected products;
- Modernize adverse event reporting and analysis; and,
- Develop and use new methods for evidence generation, synthesis and appraisal.

While all of these areas will contribute to stronger postmarket surveillance for medical devices, this document focuses primarily on the establishment of a UDI system.

With the introduction of the UDI final rule in September 2013,[4] there has been an increased interest in how providers can implement and benefit from a UDI system. Implementation will begin September 2014, and in preparation for that organizations are striving to determine the best way to implement this new information in a cost effective and clinically relevant manner.[5] For hospitals and other large healthcare organizations this means meeting the challenge of incorporating UDI information into a plethora of information systems that historically do not interface well, including electronic health records (EHR), billing systems and accounting systems.[6]

Exhibit 1: Medical Device Supply Chain[7]



The following discussion is based on following a medical device through the supply chain and into the patient care setting within the United States (Exhibit 1). Initially the discussion will focus on the supplier-distributor-provider chain and look at relevant literature in that area. The second part of this document looks at the provider-patient-payer chain, followed by lessons learned.

Supplier-Distributor-Provider Chain

With a limited number of pilot studies [8-12] completed over the past few years some valuable lessons were learned about UDI and what it can offer healthcare organizations. Each of these studies focused on different areas within an organization where a UDI system would be implemented. The first area of focus was usually the supply chain and implementing UDI to help with facilities management and asset control.

In the work done with Premier[12], the following stakeholders were involved: five large hospital systems, Premier, manufacturers, distributors, providers, information technology (IT)/electronic data interchange (EDI) and materials management. They created a hierarchical system of global location numbers (GLNs) to streamline ordering, shipping, and tracking of medical devices. While each hospital was at a different stage of GLN implementation the common lessons learned were to communicate, collaborate, advocate for themselves, and to “get started”. In 2009, the Mayo Clinic and Cardinal Health conducted a similar pilot and they found using GLNs improved their supply chain management, reducing their EDI error rate from 40 percent to less than one percent, there reducing order errors resulting in cost savings.[10, 13] By 2013, Mayo was planning on using GLN as their standard for all suppliers. Working with Becton, Dickenson, and Company, Mercy Healthcare and their distributor (ROI) implemented an end-to-end an integrated fully automated accurate electronic ordering system.[8] Using both GLN’s and Global Trade Item Numbers (GTIN) to streamline the order process, delivery, and distribution within the hospital, resulted in a 30 percent reduction in outstanding days payable, a 73 percent decrease in order discrepancies, fewer calls to customer service, improve product sourcing, and fewer instances of stock shortages. Similar to the Premier, Mayo, and Mercy experience, Intermountain healthcare also implemented GLN into their supply chain in 2010.[11] They also found it rationalized their supply chain resulting in more accurate pricing, and a reduction in purchasing and payables contact points.

All of these studies followed a similar approach in how they implemented GLNs, in that they undertook an educational campaign for suppliers/distributors, hospital purchasing staff, and senior leadership. They selected a small number of suppliers to pilot test their implementation, making it easier to clean up purchasing codes. These organizations worked closely with their information technology department, but also with the EDI and the IT department of their suppliers. A significant amount of time was spent developing the GLN hierarchy, which impacted shipping. Most importantly these UDI systems and processes must be able to adapt as new information came in and be able to communicate the information effectively to everyone involved.

In early 2013, Booz Allen Hamilton conducted a survey and detailed interviews of device manufacturers, distributors, and providers in an effort to examine the challenges facing these organizations with the

upcoming UDI implementation. [7] They found that 89 percent of responding companies were at some stage of the UDI adoption process. Of the distributors and providers that responded to the survey, the majority were being challenged in a number of ways including budget approval (93 percent), return on investment (ROI) (63 percent), integration (93 percent), priority of the work (89 percent), and upstream communication (97 percent). Yet all respondents recognized the potential benefits of increased data quality, information sharing, and patient safety. Beyond the variation in barcodes used to transmit information (1D, 2D, or RFID), the study did not examine specific issues with collecting the UDI within the supply chain, such as specific transmission standards like HL7. But when manufacturer respondents were asked about implementation cost, the responses varied greatly. Close to one third, primarily small scale manufacturers, predicted the estimated cost to be under \$100,000, while another quarter estimated expenditures of over \$10,000,000, and the remaining evenly spread in between the two extremes.

