Lessons Learned During Implementation of Barcoding ("Unique Device Identifiers") in Mercy Cardiac Catheterization Laboratories: A Report of the MDEpiNet UDI Demonstration Project

Mercy Health conducted a Demonstration Project[1] for the U.S. Food and Drug Administration (FDA) whereby prototype Unique Device Identifiers (UDIs) were implemented in its electronic data systems for safety surveillance and research purposes. The demonstration was performed for the Methodology Work Stream (Sharon-Lise Normand, Ph.D., Principal Investigator) of the FDA's Medical Device Epidemiology Network[2] (MDEpiNet) initiative. To accomplish the goal of integrating UDIs into Mercy systems, a team of supply chain and information technology personnel at Mercy implemented OptiFlex™ CL (Omnicell, Mountain View, CA), a point of use (POU) system in Mercy Cardiac Catheterization Laboratories (Cath Labs). The POU system provides for tracking items used in the Cath Lab through provider use of barcode technology that captures device identifier, expiration date, and lot number or serial number (prototype UDIs) for each item. This system also enables shelf level inventory management, automated inventory replenishment, and automated charge collection. With the UDI data electronically captured through the POU system, we were able to combine it and associated device attributes with clinical data from the EHR and create a rich clinical data set (the UDI Research database

[1] Drozda, JP, et al. Advancement of innovative methodologies and medical device specific infrastructure for evidence-based regulatory science and public health surveillance: implementation of unique device identification demonstration projects, final report. December 2013.

[2] U.S. Food and Drug Administration (FDA), *Medical Device Epidemiology Network Initiative (MDEpiNet)*, http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm (12 December 2013).

or UDIR) for device surveillance and research. The UDIR and information technology infrastructure for the UDI Demonstration Project are described fully elsewhere[3]. This document will emphasize some of the key lessons learned and additional observations from implementation of the POU system. While the current project dealt specifically with coronary stents and Cath Labs, we feel that the processes and learnings from it have applicability across all medical device types and clinical settings.

Implementation

Processes and Systems

The implementation of the POU system has impacted many functional areas at Mercy including supply management workflow, labor, revenue, inventory management, and system design. Implementing the system required effort from many individuals as well as the integration of several software systems. The implementation team consisted of operational application consultants familiar with supply chain processes as well as Cath Lab personnel. Also included were supply chain representatives and information system architects.

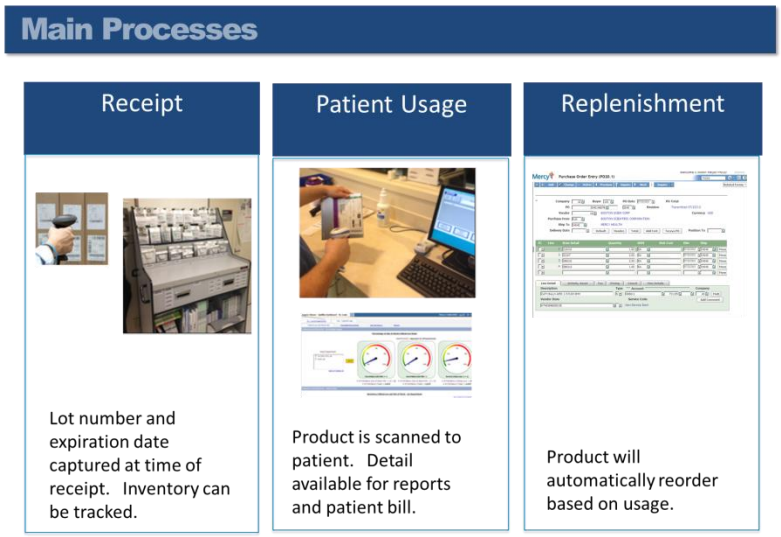
Several software programs were part of the POU system. OptiFlex™ CL is the inventory management system implemented to better track Cath Lab supplies by automating the process of tracking inventory, ordering new supplies, and billing for supplies used. Merge is the hemodynamic clinical system used to capture clinical and product information. Epic is Mercy's electronic health record system.

