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

Summary of Deliverable due December 31, 2013: "Final report of UDI demonstration project in Subtask 2.1"

Joseph P. Drozda, Jr., M.D., Principal Investigator for Subtask 2.1

Paul Helmering, B.A.

Vance Moore, B.S.I.M

Timothy R. Smith, M.D.

Introduction

Purpose

The Unique Device Identification project was an 18 month demonstration project with 3 specific aims:

1. **To implement a coronary artery stent UDI-based surveillance system in the EHR in a multi-hospital system**
   - *Hypothesis:* To satisfy the strong need for monitoring medical device safety and effectiveness, it is possible to develop and implement a coronary artery stent UDI-based surveillance system in the EHR of a multi-hospital system
   - *Methods:* Multiple health information technology (HIT) approaches will track stent product pathways and allow for the ultimate integration of UDIs along with associated attributes into EHR derived data sets.
   - *Outcomes:* An electronic communication chain will exist to not only track stent devices from manufacturer to implant to longitudinal follow up but also produce a database that can be queried for health outcomes, e.g., safety, reliability of different devices, and short-term and long-term clinical outcomes

2. **To identify obstacles to implementation of the UDI Roadmap produced by the MDEpiNet Think Tank and characterize the effectiveness of interventions to overcome them.**
   - *Hypothesis:* The ideas in the Roadmap will focus the Demonstration on addressing issues anticipated to interfere with the successful implementation of an EHR based device surveillance system.
   - *Methods:* The design of the proposed Demonstration will be altered to address the obstacles identified in the Roadmap.
   - *Outcomes:* The effectiveness of strategies put in place to address the Roadmap identified obstacles will be assessed with the results reported back to the Think Tank.

3. **To assess the validity and utility of data obtained from the EHR and incorporated UDIs for purposes of post-market surveillance.**
   - *Hypothesis:* Data in a UDI database must be valid, reliable, and generalizable and have clinical utility.
   - *Methods:* Multiple statistical and technical approaches will be used.
   - *Outcomes:* The validity and utility of the data arising from the EHR based UDI surveillance system will be assured.

To achieve these aims the project was charged with completing 6 deliverables. We have submitted 5 interim reports[1,2,3,4,5], which are included by reference in this Final Report and which delineated achievement of the following deliverables:

Identification of stakeholders and manufacturers for UDI subtask 2.1

Mercy organized an Expert Panel Meeting which including all of the identified stakeholders for the project.[1.] The purpose of the meeting was to identify key clinical attributes of coronary stents and to advise FDA on matters related to governance and operations of a Supplemental UDI Database (SUDID) and a proposed distributed data network for device surveillance. Results of this meeting are described in Appendix A, "Unique Device Identifiers (UDIs) for Coronary Stent Post-market Surveillance and Research: A Report from the FDA's MDEpiNet UDI Demonstration". This report is also under review for publication in the *American Heart Journal*.

Develop IT infrastructure for UDI subtask 2.1

Mercy developed an IT infrastructure that allows for implementation of an end-to-end (device-manufacturer to point of consumption) UDI tracking system. This infrastructure incorporates the UDI into the Mercy EHR (EpicCare) and creates an integrated view of EHR data and UDI associated data-elements along with relevant device attributes retrieved from the FDA's Global Unique Device Identification database (GUDID), as well as key clinical attributes defined by an Expert Panel of Interventional Cardiologist and incorporated in the SUDID.[2] Design modifications were made throughout the demonstration period to enhance the functionality of the system and to comport with Mercy's evolving comprehensive data strategy, in particular migrating from an Enterprise Data Warehouse design to the Integrated Patient Datamart structure. A description of the current IT architecture developed for this demonstration can be found in Appendix B, "Unique Device Identification- Architecture Study".

Establish process and systems for searchable data sets for purpose of surveillance in UDI subtask 2.1

Mercy established processes for using scanning technology to capture coronary stent UDI data in its supply chain database at the time of loading dock receipt, in an inventory management system in the Cardiac Catheterization Laboratories (Cath Labs), in the patient's medical records, and in an integrated data repository containing coronary stent device and patient data (the UDI Surveillance and Research Database or UDIR).[3] Additional details regarding the

---

[1] UDI Demonstration Milestone 1 Report, September 28, 2012
[2] UDI Demonstration Milestone 2 Report, October 31, 2012
[3] Summary of Deliverable due February 28, 2013: "Establish processes and systems for searchable data sets for purpose of surveillance in UDI Subtask 2.1"
[4] Summary of Deliverable due May 31, 2013: "Demonstrate UDI-based surveillance capabilities in UDI subtask 2.1"
[5] Summary of Deliverable due October 31, 2013: "Complete Demonstration Evaluation of UDI-based surveillance in Subtask 2.1"

implementation of UDI scanning in the cath lab and its implications for data capture, workflow and Cath Lab efficiencies can be found in Appendix C, "Lessons Learned during Implementation of Unique Device Identifiers in Mercy Cardiac Catheterization Laboratories".

Demonstrate UDI-based surveillance capabilities in UDI subtask 2.1

Mercy provided an initial evaluation of the data stored in the UDIR in the fourth interim report.[4] The report contains an initial validation of the data, a plan for further validation and a preliminary analysis looking at survival by drug stent attribute. The preliminary analysis showed patients receiving Bare Metal Stents (BMS) to be at higher risk for mortality than those receiving Drug Eluting Stents (DES). This was hypothesized to be due to selection bias.

Complete demonstration evaluation of UDI-based surveillance in UDI Subtask 2.1

Mercy's fifth interim report[5] contains a completed validation of the completeness and accuracy of the patient/case and coronary stent data stored in the UDIR and further evaluation of the safety signal identified in the survival by drug stent attribute included in the previous report. Due to a small sample size, findings were not conclusive, but were supportive of the hypothesis that the difference in mortality between DES and BMS groups seen in the unadjusted preliminary analysis was due to selection bias and represented a "false" safety signal.

Final report of UDI demonstration project in UDI subtask 2.1

This report serves as the final report in the UDI Demonstration project. The remainder of the report will cover goals and objectives achieved during this milestone period and plans for publications and future development of the surveillance system.

Baseline Characteristics

As previously reported the baseline characteristics in the UDIR consist of demographics, diagnosis, procedures, medications, medical history and laboratory values which are extracted from clinical data in the Epic Clarity database (Epic Clinical). Each characteristic is populated with a Time Period Classification code; a description of these codes with respect to each baseline characteristic can be found in Interim report 5 appendix B[5].

Our original plan for validating these characteristics included obtaining baseline characteristics from Apollo (the CathPCI Registry reporting software used in St. Louis) and comparing these characteristics to the ones obtained from Epic Clinical[4,5]. However, after further investigation we learned that automated reports for data extraction do not currently exist for Apollo and the work effort to have these created would exceed the demonstration timeframe. Alternatively, we sought to obtain submitted data from Cath PCI Registry itself, but we were unable to set up the necessary relationship with Cath PCI Registry during the demonstration period to get these data back on a case by case level. The primary advantage of doing these comparisons is to ensure that the method used in extracting data from Epic Clinical resulted in patient characteristics that met CathPCI data definitions (content validity). We intend to complete those analyses in future work.

We were able to assess face validity through our analyses of patient populations and comparing the distribution of identified patient characteristics in our population compared to those seen in registries and clinical trials and to assess their impact on measured outcomes. We feel that our identified patient characteristics do indeed have face validity as analyses included in this report demonstrate.

Longitudinal Characteristics

We began populating longitudinal characteristics in the UDIR on November 10, 2013. The longitudinal characteristics are the same as the baseline characteristics and are populated in the UDIR through a weekly surveillance run that happens weekly on Sunday. The surveillance run populates a new row in the UDIR with a time period classification of "After Implant" for each baseline characteristic for which a value was entered within that week. History of the characteristics is stored in the UDIR to allow trending of characteristics over time. Details regarding the methodology of characteristic capture can be found in interim report 5 appendix B.[5]

Scan Compliance

Scanning of UDI's at the point of care is an essential process that enables the UDI to be captured and stored in the EHR and in the UDIR for use in device safety surveillance and research and is the most critical element impacting data completeness. As indicated in the Statement of Work for the Demonstration Project, Mercy was to perform the following analyses of Cath Lab UDI scan compliance:

1. Measurement of the proportion of stent implants in which UDI were accurately captured in the Cath Lab systems overall and stratified by clinical features and system features:
   a. Clinical: STEMI, off-hours use, emergent procedures
   b. Differences among Mercy Cath Labs along with putative reasons for such.

Our previous report measured scan compliance, defined as the proportion of implanted stents that were scanned, i.e, the number of stents in the UDIR representation of Optiflex[5] divided by the number of stents in the UDIR representation of Merge, overall and by Cath Lab. We next measured scan compliance by Cath Lab stratified by time of day and emergent procedures as defined by procedures performed at the time of Acute Myocardial Infarction (AMI). In addition, Wilcoxon rank test was used to assess if the mean rank differs between Merge and Optiflex.

Mercy Hospital Joplin and Mercy Hospital Washington are not represented in these analyses, because they were not exporting data from Merge to the UDIR during the analysis timeframe. Mercy Hospital Joplin did begin exporting data in November of 2013, but we were unable to retrieve data from procedures prior to this date. Mercy Hospital Washington is still unable to export data to the UDIR. We were unable to allocate funds to turn on the export feature at Mercy Hospital Washington during the Demonstration Project.

Overall scan compliance rates are shown in Table 1. The rates ranged from a low in St. Louis of 81.8% to a high of 87.6% in Springfield.

Table 1. Overall Scan Compliance			
	Optiflex	Merge	Optiflex/Merge
Rogers	744	856	86.9% (744/856)
Springfield	1996	2279	87.6% (1996/2279)
St Louis	897	1097	81.8% (897/1097)
Total	3637	4232	85.9% (3637/4232)

Table 2 represents the scan compliance by time of day, "off-hours" vs. "regular hours," at Mercy Hospital Rogers. Regular hours were defined as 7am -7pm Monday through Friday exclusive of holidays. All other times were considered "off hours." The stent procedures included in the

analysis were performed from November 1. 2012 through October 31, 2013. Cases were removed if they had missing Medical Record Numbers (MRNs) (n = 2), missing stent counts (n =11) or missing procedure times (n = 42). Cases were also removed if they appeared in Optiflex[6] and not Merge[7] (n= 7) or if they appeared in both systems but involved stents found in Optiflex but not Merge (n= 27). The analysis was then performed on 465 cases with 677 stents in Optiflex and 819 stents in Merge. Calculated scan rates were virtually identical for case performed during regular hours and off-hours.

Table 2. Scan Compliance by Time of Day at Mercy Hospital Rogers

Regular hours	Optiflex count	Merge count	Optiflex/Merge (%)
No	94	113	83.2% (94/113)
Yes	583	706	82.6% (583/706)
Total	677	819	

Table 3 represents the scan compliance by time of day, at Mercy Hospital Springfield. Cases were removed if they had missing MRNs (n = 1), missing stent counts (n =6) or missing procedure times (n = 9). Cases were also removed if they appeared in Optiflex and not Merge (n= 5) or if they appeared in both systems but involved stents found in Optiflex but not Merge (n= 21). The analysis was then performed on 1397 cases with 1893 stents in Optiflex and 2260 stents in Merge. The calculated scan rate for cases performed during off hours was much lower than the rate for cases performed during regular hours.

Table 3. Scan Compliance by Time of Day at Mercy Hospital Springfield

Regular hours	Optiflex count	Merge count	Optiflex/Merge (%)
No	238	386	61.7% (238/386)
Yes	1655	1874	88.3% (1655/1874)
Total	1893	2260	

Table 4 represents the scan compliance by time of day, at Mercy Hospital St. Louis. Due to an upgrade to the Merge system in St. Louis we experienced gaps in the Merge data in the UDIR

---

[6] Optiflex refers to the UDIR representation of Optiflex per the definition in interim report 5, "Complete Demonstration Evaluation of UDI-based surveillance in Subtask 2.1"

[7] Merge refers to the UDIR representation of Merge per the definition in interim report 5, "Complete Demonstration Evaluation of UDI-based surveillance in Subtask 2.1"

after August 19, 2013. We have since corrected this issue and retrieved the missing data, however due to time constraints we were unable to include stents (n= 368) used in procedures occurring after August 19, 2013 in these analysis. Cases were removed if they had missing MRNs (n = 6), missing stent counts (n =33) or missing procedure times (n = 36). Cases were also removed if they appeared in Optiflex and not Merge (n= 5) or if they appeared in both systems but involved stents found in Optiflex but not Merge (n= 11). The analysis was then performed on 512 cases with 852 stents in Optiflex and 1056 stents in Merge.