Provider-Patient-Payer Chain

Based on the 2013 FDA report one of the primary drivers behind the introduction of UDI into the United States is to increase our ability to undertake postmarket surveillance work in a timely and effective manner.[2] To date many device recalls are based on 1) Federal databases (MedSun and MedWatch run by the FDA), 2) registries (such as the American College of Cardiology-National Cardiovascular Database Registry or orthopedic registries for knee and hip replacement), or 3) required manufacturer postmarket surveillance.[14, 15] This patchwork approach to device surveillance results in delays in identifying adverse events and initiating effective and timely recalls of specific devices or lots of devices.[16]

Prior to the introduction of UDI's, studies looking at device safety were primarily based on data collected from participating hospitals that collected data beyond administrative data through additional documentation, such as device type and characteristics or compliance with clinical guidelines [17] or procedure related registries [18]. While these approaches can be effective, they are also limited because of geography, such as the DELTA study that collects data from 5 hospitals within Massachusetts.[17] or devices and procedures included in a registry[18]. This study was to detect the adverse event rates specific to several classes of implantable cardiac devices, including drug eluting coronary stents, embolic protection devices, and vascular closure devices in patients undergoing percutaneous coronary interventions (PCI). [17] The system was successful in identifying issues with at least three implantable cardiac devices and is expanding to include prospective safety monitoring of hip implants. In 2012 the American Association of Hip and Knee Surgeons (AAHKS) developed a survey with researchers at Arizona State University to look at the methods and time needed to identify failed implant devices, along with perceived patient and cost impacts.[18] While patient x-rays were used in most cases, 87 percent of surgeons used 3 or more different methods and 57 percent used 5 or more methods of identification. Other top methods of identification included hospital operative record, office record, surgeons operative dictation, and hospital implant sheet/labels. Respondents reported that their preferred method to identify failed implants would be the use of a standard practice of recording UDIs in electronic medical records (EMR) or registries. This would save the surgeon's time, but also identify patients at risk in a timelier manner.

As discussed above, Mercy Hospital is undertaking end-to-end implementation of UDI's.[8, 19] Mercy instituted a pilot UDI project in their catheterization lab, by implementing UDI into their order system, cath lab, and EMR. This created an integrated database for comparative effectiveness research. Mercy found that by incorporating this data into their system it reduced the number of times the cath lab ran out of supplies, and allowed for easy access to expiration dates. More importantly, UDIs created a way to more easily manage device recalls. By implementing UDIs on multiple electronic platforms within the hospital, they were also able to track in real time the use of devices in the patient rooms and the operating rooms (OR). This created a seamless transition from the EMR to patient billing. This process allows Mercy to determine the most effective devices in different patient situations, creates operational efficiencies by reducing manual data entry and having data readily available for analysis, and cost savings by reducing inventory and using automated re-ordering.[15] In a second demonstration, Mercy implemented a UDI system for coronary artery stents. As with the OR program, Mercy implemented it in their EHR, billing, and supply chain systems. The resulting cost savings came through a reduction in inventory and automated re-ordering. This system also provided them with the ability to determine the most effective stents for specific patient populations.[15]

California Medicaid (Medi-Cal) implemented a universal product number (UPN) demonstration project in 2009 to look at the impact on payers.¹ The objectives of the demonstration were to lower program costs, increase quality of reported data, reduce fraud and abuse, and increase patient safety. [9, 15, 20] Medi-Cal received temporary authorization to convert the HCPCS field in a claims transaction to a field that accepted UPNs. During the two-year pilot Medi-Cal processed over seven million applicable claims and paid out \$600 million to over 5000 providers. Medi-Cal reported savings of about \$60 million for the two year pilot. The savings came from eliminating the need for Medi-Cal to request additional information thereby reducing operational costs and adjudicating claims faster and more accurately. Providing this level of product specificity allowed Medi-Cal to maintain better control over rate setting, medical necessity, establishment of utilization controls, and monitoring health outcomes. It also permitted Medi-Cal to analyze claims to conduct fraud and abuse investigations, thus recouping funds back to the program. Overall, they found that the benefits of including the UPN far outweighed the implementation costs for Medi-Cal.