Prior to the UDI Demonstration Project our Cath Labs did not have an automated system to manage shelf level inventory quantities. Inventory replenishment was performed by a Cath Lab department employee walking through the department and physically inspecting each item to determine if replenishment was needed. Expiration data management was performed through color-coded tabs

[3] Roach J, Helmering P, Forsyth T, Drozda J. Unique device identification – architecture study, 3 September 2013.

affixed to the supplies. The occasion for implementing the OptiFlex™ CL system was the Demonstration Project but it was felt that the system's potential for improving inventory management and tracking Cath Lab supplies and procedures was a compelling reason by itself for its deployment. This system's putative benefits at the time of implementation included improving supply management by saving time, preventing procedure delays, lowering costs, and increasing revenue. OptiFlex™ CL captures a product's lot number and expiration date at time of receipt so that inventory can be tracked. When the product is scanned for patient usage the detail is available for the clinical record, departmental reports and billing[3]. Additionally, the system will automatically reorder products based on usage. (Figure 1)

Figure 1. OptiFlex™ CL **Functions**



Obstacles and Solutions

Technology Integration: During our initial analysis of the systems and processes in the Cath Lab, we identified gaps in the Merge's ability to receive barcode product information from OptiFlex™ CL. Due to the lack of integration between OptiFlex™ CL and Merge, a workflow of "double scanning" was put into place. This meant that two scans must take place: First, a stent's Mercy-generated barcode has to be scanned into OptiFlex™ CL. Second, the same stent's GTIN or HIBC barcode has to be scanned into

Merge. This was the only workable solution during the timeframe of the Demonstration Project but a functioning interface between the two systems would be the best workflow solution for clinical staff. Discussions with each of the technology vendors regarding the creation of such an interface are ongoing and we are encouraging them to adopt UDIs and to facilitate the technical solution to systems integration.

Our discussions with Merge and OptiFlex™ CL have revealed significant obstacles to the integration of our systems. We have, for instance, discovered that Merge did not consider integration with other systems to be advantageous. In fact, they valued their closed architecture. Our discussions with both vendors have, therefore, been escalated to the senior leadership level for issue resolution. Optimizing the inventory system as well as developing a system for moving data between OptiFlex™ CL and Merge have consumed more time and resources than initially anticipated.

Capturing Information: In the initial stages of implementation, three problems were discovered: First, Merge drops a key digit from the Global Trade Identification Number (GTIN). Second, the Enterprise Resource Planning (ERP) supply chain system's item master cannot handle GTIN lineage. The FDA's UDI rule requires that, if a product undergoes significant modification, it be assigned a new UDI (GTIN for most products). GTIN lineage refers to the association of the resultant GTIN with the GTINs of previous product versions such that device history is not lost. Because the ERP system is not able to store UDI lineage, each new UDI will require a new product number in the item master. When the FDA's UDI requirements go into effect, product ordering will be more complex, and downstream analysis will require the creation of product lineages by manufacturer in order to group like items for purposes of safety surveillance and research. Finally, none of the Mercy's systems were able to store the UDI-associated device attributes. This functionality would be quite useful in that it would make the attributes immediately available to system users, thus obviating the need for obtaining them from the

FDA Global UDI Database (GUDID) and Mercy Supplemental UDI Database (SUDID) every time they are needed.

The item GTINs or Health Industry Bar Code (HIBC) numbers had to be captured in the ERP to enable the automated scanning of the product bar codes. Unfortunately, not all products had GTINs or HIBCs assigned. In those cases scanning and downstream analysis were not possible. Many manufacturers are transitioning from HIBCs to GTINs, and in our implementation, one of three coronary stent manufacturers utilized HIBCs for some of their products while the others solely utilized GTINs. However, Mercy's ERP system can only store one unique product identifier using one identifier standard per item with GTIN being the standard chosen because it is much more widely used by medical device manufacturers than HIBC. An analysis of Mercy's experience with the various identifier standards during a recent 3 month period as documented by OptiFlex™CL is illustrated in Tables 1 and 2. Whereas 41% of items have barcodes using the GTIN standard and 33% have barcodes using HIBC, 56% of items actually used have GTIN barcodes and only 7% are labeled with HIBC standards.

Table 1. Count of Barcode Types

Identifier Standard	Total	
GTIN	3,897	41%
HIBC	3,202	33%
Other	2,509	26%
Grand Total	9,608	

Table 2. Three Month Barcode Utilization Comparison

Identifier Standard	Total	
GTIN	1,943,116	56%
HIBC	233,892	7%
Other	1,296,860	37%
Grand Total	3,473,868	

Because of the decision to employ only GTIN standards for the ERP system, it was originally thought there was a need for a HIBC to GTIN crosswalk. But, it was later discovered that we could link the products from our ERP system to our POU system using our vendor item number. OptiFlex™ CL on the other hand was able to accept both versions of the device identifier which greatly enhanced our ability to manage through the transition period.