Table 4. Scan Compliance by Time of Day at Mercy Hospital St. Louis*

Regular hours	Optiflex count	Merge count	Optiflex/Merge (%)
No	149	190	78.4% (149/190)
Yes	703	866	81.2% (703/866)
Total	852	1056	

*Data contains stent cases performed between November 1, 2012 and August 19, 2013

We also looked at scan compliance in emergent cases versus non emergent procedures. Table 4 represents the scan compliance by emergent vs. non emergent procedure at Mercy Hospital Rogers. Cases were classified as emergent if they were performed on the same date as an AMI, defined as an ICD9 code of 410._1. 514 cases with 905 stents were identified in Merge that met this criterion. Cases were again removed if they appeared in Optiflex and not Merge (n= 7) or if they appeared in both systems but involved stents found in Optiflex but not Merge (n= 28). The analysis was then performed on 486 cases with 744 stents in Optiflex and 856 stents in Merge. Again, calculated scan rates for Rogers were virtually identical for emergent and non-emergent cases.

Table 5. Scan Compliance by Emergent vs. Non-Emergent Procedures at Mercy Hospital Rogers

Emergency with AMI	Optiflex count	Merge count	Optiflex/Merge (%)
No	620	712	87.1% (620/712)
Yes	124	144	86.1% (124/144)
Total	744	856	

Table 6 represents the scan compliance by emergent vs. non emergent procedures at Mercy Hospital Springfield. There were 1427 procedures with 2311 stents identified in Merge. Cases were removed if they appeared in Optiflex and not Merge (n= 5) or if they appeared in both systems but involved stents found in Optiflex but not Merge (n= 21). The analysis was then performed on 1406 cases with 1996 stents in Optiflex and 2279 stents in Merge. Interestingly, the scan compliance rate in Springfield for emergent cases was a little higher than that for non-emergent cases.

Table 6. Scan Compliance by Emergent vs Non-Emergent Procedures at Mercy Hospital Springfield

Emergency with AMI	Optiflex count	Merge count	Optiflex/Merge (%)
No	1562	1800	86.8% (1562/1800)
Yes	434	479	90.6% (434/479)
Total	1996	2279	

Table 7 represents the scan compliance by emergent vs. non emergent procedures at Mercy Hospital St. Louis. There were 546 cases with 1127 stents identified in Merge. Cases were again removed if they appeared in Optiflex and not Merge (n= 5) or if they appeared in both systems but involved stents found in Optiflex but not Merge (n= 12). The analysis was then performed on 534 cases with 897 stents in Optiflex and 1097 stents in Merge.

Table 7. Scan Compliance by Emergent vs. Non-Emergent Procedures at Mercy Hospital St. Louis*

Emergency with AMI	Optiflex count	Merge count	Optiflex/Merge (%)
No	742	912	81.4% (742/912)
Yes	155	185	83.8% (155/185)
Total	897	1097	
*Data contains stent cases performed between November 1, 2012 and August 19, 2013			

In summary, while good, the overall scan compliance rate of 85.9% is not ideal either from the standpoint of Cath Lab operations (inventory management, billing, reorder, and patient care) or from the viewpoint of data completeness. Rates closer to 99% would be considered an

achievable ideal. Having said that, we do not believe that the stent comparisons performed in this and previous interim reports have been significantly impacted by the apparent failure to scan approximately 14% of implanted stents since, to this point, we have found no evidence that one or more types of stents were systematically excluded from our analyses. This, however, requires further investigation.

The comparisons of scan compliance between regular-hour and off-hour procedures in the St. Louis and Rogers Cath Labs were reassuring in not showing any major differences. The 26.6% absolute lower scan rate during off-hours compared to regular hours in Springfield is surprising and unexplained at this point. We are investigating the causes of this finding. Interestingly and also unexpected, the scan rate for emergent cases in the Springfield laboratory is actually a little higher than for non-emergent cases. Given that most cases performed during off-hours are for ST Elevation Myocardial Infarction, this last finding is not concordant with the results of the off-hours analysis and raises a concern regarding data quality that will be investigated as well.

Methodology for Identification and Validation of Safety Signals in the UDIR

We have completed a full year (November 1, 2012-October 31, 2013) of data collection and have created a data set including 2250 patients undergoing coronary stent implantation between Nov 01, 2012 and Oct 26, 2013. There are 676 procedures excluded from the analyses due to invalid medical records due to lack of critical information, e.g., admission and discharge dates, or insufficient information to identify the stents. Among these stents, 482 had no associated attributes in the SUDID or GUDID and 189 were excluded due to an assumption that a blank Drug attribute field in the SUDID meant that data on this attribute were missing when it actually signified that these stents had no impregnated drugs. In other words, they were BMSs and the value of "none" had not been entered into the SUDID.   We are in the process of correcting this error in the SUDID but, in the meantime, have determined that excluding these stents did not have a significant impact on our previous analysis[5] since (1) most of the excluded MACE events happened after the first 30 days and (2) the significance of the p-value in step 2 for MACE events remained the same regardless of exclusion.   Therefore, we have continued to exclude them in the current 1 year analysis.

In this report, we present our extended analysis of MACE in this patient population. Using the methodology previously described[5] our new sample consists of 1545 patients as illustrated in Figure 1.

Figure 1: Case Selection Flow Diagram

676 procedures excluded:
  *482 with no stent attributes
  *189 with blank Drug attribute SUDID fields
  *5 invalid medical records, e.g. missing admission or discharge dates or discharge date

1808 procedures with 1963 stents
(total 1657 patients)

1640 procedures with 1772 stents
(total 1545 patients)
*1166/1545 with Everolimus drug stents
*176/1545 with Zotarolimus drug stents
*19/1545 with Paclitaxel drug stents
*184/1545 with bare metal stents

Statistical Methods

The analysis was performed in 5 steps. Step 1 was a preliminary survival analysis to detect the overall safety signal for the 1640 procedures. Step 2 was to demonstrate the distribution of MACE events across follow up time periods of varying lengths. If a safety signal appeared in both steps 1 and 2, steps 3 through 5 were carried out. All analyses were performed with SAS version 9.3.

MACE outcome: Mortality

Step 1: Preliminary Survival Analysis to Detect Safety Signal

Mortality was chosen as the first MACE safety outcome for analysis. In our previously reported analysis of the experience in the first 6 months of data collection,[5] the mortality was higher for BMS compared to DES—Everolimus, ,Paclitaxel, and Zotarolimus—individually and in an analysis combining DES. We detected the same signals in the final 1640 procedure dataset with the omnibus test for mortality comparing different stent drug attributes being significant (p-value <0.0001) as was the difference between BMS and DES in the combined DES analysis (Figures 2a and 2b).

Figure 2a: Survival by Drug Attribute
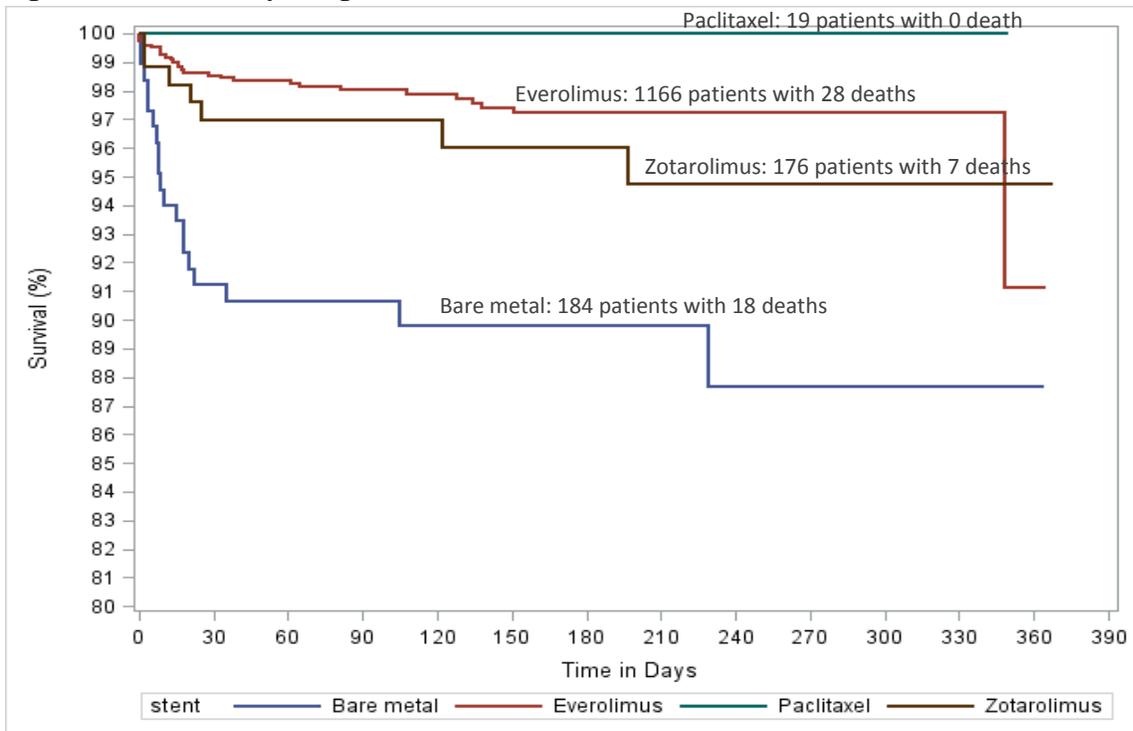
Figure 2b Survival by DES vs BMS
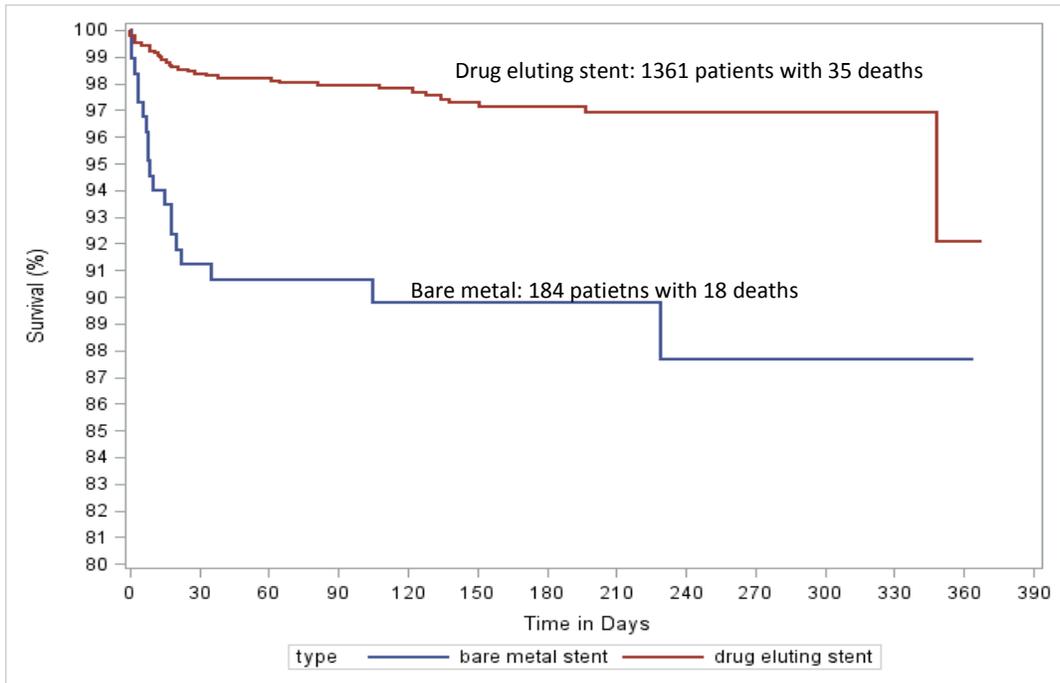
Step 2: Mortality during Different Follow-up Time Periods

Table 8 represents the mortality at differing follow up time periods for the first year after initial stent implant. Since 35 of the 53 total deaths (66.0%) occurred in the first 30 days of follow-up, we focused additional analyses on that period using the method described previously,[5]

Table 8. Mortality During Different Follow-up Periods

total death=53 (35-DES, 18-BMS)

Mortality	DES	BMS	p-value
30 days (N=1405)			
death (n=35)	1.6% (20/1230)	8.6% (15/175)	<0.0001
60 days (N=1246)			
death (n=40)	2.2% (24/1096)	10.7% (16/150)	<0.0001
90 days (N=1111)			
death (n=43)	2.8% (27/982)	12.4% (16/129)	<0.0001
120 days (N=947)			
death (n=45)	3.4% (28/832)	14.8% (17/115)	<0.0001
150 days (N=798)			
death (n=49)	4.6% (32/702)	17.7% (17/96)	<0.0001
180 days (N=665)			
death (n=50)	5.6% (33/586)	21.5% (17/79)	<0.0001
210 days (N=539)			
death (n=51)	7.2% (34/472)	25.4% (17/67)	<0.0001
240 days (N=374)			
death (n=52)	10.6% (34/322)	34.6% (18/52)	<0.0001
270 days (N=281)			
death (n=52)	14.2% (34/240)	43.9% (18/41)	<0.0001
300 days (N=202)			
death (n=52)	20.4% (34/167)	51.4% (18/35)	0.0004
330 days (N=129)			
death (n=52)	33.3% (34/102)	66.7% (18/27)	0.0035
360 days (N=61)			
death (n=53)	85.4% (35/41)	90% (18/20)	NA

p-values are obtained from Fisher's exact test.
N=patients eligible for follow up

Step 3: Identifying Selection Bias

We hypothesized previously[5] that the mortality difference between BMS and DES was probably due to selection bias although the sample size was too small to perform a meaningful propensity analysis. We used variables for our propensity score model based on the analysis found in

Massachusetts CathPCI data (Mass-DAC registry).[8]   Only 12 of the 63 variables were available in the UDIR database and were utilized in our final model.