In 2014, Workgroup for Electronic Data Interchange (wedi) convened a series of stakeholder meetings to address postmarket surveillance using UDI information.[15] The report discussed three options: 1) maintain the status quo; 2) enable EHR's to collect UDI data; and 3) change billing claims to allow for the transmission of UDI data. The final recommendations from the report were to create a staged approach to collecting UDI information. Initially, it suggests modifying the Accredited Standard Committee (ASC X12) claim transaction to carry structured UDI data. This allows for the creation of an all-payer claims database, such as Sentinel or the one maintained by the Health Care Cost Institute [21]. Ultimately, UDI information would be collected via EHR's but currently the interoperability and the export ability of EHR's makes this unfeasible. While collecting the UDI via claims would be voluntary for providers and

¹ UPN's were used because UDI's did not exist at the time.15. Foundation, w., *Unique Device Identifiers: Facilitating the Capture and Transmission of UDI*. 2014, wedi. p. 28.

payers, it represents the best available option and set the stage for organizations to work together to identify the safest, best performing and cost-effective devices.

Challenges and Benefits

While the studies previously discussed outline the benefits of implementing UDI, there are considerable organizational, workflow, and technological challenges associated with incorporating UDIs into electronic health records (EHR) and billing data.[6] Integrating UDIs into EHRs is a challenge and requires organizational change within the institution. There are also workflow challenges educating staff to understand the benefit of capturing the UDI information, and prevent “work arounds” that can result in non-compliance with clinical protocols and result in putting patients at an increased risk for a safety event. For example, in surgical suites, label damage, disposal of the product packaging with the UDI, or outside management of data and products may interfere with the surgery.

As many of the papers discussed, the technological challenges are significant. Creating an interface with interoperability between the various IT systems within a hospital to ensure UDI information is successfully shared between departments can be expensive to implement and maintain. The task of achieving interoperability between EHR systems and other patient data is still a hurdle that has not been overcome.[22, 23] The ability to extract UDI information from various EHR systems to conduct system-level research is very difficult and to date there is no structured way to represent UDI information in an EHR.[6] In early 2014, the Office of the National Coordinator (ONC) and the Health Information Technology Policy Committee (HITPC) released Meaningful Use 3 recommendations, which included having UDI’s become a part of certified EHRs.[24] While they acknowledge some of the difficulties associated with this, the benefit for patient safety is greater.

The FDA currently uses the Sentinel Initiative to conduct postmarket surveillance on pharmaceuticals using administrative claims.[1-3, 15, 16, 25] Unfortunately this system cannot perform the same surveillance for medical devices. With the implementation of the UDI and the possibility of inclusion on billing claims, the Sentinel Initiative presents an extraordinary opportunity to undertake new studies analyzing device safety. But more importantly in the event of a product recall patients can be easily identified and followed up to ensure their health. Currently, most postmarket surveillance is done via registries. While registries provide very detailed information on a large number of patients, the information is generally only collected for a short time, such as when the patient is in the hospital. There is limited ability for long-term follow up of patient outcomes. Linking registries and administrative data can provide detailed information on the patient with the ability to look at long term patient outcomes. Capturing information in administrative data outside the current system of registries would be even more efficient.

As with the Medi-Cal demonstration, health plans and payers have an interest in UDIs for both patient safety reasons in the event of a product recall by reaching out to the healthcare organization, even if the procedure was performed years earlier. [9, 15] However, health plans and payers provide another, potentially more efficient, avenue to contact patients in the event of a device recall. By using the UDI it

also allows payers and health plans to streamline their processes to reduce costs, more effectively manage their list of covered benefits while reducing fraud and abuse.

Conclusions:

There are a number of benefits for healthcare organizations associated with the implementation of the UDI system, including creating operation and clinical efficiencies thereby freeing up additional time for direct patient care.[25] Using the UDI in the supply chain will improve efficiencies, reduce errors, and result in cost savings. More importantly, UDI's raise the possibility of increasing patient safety through better information for providers about the devices, postmarket surveillance, and reducing medical errors.[3, 14-16, 25, 26]

With the upcoming September 2014 deadline for implementation of UDI for Class III devices, healthcare facilities are facing the immediate challenge of incorporating a new data stream into the IT infrastructure. While many barriers exist and recent studies show that it requires a significant amount of work to implement, it is feasible and can result in cost savings and increased patient safety.

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