Application Limitations – The automated inventory system implemented was not without flaws. Several application-related issues arose during system implementation that limited the success of the Demonstration Project. First, it was discovered that OptiFlex™ CL requires a serial number to track inventory at the shelf level but manufacturers do not place serial numbers on coronary stents. They instead use lot numbers which required Mercy to create custom labels with "dummy" serial numbers and barcodes for coronary stents. When stents are received at the Cath Lab, the manufacturers' product identifiers are manually linked with the Mercy-generated "dummy" serial numbers within Optiflex. The flaw within the system necessitating this work-around can only be resolved by Omnicell—OptiFlex™ CL's manufacturer. A product upgrade due from Omnicell in March,2014, is expected to eliminate the need for "dummy" serial numbers.

Secondly, each Mercy Cath Lab operates on a separate instance of Merge. This made it necessary to create multiple versions of each interface between Merge and the UDIR to support consistent implementation across all Cath Labs. Health systems that employ more than one cath lab software system in their hospitals will face an even greater challenge in this regard. In addition to these software limitations, there were some differences between Mercy and FDA requirements that necessitated additional adjustments. One such difference was that Mercy and many other providers utilize the GS1 Global Location Numbers (GLNs) for uniquely identifying facilities, while the FDA utilizes the D-U-N-S®

number (Dun and Bradstreet, Milburn, NJ). To ensure consistent data between Mercy and the federal government, a "GLN to D-U-N-S" cross-reference database was constructed.

Thirdly, even though FDA draft requirements for UDIs standardize the device identifier number, device descriptions are not standardized so we continue to employ multiple descriptions for each UDI throughout our systems. In the future these descriptions need to be standardized—perhaps through the use of the GUDID.

Implementation Effort – The Mercy implementation team was very experienced in systems implementation. All of the team members had over 10 years of experience as well as specific experience implementing other POU systems. POU systems had already been implemented at Mercy, in Nursing, Electrophysiology Laboratories, Interventional Radiology, CT scanning, and the Emergency Department. The amount of effort required of the implementation team in implementing the system in the Cath Labs was, therefore, surprising. Further, the implementation required the assistance of Cath Lab personnel as well. Cath Lab leaders were required to put in a significant amount of effort for the first 3 months of the implementation. Additionally, one person on the Cath Lab team was given the assignment of leading the effort to develop new work streams and of incorporating new activities which were not part of the department's prior labor plans or productivity standards. Examples include item master maintenance, establishing and maintaining reorder points, and regular physical inventory counts.

After the 3 month mark the operations processes began to stabilize and the benefits of the system began to take hold. Figure 3 shows the additional support team Full Time Equivalent (FTE) required over the 3 months immediately following implementation at the Mercy Hospital St. Louis Cath Lab. St. Louis saw a steady decrease in support hours required and by the 3 month mark the support hours had stabilized.

Training Method – Training programs were developed and customized to specific roles in using the OptiFlex™ CL system. Inventory Management training was targeted towards departmental staff designated for that function. Their training included an initial in-person classroom style session followed by online e-learning sessions to provide additional training and refresher courses. The classroom style training was found effective for those involved in inventory management due to the depth of training required. The e-learning system was convenient for personnel to learn new material or refresh what was taught in the classroom. POU scanning training was provided to Cath Lab clinicians who utilized patient supplies. The e-learning system proved to be the most effective for POU scanning training because it allowed the co-workers to balance training time with patient care time in their busy schedules.

Charging / Billing – Prior to implementation the revenue team in the Mercy Finance Department and Cath Labs stated that each item was uniquely identified in our billing system with its own charge code. In the course of implementation, this was found not to be the case. Many items were found not to have unique charge codes and codes of similar items were being used instead. The failure to identify each item uniquely was found to be due to a misunderstanding related to differing perspectives with respect to the meaning of uniqueness on the part of clinical and operational staff. Clinicians look on "uniqueness" in terms of function while operational staff equate uniqueness with specific catalog items. In the clinician's mind all 2.3 mm stents would have a unique charge code. From an operational perspective, each vendor's 2.3 mm stent (catalog item) should have its own unique charge code. This discovery supported the use of an automated inventory system with product scanning at the point of care as the best approach to track item use in the Cath Lab and to avoid capturing erroneous product data as a result of incorrect charge codes being entered by clinical personnel.

Additionally, POU scanning enabled charge data transfer from OptiFlex™ CL to the billing system through an automated interface. Prior to the implementation of scanning, all charges were manually entered directly into the billing system by a unit secretary.