To ensure that differences in outcome between DES and BMS groups were not influenced by the imbalanced sample size, absolute standardized percentage difference was used as an indication (≥20%) of potential selection bias. As Table 9 shows, patients who had acute MI or shock were more likely to receive BMS whereas diabetics were more likely to receive DES. The finding was similar to that in our 6 month analysis.[5] The only difference between the 6 month and 12 month analyses was that the absolute standardized percent of EF < 30% that was over 20% for the shorter timeframe and was just under that cut-off on the 12 month assessment.

Table 9. Baseline Characteristics Before Propensity Score Matching of Patients Completing 30-day Follow-up

| Baseline characteristic (N=1405) | Stent Type | | | standardized difference |
	DES (n=1230)	BMS (n=175)	p-value	(DES-BMS) %
Female	32.4% (398/1230)	32.6% (57/175)	0.9549[c]	-0.43
Age > 65	53.1% (653/1230)	53.1% (93/175)	0.9894[c]	0
Caucasian	95.9% (1177/1227)	92.5% (161/174)	0.0505	14.58
Married	69.6% (854/1227)	59.2% (103/174)	0.0069	21.95
Risk factors				
Alcohol used (Yes)	37.4% (440/1178)	32.9% (53/161)	0.2964	9.44
Illicit drug used (Yes)	6.0% (66/1106)	10.9% (16/147)	0.0319	-17.69
Acute MI (Yes)	35.0% (431/1230)	53.1% (93/175)	<0.0001	-37.08
Cardiac arrest (Yes)	0.3% (4/1230)	1.1% (2/175)	0.1652	-9.61
Shock (Yes)	1.9% (23/1230)	9.7% (17/175)	<0.0001	-33.84
COPD (Yes)	12.9% (158/1230)	18.9% (33/175)	0.0339	-16.46
Diabetes mellitus (Yes)	37.0% (455/1230)	27.4% (48/175)	0.0144	20.66
Dialysis (Yes)	1.9% (23/1230)	0.6% (1/175)	0.3482	11.72
EF < 30%	2.0% (25/1230)	5.7% (10/175)	0.0078	-19.32

p-values obtained from Fisher's exact test except gender and age chi-square test was used.
Missing data for some patients because of non-response or question unavailability

Step 4: Reducing Selection Bias using Propensity Score Modeling[9]

[8] Mauri L, Silbaugh TS, Wolf RE, Zelevinsky K, Lovett A, Zhou Z, Resnic F, Normand ST. Long-term clinical outcomes after drug-eluting and bare-metal stenting in Massachusetts. *Circulation* 2008;118:1817-1827.
[9] Lori, S. nd. "Reducing Bias in a Propensity Score Matched-Pair Sample Using Greedy Matching Techniques". Available http://www2.sas.com/proceedings/sugi31/115-31.pdf.

Our propensity score model was comprised of the characteristics in Table 8.   We used the model to perform 1-to-1 matching of DES and BMS patients without replacement.   Using this methodology we were able to match 145 of the 175 BMS patients available for analysis at 30 days post-procedure with 145 DES patients. The baseline characteristics of these 145 pairs of patients are shown in Table 10.

Table 10. Baseline Characteristics After Propensity Score Matching of Patients Completing 30-day Follow-up

	Stent Type			standardized difference (DES-BMS) %
Baseline characteristic (N=290)	DES (n=145)	BMS (n=145)	p-value	
Female	33.1% (48/145)	34.5% (50/145)	0.9012	-2.96
Age > 65	46.9% (68/145)	42.8% (62/145)	0.5550	8.25
Caucasian	95.9% (139/145)	94.5% (137/145)	0.7853	6.55
Married	57.2% (83/145)	56.6% (82/145)	0.9056	1.21
Risk factors				
Alcohol used (Yes)	28.3% (41/145)	31.0% (45/145)	0.6998	-5.91
Illicit drug used (Yes)	10.3% (15/145)	10.3% (15/145)	NA	0
Acute MI (Yes)	53.1% (77/145)	52.4% (76/145)	0.9064	1.4
Cardiac arrest (Yes)	0	0.7% (1/145)	NA	0
Shock (Yes)	9.0% (13/145)	8.3% (12/145)	0.8343	2.49
COPD (Yes)	20.7% (30/145)	20.7% (30/145)	NA	0
Diabetes mellitus (Yes)	28.3% (41/145)	29.7% (43/145)	0.8971	-3.09
Dialysis (Yes)	0	0.7% (1/145)	NA	-11.87
EF < 30%	4.8% (7/145)	6.2% (9/145)	0.7980	-6.14

p-values obtained from Fisher's exact test except married, acute MI, and shock for which chi-square test was used.

Step 5: Examining the Difference between Two Correlated Proportions Based on Match-Pair Samples

We compared the mortality for the 145 matched pairs from Step 4 with McNemar's Test as shown in Table 11. In summary, in the pairs of DES and BMS patients, there were 2 pairs in which both patients died within 30 days post-procedure and there were 129 pairs in which both patients remained alive at 30 days. Additionally, there were 9 pairs in which BMS patients were dead and the DES patients were alive at 30 days. Finally, there were 5 pairs in which BMS patients were alive while the DES patients had died. Kappa statistics were used to evaluate the agreement in mortality between BMS and DES as shown in table 11.   The insignificant McNemar's test is consistent with no association between mortality and the Drug stent attribute. However, the kappa statistics also showed the agreement was poor (kappa=0.1735 with the asymptotic standard error =0.1348). As in the 6 month study,[5] we conclude that the results of the

propensity analysis could be due to insufficient sample size and we cannot be confident in our conclusion of selection bias even though it has some clinical face validity. We have also not taken into account operator skill in this analysis and recognize variations in this parameter as a potential confounder.

Table 11. McNemar's Test and Kappa Statistics to Compare 30-day Mortality Between DES and BMS Using Matched Pairs (n=145)

		BMS		
		Death	Alive	Totals
DES	Death	2	5	7
	Alive	9	129	138
	Totals	11	134	145

McNemar's Test

Statistic	1.1429
DF	1
Pr > S	0.2850

Simple Kappa Coefficient

Kappa	0.1735
ASE	0.1348
95% Lower Conf Limit	-0.0907
95% Upper Conf Limit	0.4376

Test of H0: Kappa = 0

ASE under H0	0.0807
Z	2.1494
One-sided Pr < Z	0.0158
Two-sided Pr > |Z|	0.0316

MACE Outcome: Myocardial Infarction (MI)

In evaluating the MACE outcome of MI we used ICD9 codes (410.X1) to identify events. We initially experienced some difficulties with encounters in which acute MI codes were used incorrectly. After eliminating those "events," the total number of patients experiencing MI in the

follow up period after coronary stenting was 45. We then completed the analysis employing the same 5 step methodology we followed in the mortality analysis.

Step 1: Preliminary Survival Analysis to Detect Safety Signal

Figure 3a represents the survival analyses by Drug attribute for time to first MI event after the initial stent implant and figure 3b is the same analysis combining the DES types. No MI event was captured following implantation of Paclitaxel stents. The survival curves of bare metal, Everolimus, and Zotarolimus stents cross over time indicating visually that there are not likely any significant differences among them. This conclusion is confirmed statistically by the omnibus test in the survival analysis by stent Drug attribute (p=0.9992) and in the survival analysis combining DES (p=0.9710).

Figure 3a: Survival to First MACE MI Event by Drug Attribute
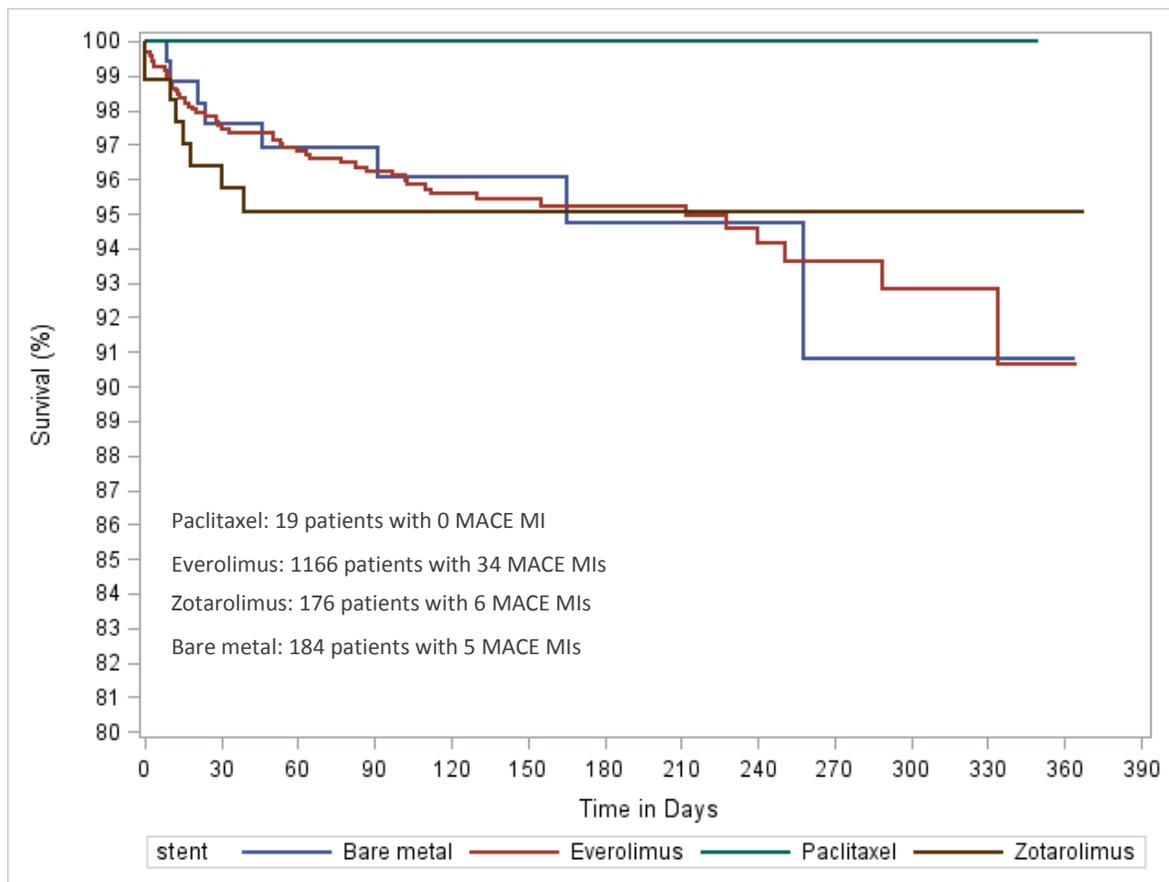
Figure 3b: Survival to First MACE MI Event by DES vs BMS