Product barcodes – Our approach to putting in place a barcode scanning system for capturing the prototype UDIs of coronary stents was to implement a comprehensive inventory system that included all items used in the Cath Lab, not just the implantables. In so doing we discovered that many products have multiple barcodes located on them and some have no barcodes at all. In instances of coronary stents, the Mercy-generated "dummy" serial number/barcode was scanned as the "UDI" and eliminated the confusion that other products with multiples codes tend to create even though clinicians were also required to identify the manufacturer's GTIN or HIBC barcode for scanning into Merge. For items with multiple codes, we had to identify the correct "UDI" (e.g., GTIN) codes and point them out to the clinicians as the correct ones to scan. The remaining barcodes on these products were considered incidental, i.e., not UDI-related, and were not to be scanned. Additionally, a specific GS1 bar code format[4] was favored because it was easily recognizable by staff further lessening incorrect scanning. Some confusion regarding multiple barcodes remains; however, it is decreasing over time as clinicians gain scanning experience. For those items that had no barcode at all we created a process for application of internally generated barcodes.

Inventory Value – Prior to the implementation of the system annual physical inventories were performed to obtain a value of all supplies for the General Ledger. In one of our facilities the last annual value prior to the introduction of the automated system was approximately $800,000. After the system was put in place and each item on every shelf was scanned and uniquely identified, the inventory value was actually found to be over $1.9 million. During the first 6 months of system implementation the

[4] GS1, *Bar Code Types*, http://www.gs1.org/barcodes/technical/bar_code_types (Dec. 12, 2013).

inventory value was managed down to $1.56 million resulting in significant cost savings related to excess inventory.

Post-Implementation

Expired Inventory – The automated system permitted tracking of products not only to the patient but also "on the shelf" in the Cath Lab. For the first time ever we had visibility of expiration dates of products on the shelf. This has allowed us to efficiently transfer products about to expire to another facility where they can be used more quickly or return them to the vendor. Since many of these products are on consignment from the vendor we have been able to initiate discussions with vendors regarding lower per product costs to Mercy because of this capability and the resultant cost savings for the vendor related to reduction in product wastage. In the assessment period prior to the project, we found that one vendor lost $300,000 of expired product in a six month period of time. We have initiated discussions with this vendor regarding a potential shared savings arrangement related to better inventory management.

Improved Charge Capture- Implementation of the system has improved both our charge reconciliation and the accuracy of our charges. Uniquely identifying the items by utilizing the barcode at the time of use and tracking inventory has enabled us to improve our overall charging process. Further barcode scanning at the point of care has also enabled automation of the charging process. Prior to the implementation charges were compiled manually on a piece of paper and handed to a unit secretary for entry after the procedure. Now our charges are collected at the time of care in the scanning process offering quicker and more accurate documentation.

Data Quality –Data quality in the patient implant log, which resides in the Merge software, has improved significantly during the Demonstration Project. Data quality was assessed by measuring

whether or not production identifier information (lot number or serial number) was present in patient implant records. Further, data quality was compared before and after implementation of the automated OptiFlex™ CL system. Previously, the production identifier and lot or serial numbers had been hand entered leaving the potential for error that was obviated through use of barcode scanning.

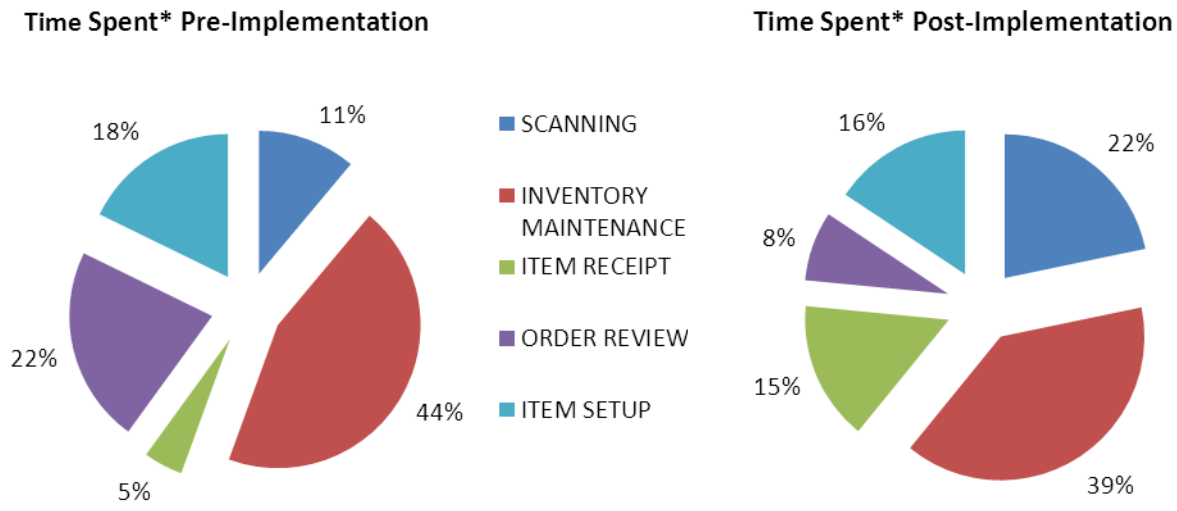
Overall Complexity – Prior to OptiFlex™ CL implementation Cath Lab personnel required very little knowledge of information systems in order to perform supply management activities. After implementation, in addition to learning the new POU system, staff had to learn how to navigate and operate other support systems. An example is the Business Intelligence (BI) reporting tool. Now that the supply information is stored electronically, it can be accessed easily and reports can be generated faster through the BI tool. We initially failed to recognize fully the implications for clinical staff of these additional 3rd party support systems, but have since learned more about the training needs related to these systems and worked with staff to ensure their familiarity with these valuable tools for improving both patient care and operational efficiencies.

Perspectives of Mercy Cath Lab Directors – From the viewpoint of Mercy Cath Lab leaders, the new automated inventory management system has offered a number of advantages. OptiFlex™ CL has improved efficiency in the Cath Lab by expediting the process of counting and reordering supplies, allowing clinical personnel to better track product expiration, charge for items used, and easily double check charging. OptiFlex™ CL also has also enabled the scheduling of necessary departmental reports and creation of custom reports by vendor and product group. Additionally, the system offers visibility of inventory by location within the department as well as the automated replenishment of supplies while giving Cath Lab personnel the information needed to determine the appropriate inventory levels within the department.

It was initially difficult for Cath Lab staff to learn a new system and to change the familiar workflow. Figure 4 and Table 3 illustrate the number of clinical staff hours and their distribution among various functions related to inventory management before and after OptiFlex™ CL implementation. Prior to implementation Cath Lab personnel had been scanning manufacturer barcodes into Merge at the time items were used but the data were not shared with any other system. As mentioned above, OptiFlex™ CL requires a second scan to capture data in the inventory management system in order to obtain the charging, reporting, and reorder advantages. This has led to a doubling of the amount of time spent scanning items at the point of use. However, the primary benefit of automated reorder resulting from this process is that it has virtually eliminated last minute supply acquisition that decreases staff efficiency and often delays procedures. Scanning has also significantly increased the time spent in inventory receipt but has simultaneously decreased time required for item set-up and inventory maintenance while greatly expediting order review. Prior to the implementation of the new inventory management system, order review included entering supply orders manually—a process that OptiFlex™ CL automated**.**

Overall the new inventory management system has added significant operational and data procurement functionality without increasing staff workload or significantly disrupting workflow. As a matter of fact, staff feel that it has improved workflow with the exception of double scanning, which is seen as a temporary problem. Once this process is eliminated, we estimate that Cath Lab personnel will see an actual reduction in inventory workload of approximately 200 hours per year. Finally, the issue of multiple barcodes on products makes it difficult to be efficient and needs to be addressed.

Figure 4. Cardiac Cath Lab Inventory Process



*Includes all inventory processes as well as charging and documentation of items

Table 3. Breakdown by Hours

PRE- OPTIFLEX™CL	Hours
POINT OF USE SCANNING	260
INVENTORY MAINTENANCE	1040
ITEM RECEIPT	104
ORDER REVIEW	520
ITEM SETUP	416
TOTAL	2340

POST-OPTIFLEX™CL	Hours
POINT OF USE SCANNING	520
INVENTORY MAINTENANCE	936
ITEM RECEIPT	374.4
ORDER REVIEW	187.2
ITEM SETUP	374.4
TOTAL	2392

Summary

The POU system was essential to capturing UDI in a fully automated fashion in all of the pertinent Mercy systems (Merge, Epic Clinical, and Epic Billing) as well as in the UDIR. Implementation of the system in 5

busy Cath Labs across Mercy was an ambitious and time consuming endeavor. Mercy encountered a host of workflow, technical, and supply chain challenges during the implementation that were for the most part overcome although a few vexing problems remain, e.g., the lack of an interface between the inventory management and clinical systems that requires users to "double scan" items. The implementation team and Mercy system architects are continuing their efforts to resolve these issues. In the meantime, Mercy is already seeing benefits arising from the new POU processes for supply chain and inventory management, workflow, and billing. Finally, the POU system enables the inclusion of UDI and UDI-associated attributes in Mercy's coronary stent UDIR that is now being used to assess both device safety and research.