Drug eluting stent: 1361 patients with 40 MACE MIs

Bare metal: 184 patients with 5 MACE MIs
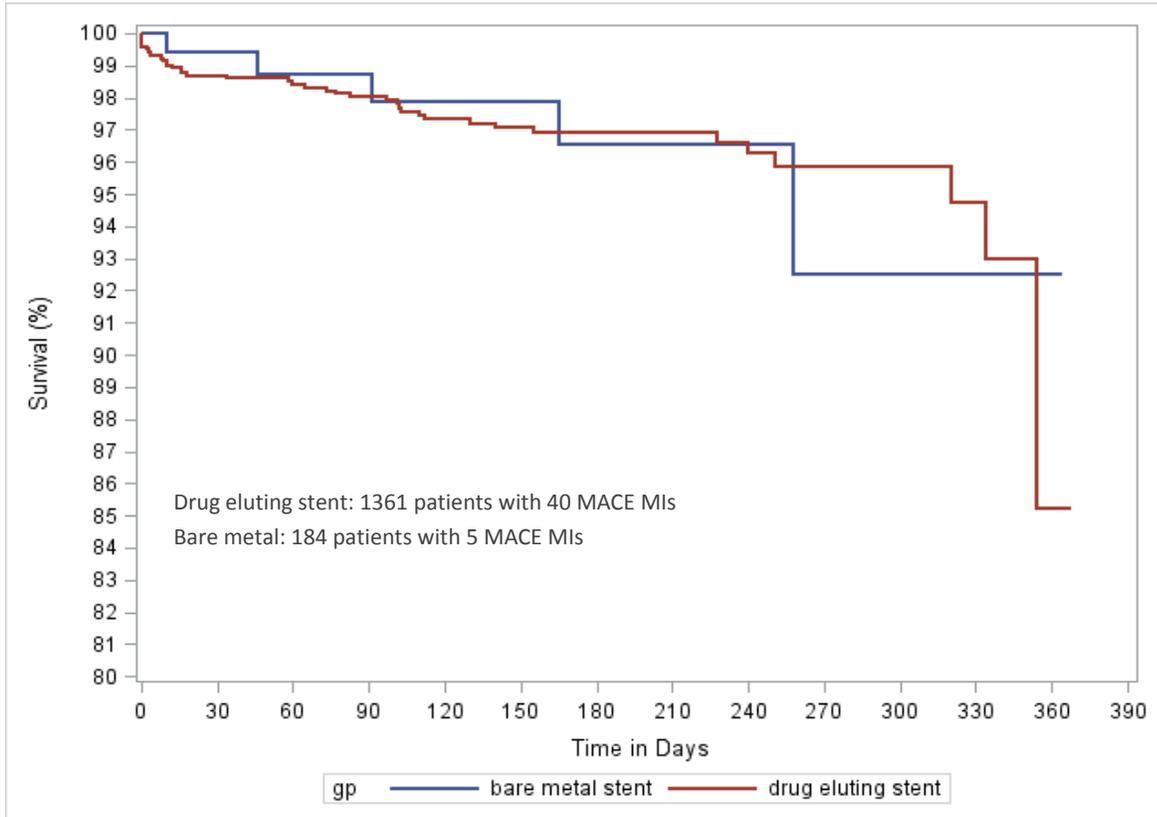
Step 2: Time to MI During Different Follow-up Time Periods

Table 12 represents the occurrence of MI during the first year after initial stent implant for BMS and the combined DES. Since most of the MI events (33%) occurred in the first 30 days of follow-up, we focused our analysis on that period.

Table 12. MI at Different Follow-up Periods

total MI =45 (40-DES, 5-BMS)

MI	DES	BMS	p-value
30 days (N=1405)			
MI (n=15)	1.1% (14/1230)	0.6% (1/175)	0.7094
60 days (N=1248)			
MI (n=20)	1.6% (18/1098)	1.3% (2/150)	0.7795*
90 days (N=1120)			
MI (n=25)	2.3% (23/990)	1.5% (2/130)	0.7590
120 days (N=961)			
MI (n=33)	3.6% (30/845)	2.6% (3/116)	0.7880
150 days (N=815)			
MI (n=35)	4.5% (32/718)	3.1% (3/97)	0.7889
180 days (N=685)			
MI (n=37)	5.5% (33/605)	5.0% (4/80)	0.8658a
210 days (N=560)			
MI (n=37)	6.7% (33/492)	5.9% (4/68)	0.7974a
240 days (N=398)			
MI (n=39)	10.1% (35/345)	7.6% (4/53)	0.8035
270 days (n=309)			
MI (n=41)	13.5% (36/266)	11.6% (5/43)	0.7325a
300 days (N=232)			
MI (n=41)	8.6% (36/194)	13.2% (5/38)	0.4948
330 days (N=162)			
MI (n=42)	28.0% (37/132)	16.7% (5/30)	0.2522
360 days (N=100)			
MI (n=45)	52.6% (40/76)	20.8% (5/24)	0.0090

p-values obtained with Fisher's exact test except those indicated as "a" for which chi-square test was used.
N=patients eligible for follow up.

As seen in figure 3a, 3b and table 12, there were insignificant differences between the stent types in MI at 30 days post-procedure such that our analysis ended at this step.

MACE Outcome: Stent Thrombosis (ST)

In evaluating the MACE outcome of MI we used ICD9 code 996.72 to identify events   As noted in the fifth interim report,[5] we hypothesize that confining ST to this definition likely results in an

underestimation of events that will require review of a sample of charts of patients suffering AMI or death in order to investigate the possibility together with the magnitude of any underestimation of events. We were not able to accomplish this review during the time of this Demonstration Project due to resource constraints and completed our analysis using only the 996.72 code. We captured 38 ST using the time to the first ST event and performed the analysis using our 5 step methodology.

Step 1: Preliminary Survival Analysis to Detect Safety Signal

Figure 4a represents the survival analyses for time to first MI event after the initial stent implant by Drug attribute and figure 4b is the same analysis combining the DES types. Only 1 ST event was detected following implanation of a Paclitaxel eluting stent. As the graphs show, the survival curves of bare metal, Everolimus, and Zotarolimus stents cross over time indicating visually that there are likely no significant differences among them. This conclusion is confirmed statistically by the omnibus test in the survival analysis by stent Drug attribute (p=0.05685) and in the survival analysis combining DES (p=0.7414).

Figure 4a: Survival to First MACE ST Event by Drug Attributes
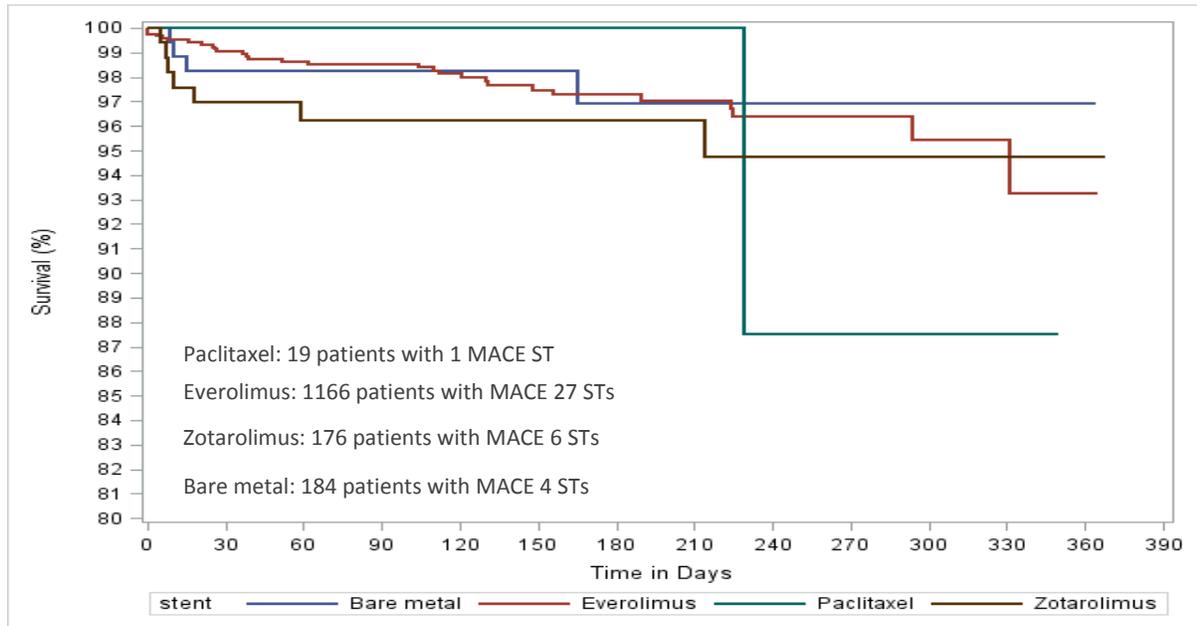
Figure 4b: Survival to First MACE ST Event by DES vs BMS

Drug eluting stent: 1361 patients with 34 MACE STs

Bare metal: 184 patients with 4 MACE STs
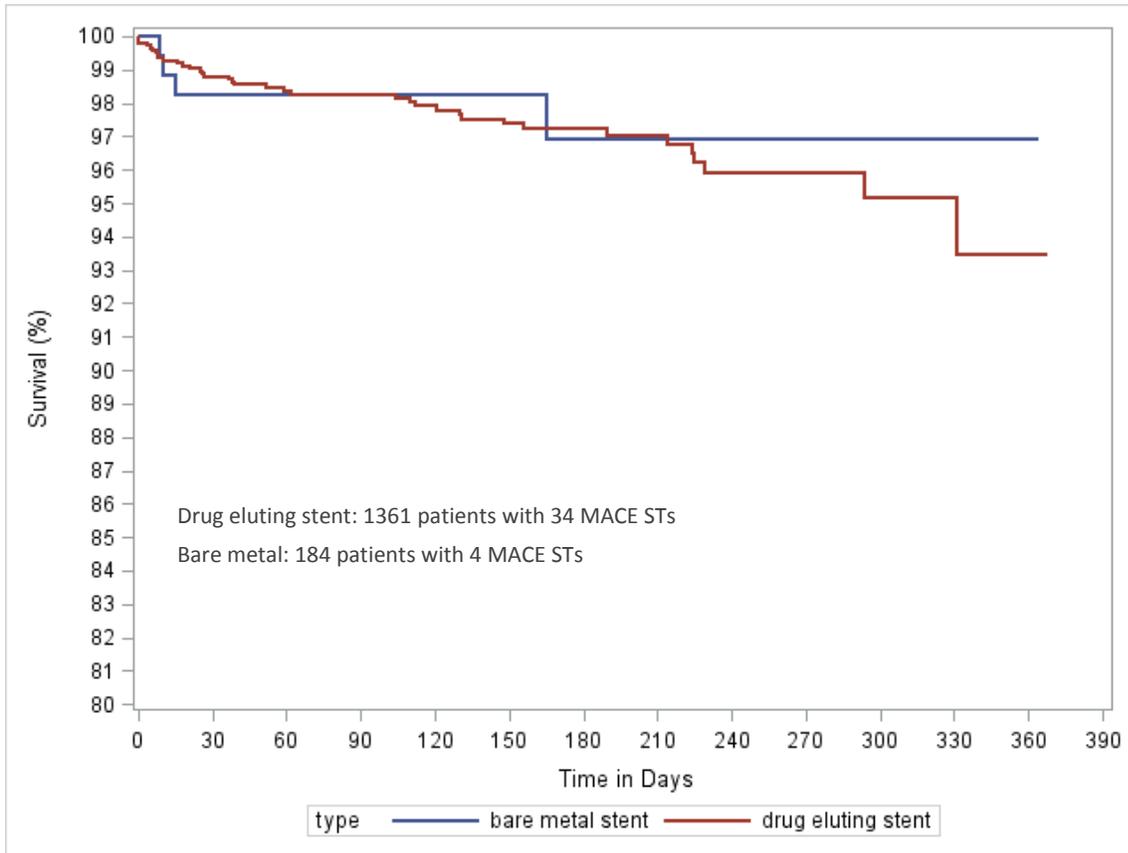
Step 2: Time to ST During Different Follow-up Time Periods

Table 13 represents the occurrence of ST during the first year after initial stent implant for BMS and the combined DES. Since a large proportion of ST events (36.8%) occurred in the first 30 days following implant, we focused our analysis on that period.

Table 13. Stent Thrombosis: Time to Event with Follow-up Data

total stent thrombosis =38 (34-DES, 4-BMS)

	DES	BMS	p-value
30 days (N=1408)			
ST (n=14)	0.9% (11/1233)	1.7% (3/175)	0.4022
60 days (N=1250)			
ST (n=16)	1.2% (13/1100)	2% (3/150)	0.4271
90 days (N=1117)			
ST (n=21)	1.8% (18/988)	2.3% (3/129)	0.7260
120 days (N=954)			
ST (n=25)	2.6% (22/838)	2.6% (3/116)	0.9803a
150 days (N=810)			
ST (n=27)	3.4% (24/713)	3.1% (3/97)	0.8881a
180 days (N=680)			
ST (n=30)	4.3% (26/599)	4.9% (4/81)	0.7727
210 days (N=558)			
ST (n=32)	5.7% (28/489)	5.8% (4/69)	0.9810a
240 days (N=395)			
ST (n=36)	9.4% (32/341)	7.4% (4/54)	0.8018
270 days (N=305)			
ST (n=36)	12.2% (32/262)	9.3% (4/43)	0.7991
300 days (N=229)			
ST (n=37)	17.3% (33/191)	10.5% (4/38)	0.4681
330 days (N=160)			
ST (n=37)	25.4% (33/130)	13.3% (4/30)	0.2293
360 days (n=96)			
ST (n=38)	40.6% (34/73)	17.4% (4/23)	0.0147

p-values were obtained with Fisher's exact test except those indicated as "a" for which the chi square test was used. N=patients eligible for follow up.

As seen in figure 4a, 4b and table 12, there were insignificant differences between the stent types in ST at 30 days post-procedure such that our analysis ended at this step.

MACE Outcome: Total Revasculization (TR)

TR refers to all Coronary Artery Bypass Graft (CABG) and coronary stenting procedures performed at Mercy facilities. We utilized ICD9 codes 36.06, 36.07, 36.11 to 36.16 and 36.19 to identify TR events. During the evaluation of our data on TR we discovered that, in 25 instances

(23 from Springfield, 1 from St. Louis, and 1 from Rogers), the stenting procedure date in the Merge UDIR tables was different from that in Epic Billing. Since we could not readily differentiate between incorrectly entered procedure dates and staged procedures we determined to exclude these cases from our analysis. We captured a total 149 TR events in our analysis.

Step 1: Preliminary Survival Analysis to Detect Safety Signal

Figure 5a represents the survival analyses for time to first TR event after the initial stent implant by Drug attribute and figure 5b is the same analysis combining the DES types. No TR events were detected during follow-up in the 19 patients receiving Paclitaxel eluting stents As the graphs show, the survival curves of bare metal, Everolimus, and Zotarolimus stents cross over time indicating visually that there are likely no significant differences among them. This conclusion is confirmed statistically by the omnibus test in the survival analysis by stent Drug attribute (p=0.9033) and in the survival analysis combining DES (p=0.9719).

Figure 5a: Survival to First MACE TR Event by Drug Attribute
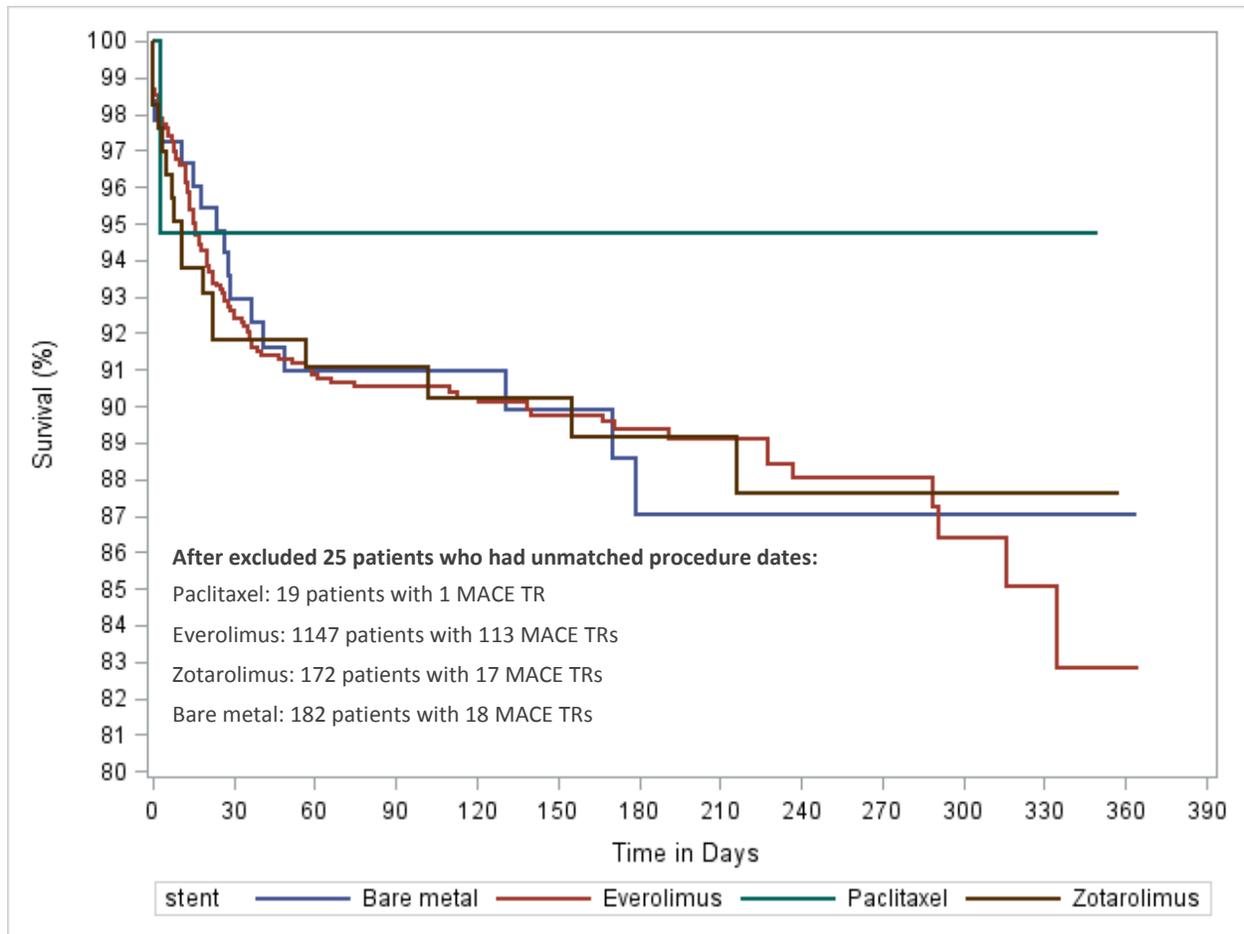
Figure 5b: Survival to First MACE TR Event by DES vs BMS
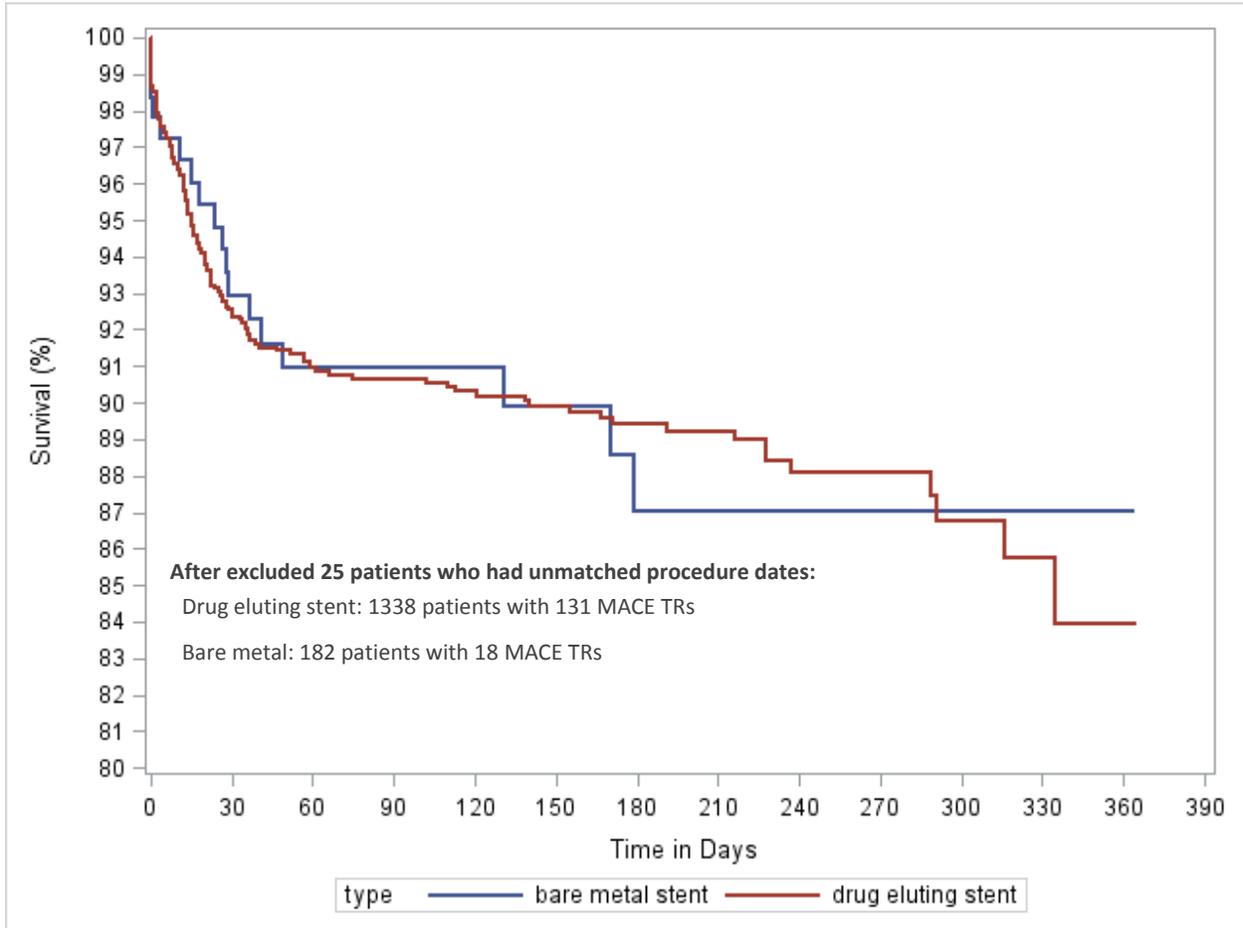
Step 2. Time to TR During Different Follow-up Time Periods

Table 14 represents the occurrence of TR during the first year after initial implant. Since 94 of the 149 total MIs (63.1%) occurred in the first 30 days of follow-up, we focused our analysis on that period.

Table 14. TR: Time to Event with Follow-up Data

total TR=149 (131-DES; 18-BMS)

	DES	BMS	p-value
30 days (N=1387)			
TR (n=94)	6.8% (83/1213)	6.3% (11/174)	0.7983a
60 days (N=1240)			
TR (n=116)	9.4% (102/1088)	9.2% (14/152)	0.9480a
90 days (N=1130)			
TR (n=122)	10.9% (108/995)	10.4% (14/135)	0.8650a
120 days (N=989)			
TR (n=129)	13.2% (114/866)	12.2% (15/123)	0.8864
150 days (N=862)			
TR (n=133)	15.5% (117/757)	15.2% (16/105)	0.9539a
180 days (N=740)			
TR (n=138)	18.5% (120/650)	20.0% (18/90)	0.7727
210 days (N=632)			
TR (n=139)	21.9% (121/553)	22.8% (18/79)	0.8847
240 days (N=477)			
TR (n=143)	30.3% (125/412)	27.7% (18/65)	0.7712
270 days (N=393)			
TR (n=144)	37.2% (126/339)	33.3% (18/54)	0.6499
300 days (N=323)			
TR (n=146)	46.6% (128/275)	37.5% (18/48)	0.2736
330 days (N=256)			
TR (n=147)	60.0% (129/215)	43.9% (18/41)	0.0603
360 days (N=201)			
TR (n=149)	78.9% (131/166)	51.4% (18/35)	0.0014

p-values are obtained from Fisher's exact test except those indicated as "a" that used chi-square test.
N=patients eligible for follow up.

As seen in figure 5a, 5b and table 14, there were insignificant differences between the stent types in TR at 30 days post-procedure such that our analysis ended at this step.

Any MACE Outcome

We defined any MACE outcome for purposes of this analysis as the First MACE Outcome of any kind (MI, ST, TR or mortality) following the index stenting procedure. For example, if a patient suffered an MI at 7 days after the initial stent implant followed by a TR event at 14 days and death at 20 days, the analysis included only MI as the "first event." We captured 237 First

MACE Outcomes. We employed the same 5-step analytic methodology as we followed with the individual MACE outcomes.

Step 1: Preliminary Survival Analysis to Detect Safety Signal

Figure 6a represents the survival analysis for time to First MACE Outcome after the initial stent implant by Drug attribute and figure 6b is the same analysis combining the DES types. As shown in Figure 6a, the survival curves of bare metal, Everolimus, and Zotarolimus stents cross over time indicating visually that there are likely no significant differences among them. This conclusion is confirmed statistically by the omnibus test in the survival analysis by stent Drug attribute (p=0.1959). However, in the BMS-DES comparison, a safety signal was detected and the omnibus test was significant (p=0.0393).

Figure 6a: Survival to First MACE Outcome by Drug Stent Attribute
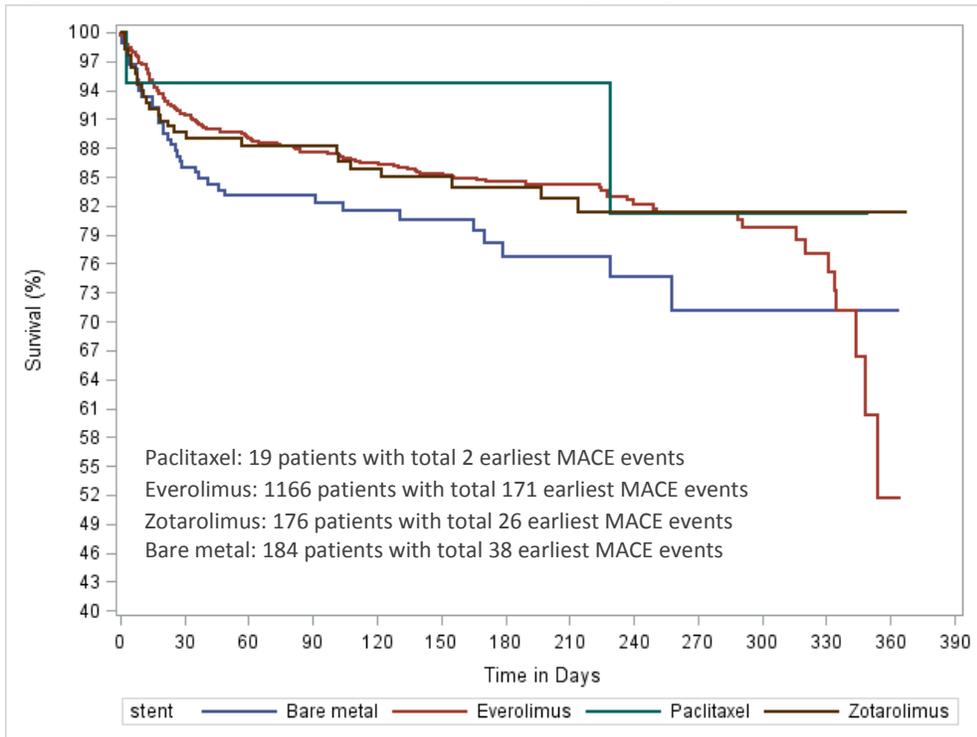
Figure 6b: Survival to First MACE Outcome by DES vs. BMS

Drug eluting stent: 1361 patients with total 199 first MACE events
Bare metal: 184 patients with total 38 first MACE events
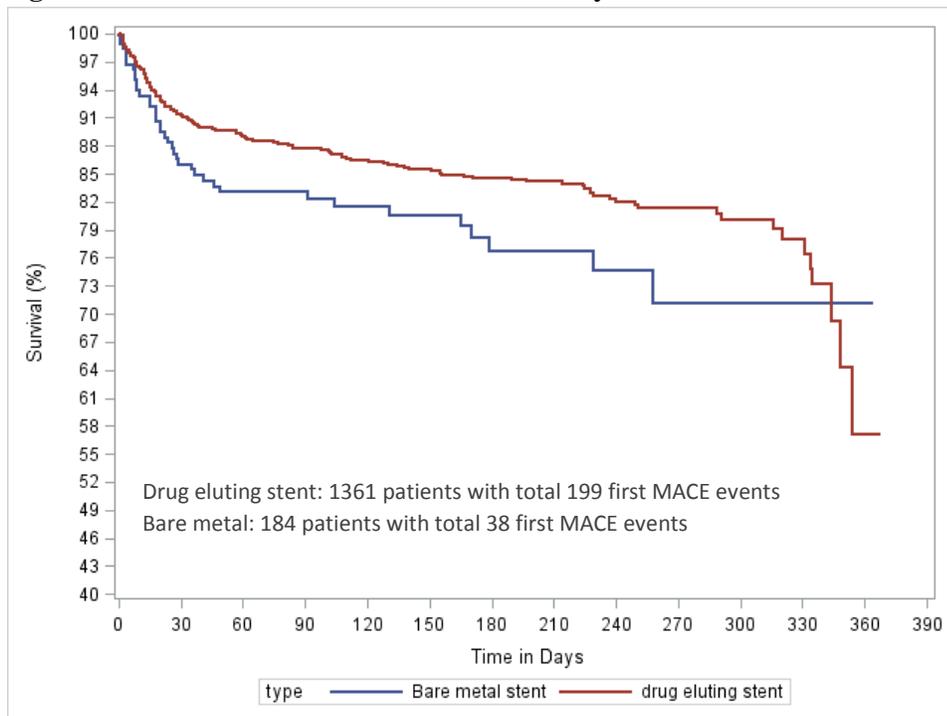
Step 2: Time to First MACE Outcome During Different Follow-up Time Periods

Table 15 represents the occurrence of the First MACE Outcome during the first year after initial implant. Since 138 of the 237 total MACE (58.2%) occurred in the first 30 days of follow-up, we focused our analysis on that period. The distribution of 30-day MACE Outcomes by MACE category and stent type is shown in Table 16. The majority of MACE Outcomes for DES were TR procedures while the majority of MACE Outcomes for BMS patients were deaths. Because of difficulties in discriminating the order of events occurring on the same day within our data set, we were forced to make arbitrary decisions about the timing of events. We devised a "hierarchy" for determining which MACE should be considered the First MACE Outcome for the analysis. The hierarchy is reflected in Table 16 with Mortality always considered the First MACE Outcome for analysis when it occurred on the same date with another MACE because of its obvious importance. The order after Mortality is as follows: MI, ST, and TR. This timing issue is a limitation of our data set for which we are continuing to investigate solutions.

Table 15. Time to First MACE Event with Follow-up Data

total events: 237

	DES	BMS	p-value
30 days (N=1413)			
any event (n=138)	9.1% (113/1237)	14.2% (25/176)	0.0412
60 days (N=1266)			
any event (n=168)	12.4% (138/1113)	19.6% (30/153)	0.0213
90 days (N=1159)			
any event (n=181)	14.8% (151/1022)	21.9% (30/137)	0.0439
120 days (N=1015)			
any event (n=195)	18.3% (163/890)	25.6% (32/125)	0.0681
150 days (N=887)			
any event (n=204)	21.9% (171/780)	30.8% (33/107)	0.0494
180 days (N=766)			
any event (n=213)	26.2% (177/675)	39.6% (36/91)	0.0122
210 days (N=657)			
any event (n=215)	31.0% (179/577)	45.0% (36/80)	0.0155
240 days (N=503)			
any event (n=224)	42.8% (187/437)	56.1% (37/66)	0.0469
270 days (N=423)			
any event (n=227)	51.5% (189/367)	67.9% (38/56)	0.0302
300 days (N=352)			
any event (n=229)	63.5% (191/301)	74.5% (38/51)	0.1531
330 days (N=290)			
any event (n=231)	78.5% (193/246)	86.4% (38/44)	0.3095
360 days (N=241)			
any event (n=237)	98.5% (199/202)	97.4% (38/39)	0.5088

p-value obtained with Fisher's exact test
N=patients eligible for follow up.

Table 16. 30-Day MACE Outcomes

	DES	BMS
Mortality (n=37)	21	16
MI (n=11)	11	0
ST (n=10)	8	2
TR (n=80)	73	7
Total=138	113	25

Step 3: Identifying Selection Bias

As demonstrated above in the mortality analysis (Table 8), patients who had acute MI or shock were more likely to receive BMS whereas diabetics were more likely to receive DES. In a separate analysis for baseline patient characteristics, we captured 8 additional patients but found the same imbalances as in the mortality analysis (Table 17).

Table 17. Baseline Characteristics Before Propensity Score Matching of Patients Completing 30-day Follow-up

| Baseline characteristic (N=1413) | Stent Type | | p-value | standardized difference (DES-BMS) % |
	DES (n=1237)	BMS (n=176)		
Female	32.2% (398/1237)	32.4% (57/176)	0.9551	-0.43
Age > 65	53.0% (656/1237)	52.8% (93/176)	0.9622	0.40
Caucasian	95.9% (1183/1234)	92.6% (162/175)	0.0771	14.21
Married	69.7% (860/1234)	59.4% (104/175)	0.0071	21.66
Risk factors				
Alcohol used (Yes)	37.4% (443/1184)	33.3% (54/162)	0.3402	8.58
Illicit drug used (Yes)	6.0% (66/1110)	10.9% (16/147)	0.0315	-17.69
Acute MI (Yes)	35.2% (435/1237)	53.4% (93/176)	<0.0001	-37.27
Cardiac arrest (Yes)	0.3% (4/1237)	1.1% (2/176)	0.1653	-9.61
Shock (Yes)	1.9% (23/1237)	9.7% (17/176)	<0.0001	-33.84
COPD (Yes)	12.8% (158/1237)	18.8% (33/176)	0.0340	-16.51
Diabetes mellitus (Yes)	37.0% (458/1237)	27.8% (49/176)	0.0186	19.75
Dialysis (Yes)	1.9% (23/1237)	0.6% (1/176)	0.3483	11.72
EF < 30%	2.0% (25/1237)	5.7% (10/176)	0.0078	-19.32

p-values obtained with Fisher's exact test except for gender and age where chi-square was used
Missing data for some patients because of non-response or question unavailability

Step 4: Reducing Selection Bias using Propensity Score Modeling

Our propensity score model was comprised of the characteristics in Table 18. As previously, we identified 145 matched pairs. There were only a few patients that we needed to rematch in the model.

Table 18. Baseline Characteristics After Propensity Score Matching of Patients Completing 30-day Follow-up

| Baseline characteristic (N=290) | Stent Type | | p-value | standardized difference (DES-BMS) % |
	DES (n=145)	BMS (n=145)		
Female	33.1% (48/145)	34.5% (50/145)	0.9012	-2.96
Age > 65	53.8% (78/145)	57.2% (83/145)	0.6365	-6.85
Caucasian	97.2% (141/145)	94.5% (137/145)	0.7853	13.57
Married	56.6% (82/145)	56.6% (82/145)	NA	0
Risk factors				
Alcohol used (Yes)	29.7% (43/145)	31.0% (45/145)	0.8984	-2.83
Illicit drug used (Yes)	9.7% (14/145)	10.3% (15/145)	0.8448	-2.00
Acute MI (Yes)	50.3% (77/145)	52.4% (76/145)	0.9064	-4.20
Cardiac arrest (Yes)	0	0.7% (1/145)	NA	0
Shock (Yes)	9.7% (14/145)	8.3% (12/145)	0.8376	4.89
COPD (Yes)	20.0% (29/145)	21.0% (30/145)	0.8840	-2.48
Diabetes mellitus (Yes)	28.3% (41/145)	29.7% (43/145)	0.8971	-3.09
Dialysis (Yes)	0	0.7% (1/145)	NA	-11.87
EF < 30%	5.5% (8/145)	6.2% (9/145)	0.8026	-2.98

p-values obtained with Fisher's exact test except illicit drug used, acute MI, COPD, and EF<30% for which chi-square test was used.

Step 5: Examining the Difference between Two Correlated Proportions Based on Matched-Pair Samples

McNemar's Test was performed to evaluate the difference of any MACE event between the matched pairs. Table 19 shows that in 4 pairs of patients receiving DES or BMS both encountered any MACE event in the first 30 days post-procedure. There were 109 pairs that did not have any MACE event at 30 days. In 19 pairs MACE Outomes were captured for patients that received DES but not for patients receiving BMS, In 13 pairs, MACE Outcomes were found in patients receiving BMS but not in the patients receiving DES. The insignificant McNemar's test is consistent with no association between any MACE Outcome and stent drug type. This is further supported by the poor agreement in Kappa coefficient (kappa=0.0753 with the asymptotic standard error =0.0931). We conclude that the results of the propensity analysis could be due to insufficient sample size and we cannot be confident in our conclusion of selection bias even though it has some clinical face validity. We have also not taken into account operator skill in this analysis and recognize variations in this parameter as a potential confounder.

Table 19. McNemar's Test and Kappa Statistics to Compare 30-day Any MACE Events Between DES and BMS Using Matched Pairs (n=145)				
		BMS		
		Any MACE - Yes	Any MACE - No	Totals
DES	Any MACE - Yes	4	19	23
	Any MACE - No	13	109	122
	Totals	17	128	145

McNemar's Test	
Statistic	1.1250
DF	1
Pr > S	0.2888

Simple Kappa Coefficient	
Kappa	0.0753
ASE	0.0931
95% Lower Conf Limit	-0.1072
95% Upper Conf Limit	0.2579

Test of H0: Kappa = 0	
ASE under H0	0.0818
Z	0.9210
One-sided Pr < Z	0.1785
Two-sided Pr > |Z|	0.3570

Conclusion

As per Aim 3 of this Demonstration Project we have demonstrated the utility of the UDIR for bringing together data from disparate sources (EHR, supply chain and hemodynamic software, GUDID, and SUDID) to identify in a timely fashion safety signals related to coronary stents and to support additional analyses to filter out "false signals." Further, we have previously[5] demonstrated the validity of the data arising from our EHR based UDI surveillance system. In this report we have added analyses of other MACE Outcomes including MI, ST, TR, and any MACE.

Our findings related to the differences in 30 day mortality between DES and BMS are similar to those of others.[10] To this we now add similar finding for any MACE Outcome at 30 days. Although the findings of higher mortality and any MACE in patients receiving BMS appear to be due to selection bias, we remain unable to draw firm conclusions in this regard because of problems related to small sample sizes even thought we have 6 more months of patient data than in our prior report.[5] These findings will require further investigation in larger datasets. If we obtain additional funding, we will be able to continue our research with longitudinal data analyses for MACE events and expand the data available by partnering with additional Healthcare Transformation Group health systems in a distributed data network.

Limitations to our analyses include the possibility of incorrect or incomplete information from the Social Security Death Master File, which is becoming a less reliable source of mortality data as a result of policy changes.[11] We attempted to compensate for this by also obtaining mortality data from the EHR. Further, we were unable to capture all of the variables in the propensity score model that were used in the analysis of a highly respected PCI registry and we are investigating how we might obtain additional variables in the future. In the meantime, we feel we have captured most of the important patient characteristics impacting mortality and stent selection.

Future Analysis

As mentioned above, the UDIR enables safety surveillance analyses to be carried out employing 3 categories of data: Device Attribute, Patient Characteristic, and MACE. The analyses described in this report have focused on all MACE outcomes but have restricted analyses to comparing the outcomes associated with the Drug attribute (DES vs. BMS) in all patients. In the future, we will investigate outcomes using patient characteristics such as age, gender and diabetes mellitus.

---

[10] Yeh, R W, Chandra M, McCulloch E, Go A S. Accounting for the mortality benefit of drug-eluting stents in percutaneous coronary intervention: a comparison of methods in a retrospective cohort study. BMC Medicine 2011; 9:78. doi:10.1186/1741-7015-9-78. Available at http://www.biomedcentral.com/1741-7015/9/78. Accessed December 23, 2013.

[11] Da Graca B, Filardo G, Nicewander D. Consequences for healthcare quality and research of the exclusion of records from the death master file. *Circ Cardiovasc Qual Outcomes* 2013;6;124-128.

Additionally, we will also look at other stent SUDID attributes such as Length, Diameter, and Coating.

Summary

We have completed this Demonstration Project and achieved all 3 of the specific aims as per the Statement of Work. A surveillance system for monitoring coronary stents has been created in Mercy Health's electronic systems, i.e., supply chain, inventory management, catheterization laboratory clinical software, and the electronic health record. Further, with the help of the American College of Cardiology and the Society of Cardiac Angiography and Interventions, we have identified key clinical attributes impacting the performance of coronary stents and created a database in which we have housed the attributes of almost all currently available coronary stents. Finally, we have developed a robust and continually renewing database containing clinical information from the EHR and device attributes gleaned from our attribute database and the FDA's GUDID.

In order to build our database and to incorporate device information into our systems, we implemented a bar-coding system in our cardiac Cath Labs and developed prototype Unique Device Identifiers to assign to each coronary stent. This entailed a significant operational implementation effort at our Cath Labs that has resulted in all items being scanned and not just coronary stents. This has led to overall operational efficiencies for our Cath Lab, supply chain, and billing processes.

In the process of designing and implementing the IT infrastructure and the scanning processes on which the surveillance system was built, we have identified a number of obstacles and have developed solutions or potential solutions for all of them. In addition, we have been sharing this knowledge with our health system partners (the Healthcare Transformation Group) who have helped in developing solutions. We have also reported on these and other issues to the Brookings Institution, which is leading the Think Tank that is part of the MDEpiNet initiative. We are currently working with Brookings on the creation of the "UDI Roadmap" that will be published later in 2014. A partial list of issues that will need to be addressed in future work is as follows:

- The requirement of "double scanning" by Cath Lab clinicians because of the lack of an interface between OptiFlexCM and Merge software systems

- The requirement to generate a Mercy serial number and barcode because of the inability of OptiFlexCM to track non-serialized items at shelf level

- Manual Submissions to Cath PCI Registry from Merge

- The inability to accurately discriminate in our EHR data the order of events occurring on the same day

Further, we have demonstrated through a series of analyses the utility and validity of the data contained in our surveillance database. These analyses have also pointed to the need for database refinements and for additional investigations, e.g., the reasons for the apparent selection bias in the use of BMS in patients with MI and shock. It is our intent to pursue these investigations and to generate abstracts, presentations, and journal papers from our work. We currently have our "Panel Meeting Paper" (Appendix A of this document) under consideration for publication in the *American Heart Journal* and plan to submit the "Lessons Learned" manuscript to a health care administration journal.

As indicated elsewhere in this document, it is the investigators' plan to continue and extend this work to involve the other HTG health systems and the National Cardiovascular Data Registry's CathPCI Registry and to create a distributed data network involving research databases at each of 3 other systems along with Mercy and utilizing the registry as the hub. This will test this concept of registry-led device surveillance and research that we hypothesize would be scalable and extensible to other device types. We hope to work with FDA on these initiatives.

Appendices

Appendix A: Unique Device Identifiers (UDIs) for Coronary Stent Post-market Surveillance and Research: A Report from the FDA's MDEpiNet UDI Demonstration

Appendix B: Unique Device Identification- Architecture Study

Appendix C: Lessons Learned during Implementation of Unique Device Identifiers in Mercy Cardiac Catheterization Laboratories

Unique Device Identifiers (UDIs) for Coronary Stent Post-market Surveillance and Research: A Report From the FDA's MDEpiNet UDI Demonstration

James E. Tcheng, MD, FACC,* Jay Crowley, MS,† Madris Tomes, MBA,† Terrie L. Reed, M.S., † Joseph M. Dudas, MBA,‡ Kweli P. Thompson, MD, MPH,§ Kirk N. Garratt, MSc, MD, FACC,‖ Joseph P. Drozda, Jr, MD, FACC¶
On behalf of the MDEpiNet UDI Demonstration Expert Work Group

*Duke University Medical Center, Durham, NC, †Center for Devices and Radiological Health, Food and Drug Administration, Silver Spring, MD, ‡Mayo Clinic, Rochester, MN, §Medtronic Corporation, Minneapolis, MN, ‖North Shore Long Island Jewish - Lenox Hill Hospital, New York, NY, ¶Mercy Health, Chesterfield, MO

Brief Title: Unique Device Identifiers for Stent Surveillance

Relationship with Industry: Dr. Thompson is an employee of Medtronic, Inc. Dr. Garratt is a consultant for Boston Scientific and The Medicines Company. Dr. Garratt currently has equity holdings with Guided Delivery Systems (GDS) and Infarct reduction Technologies (IRT). One of Dr. Drozda's sons is a sales representative for Boston Scientific Corporation. All other authors have no relevant relationships with industry to declare.

Word Count: 5,620

Address for Correspondence:
Joseph P. Drozda, Jr., M.D.
Center for Innovative Care
Mercy
14528 South Outer Forty
Chesterfield, MO 63017
314-628-3864
Fax: 314-628-3471
Joseph.Drozda@Mercy.net

Abstract

Background. While consumer product identification is ubiquitous, a system for unique identification of medical devices has yet to be implemented. To evaluate the utility of Unique Device Identifiers (UDIs) in healthcare information systems, the U.S. Food and Drug Administration (FDA) Medical Device Epidemiology Network (MDEpiNet) initiative includes a Demonstration of the implementation of coronary stent UDIs into the information technologies of a multi-hospital system (Mercy Health). This report describes the first phase of the Demonstration.

Objectives. An Expert Panel of interventional cardiologists nominated by the American College of Cardiology Foundation (ACCF) and the Society for Cardiovascular Angiography and Interventions (SCAI) was convened with representatives of industry, the health system members of the Healthcare Transformation Group, the ACCF National Cardiovascular Data Registry, and FDA to identify key clinical attributes of coronary stents (e.g., structural material), articulate the use cases of those attributes, and describe administrative, governance, and technical considerations for the authoritative management of these data.

Results. Eighteen use cases were identified, encompassing clinical care, supply chain management, consumer information, outcomes, research, regulatory, and surveillance domains. In addition to the attributes proposed for the FDA Global Unique Device Identification Database, 9 supplemental coronary stent-specific attributes were identified to address requirements of the use cases. Summary recommendations regarding administration and governance provided foundational principles for further evaluation and testing.

Conclusion. This process for identifying key device-specific attributes should be generalizable to other device types. Implementation of an optimally useful UDI system must anticipate the inclusion of both global and device-specific information.

Introduction

Unique identifiers have been common in the consumer market for many years, greatly improving inventory control while reducing costs to manufacturers, wholesalers, retailers, and consumers. The Universal Product Code (UPC) bar code system is widely embraced, allowing for the precise identification of consumer products and enabling the automation of inventory management and reorder. With medical devices, unique identification has a myriad of potential applications and benefits including improved patient access to device-specific information, provision of complete and authoritative data to providers at the point of care, improved care coordination, reduced medical errors, efficiencies in supply chain management, targeted approaches to active device surveillance and recalls, opportunities to create device-specific alerts and clinical decision support, facilitation of clinical and comparative effectiveness research, more accurate claims and payment processes, and long-term reductions in the overall cost of healthcare.

For several years, the United States Food and Drug Administration (FDA) has been working to develop requirements and specifications of a unique device identification system applicable to medical devices distributed in the United States (1-3). The FDA Unique Device Identifier (UDI) proposal, published on July 10, 2012, specifies that most devices are to include a numeric or alphanumeric code on the label, comprised of a device identifier specific at the device model level, along with production (e.g., lot, batch, or serial number) and expiration date information (4). The UDI proposal also stipulates that FDA create the Global Unique Device Identification Database (GUDID) to manage the data of a standard set of attributes such as those listed in Table 1. Data in the GUDID are to be specific to the level of the model and version of the device. Importantly, while the GUDID provides an electronic catalog of device

specific attribute information, it is not a repository of device usage data, including personal health information.

The UDI system is viewed as a key and requisite component for improving FDA post-market device surveillance capabilities (3,4). To evaluate the UDI system and other FDA post-market efforts, the FDA separately created the Medical Device Epidemiology Network (MDEpiNet) initiative (5). This initiative includes a Demonstration Project to evaluate the logistics and utility of a prototype UDI system, including the integration of prototype UDIs into the information systems of a large health system (Mercy Health). Management of coronary stent data was chosen as the archetype for the Demonstration Project. To develop this use case, an Expert Panel of interventional cardiologists was identified to lead a multi-stakeholder Expert Work Group in identifying the additional stent-specific attributes to be included in the UDI Demonstration Project. This paper describes the project in more detail and reports on the face-to-face meeting and 2 subsequent teleconferences of the Expert Panel and the related Expert Work Group. The in-person meeting took place at the American College of Cardiology Foundation headquarters in Washington, D.C., on August 6 and 7, 2012, and the teleconference discussions were held in October and November, 2012.

The Demonstration Project and Mercy Health

The Demonstration Project described herein is a contracted award of the MDEpiNet initiative. The MDEpiNet initiative, which the FDA established in 2010 as part of the Epidemiology Research Program at the Agency's Center for Devices and Radiological Health (CDRH) (5), focuses on evaluating strategies for strengthening post-market device surveillance. It includes 2 major "work streams": a Methodology Work Stream contracted to the Methodology Center at Harvard University and an Infrastructure Work Stream assigned to Cornell University.

The Methodology Work Stream houses the coronary stent UDI Demonstration Project. The Project has 3 principal aims:

1.   To implement a prototype UDI solution for coronary stents in the information systems of a multi-hospital system

2.   To identify obstacles to implementation of the prototype UDI solution and to characterize the effectiveness of interventions to overcome them; and

3.   To assess the validity and utility of data obtained from an EHR system in post-market surveillance using the UDI.

Mercy Health is a 4 state integrated delivery system headquartered in St. Louis, Missouri (6) that owns 34 hospitals with a total of 4,396 licensed beds ranging from small, critical access rural facilities to large, tertiary care urban medical centers. Mercy's medical staff membership totals 4,659, including 1,235 employed physicians.   Four of Mercy's 34 hospitals have cardiac catheterization laboratories that collectively implant over 5,000 coronary stents annually. To model incorporation of UDI data into the information management solutions of a health system, Mercy Health will serve as the test environment. The system design for the Demonstration Project is depicted in Figure 1. The approach envisions an end-to-end (manufacturer to point of consumption) UDI tracking system with incorporation of UDI data into the Mercy supply chain, catheterization laboratory, electronic health record (EHR), and associated information systems. Ultimately, a data set for device surveillance containing both EHR clinical (usage) data and UDI-associated device attribute data will be created for surveillance and research purposes. Figure 2 is a schematic illustrating the flow of data through the proposed system. This approach also anticipates the establishment of a larger network spanning multiple health systems that uses a national device registry as the hub for the sharing of UDI and UDI-related datasets. This will necessarily drive the specification and establishment of data sharing protocols, controlled

vocabularies, and research methodologies to be used by the network. Of note, these latter 2 phases are out of scope for this Demonstration Project.

As stipulated in the Demonstration Project scope of work, key supplemental coronary stent device attributes are included in the flow of data. Given the limited set of attributes of the GUDID, it was recognized that supplemental attributes would be needed to satisfy the data requirements of the potential uses of this information. Specifically, properties (attributes) of devices (such as stent dimensions and strut thickness) impact clinical applicability and performance. Having this information readily available through the association of data with UDIs and joining it with clinical data from the EHR will enable a robust system of device surveillance and research. For the Demonstration Project, the supplemental attributes are to be housed at Mercy Health in a reference database termed the Supplemental UDI Database (SUDID). As described below, selection of the supplemental attributes was the work of the Expert Panel and the attendees of the Expert Work Group meeting.

Multiple information systems of the Mercy Health information management environment will be extended to incorporate UDI data for the Demonstration Project. These include the Mercy Item Master, which is contained within its Enterprise Resource Processing supply chain software (ERP); the cardiac catheterization laboratory clinical reporting software solution (Merge/Camtronics); and the electronic health record (EpicCare). UDI data will be sent from these systems to be aggregated in the Mercy Health Enterprise Data Warehouse (EDW) with attribute data from the SUDID and the FDA GUDID and patient level clinical data to create an analysis dataset. UDI information retained in these systems will be available to clinicians, allowing for links to current product and recall information at the patient level. Finally, the catheterization laboratory software will transmit UDI data to the American College of Cardiology Foundation National Cardiovascular Data Registry (NCDR) CathPCI Registry along with the standard set of data required for registry participation. This will enhance the ability of the NCDR

to link with other data sets containing UDI, i.e., claims and electronic health records, and allow for evaluation and modeling in safety surveillance and device research.

Coronary Stent Expert Panel and Expert Work Group

Participants

Critical to the Demonstration Project and to the larger UDI strategy was the establishment of partnerships with key stakeholders of a coronary stent UDI system. For this reason, we identified pertinent stakeholders and invited representatives to participate in an Expert Work Group in-person meeting and follow-up teleconference sessions. These included stent manufacturers, health system supply chain divisions, cardiology professional societies, and the NCDR. Specifically, the 3 companies manufacturing all of the FDA approved coronary stents actively marketed in the US at the beginning of the project (Abbott Vascular, Abbott Park, IL; Boston Scientific, Natick, MA; and Medtronic, Minneapolis, MN) agreed to participate. In addition to Mercy Health, 4 large health systems (Geisinger, Intermountain Healthcare, Kaiser Permanente, and Mayo Clinic) were engaged to ensure generalizability. Finally, the American College of Cardiology Foundation (ACCF), the Society for Cardiovascular Angiography and Interventions (SCAI), and NCDR were solicited to participate in various aspects of the Demonstration Project. Representatives from each of these stakeholder entities comprised the membership of the Expert Work Group.

The Expert Work Group meeting was led by 5 interventional cardiologists (the Expert Panel) selected via recommendations of the ACCF and SCAI and vetted per the ACCF Relationships With Industry policy (7). The members of the Expert Panel and other members of the Expert Work Group are listed in Table 2. Of note, while we believe the opinions and recommendations described herein reflect the consensus of the Expert Work Group on behalf

of the health care community, these do not necessarily reflect the policies or positions (nor the formal endorsement) of the participating organizations.

Purpose

The Expert Panel identified five primary tasks for the Expert Work Group:

1. Review the FDA Unique Device Identification System Proposed Rule (FDA-2011-N-0090-0001) and gain a greater understanding about FDA expectations of manufacturers, researchers, providers and other stakeholders.

2. Identify key supplemental device attributes of coronary stents to be systematically managed in an SUDID.

3. Identify and describe key use cases where UDI data would be essential or useful.

4. Discuss approaches to the operations and governance of a permanent SUDID system.

5. Discuss future opportunities to leverage the findings and recommendations of the Demonstration Project, including potential incorporation of SUDID and EHR data into a distributed device data sharing network and the governance and operational issues related to such a network.

Proposed Supplemental Stent-Specific Attributes

The Expert Panel was tasked with identifying those supplemental coronary stent attributes not otherwise captured in the GUDID that would be clinically valuable in one or more of the dimensions of patient care, process and quality management, and clinical outcomes assessment. The task of selecting this high value set of attributes was accomplished with substantial input from the entire Expert Work Group. The Panel identified several dozen

potential attributes and agreed upon ten attributes as key parameters for the proposed coronary stent SUDID. The proposed attributes are listed in Table 3. An unexpected finding was that the attributes (save one) selected to be included in the SUDID set are publically available. The single attribute (stent surface to artery ratio) not available as a published specification was ultimately removed from the final list of attributes in order to complete the Demonstration Project in the required timeframe. Table 4 is an example of the data of the final 9 attributes for 3 similarly sized stents manufactured by each of the participating companies.

Use Cases

To test the validity of both GUDID and SUDID data specific to coronary stents, another key task of the Expert Work Group was to develop a list of representative use cases for UDI data. The Work Group was asked to articulate use cases where UDI data would be required and determine which device attributes in the UDI dataset and the SUDID dataset would be needed to support the identified use case. The Expert Work Group identified and reviewed 18 use cases, including the determination of whether each use case could be supported with information housed only in the GUDID or if SUDID attributes were also needed (Table 5). A key and unexpected observation was that the use cases could be divided into 2 groups: ones where only global UDI data were needed and ones where both data from the GUDID and the SUDID would be required to address the use case.

Technological and Operational Framework of SUDID

In the context of the Demonstration Project, Mercy Health will create and operate a prototype SUDID. If this approach proves successful, a permanent and sustainable solution for storing and accessing clinically relevant supplemental attributes will need to be created and an organization empowered to manage SUDID operations. The Expert Work Group deliberated on the approach best suited for providing a permanent SUDID solution and associated services.

The discussion included the advantages and disadvantages of each option. In addition, as the Work Group members discussed the provision of SUDID services, it was recognized that the generalizability of their recommendations with respect to the technological and operational framework of the coronary stent SUDID would require testing in other device types and specialty areas as a single SUDID solution for all devices may not be sufficient or appropriate.

Organization to Provide SUDID Services

The Expert Work Group reached agreement that there were 3 logical options for managing SUDID operations. Firstly, there was consensus that the FDA should continue to be involved in operations as well as governance in order to ensure ongoing coordination between the SUDID and GUDID. The option of actually housing the data at FDA and integrating the collection of the supplemental attributes into the FDA process for collecting GUDID device attributes was strongly favored as a means of simplifying data submission for manufacturers. In this scenario, the GUDID and SUDID would be stand-alone databases with different processes for determining the content and operations of each.

However, as a regulated governmental entity, the activities and actions of FDA are not necessarily in concert with the extended needs of the manufacturing, clinical, and research environments. The processes that the FDA is required to follow could result in challenges to the nimbleness of the SUDID, making clinically relevant modifications of the database cumbersome. Particularly problematic is the differential between FDA-approved indications and actual real-world (particularly off-label) uses of devices, a difference that could limit the FDA's ability to provide device-specific SUDID information for use in analyzing device performance and might require specific regulatory authorization.

A second option was for medical professional society registries such as the NCDR to manage SUDID operations. NCDR, being an established national repository for cardiac

procedural data with an extensive record of high-quality data analysis and publication, would bring many advantages to providing SUDID services. NCDR is already positioned to systematically collect stent implantation data, and having the SUDID operationally close to the NCDR and readily available to registry users should provide a data management advantage. Also, as there are a multitude of implantable devices used in the cardiovascular space (including peripheral arterial stents, pacemakers, implantable cardioverter-defibrillators, heart valves, vascular closure devices, and conduits), another advantage is extensibility and scalability to other classes of cardiovascular devices. While the SUDID would be a stand-alone database and function independently of the NCDR registries, proximity would foster integration of the SUDID data with registry datasets that would facilitate outcomes and comparative effectiveness research. Establishing NCDR administration of a SUDID related to cardiac interventional products could serve as a template for future development of similar relationships between non-cardiovascular product SUDIDs and other specialty registries. However, as the mission of the NCDR is specific to cardiovascular medicine, this would limit the ability to expand to other branches of medicine.

Finally, the Expert Work Group discussed the possibility of a third party contractor to manage SUDID operations. It was observed that there are existing organizations which have commercialized databases that are self-sustaining through licensing fees. Examples include GHX, IMS, and First Data Bank. An important consideration in utilizing such an organization for database operations is that the for-profit entities might be more likely to make the initial investment necessary for "start-up" while not-for-profits would likely need seed money from donations or grants. A contractor would also be challenged with making data readily available to all potential users.

SUDID Operational Considerations

As noted above, any organization responsible for SUDID operations will face the task of making SUDID data readily available to users. The term "readily available" can have multiple meanings, so determining whether real-time data are needed or whether the users would be best served by having periodic downloads of the data will need to be determined. Indeed, this question is being explored as part of the Demonstration Project. The need for real-time access to the information should also be balanced against the time needed for quality checks, data matching, and validation. For example, web services have the ability to provide data immediately to the user, but are reliant upon network availability and reliability, while managing the data locally through a cached process may improve data availability at the cost of synchronization with the authoritative source of information, depending on the update frequency.

All agreed that the ultimate solution for SUDID operations must consider end-to-end needs, meet stakeholder requirements, and be generalizable to other device types. Understanding the potential relationships between EHRs, clinical software (e.g. catheterization procedure documentation and reporting systems) and the SUDID at the outset of system creation will allow it to be built in a scalable manner that will meet future needs. Creating a system that is easily populated, maintained, and relevant is of the utmost importance. The data interoperability standards need to ensure that data is uniform and consistent, and the SUDID itself must be replicable for devices outside of the coronary stent arena.

Data Ownership and Governance of SUDID Services

The Expert Work Group recognized that data ownership and database governance with respect to a permanent solution were important issues to discuss at this early stage in the development of the supplemental UDI system in order to increase transparency and to build trust among the stakeholders. With respect to data ownership, the data used to build the

database (the attributes) are publically available, the specifications of the data were originally generated by the manufacturers and are thus "owned" by the manufacturers. An SUDID system thus serves as a data aggregation service, facilitating public access to these data without altering ownership of the data itself.

It was recognized that governance of the SUDID and related services is a question separate from ownership of the data itself. SUDID services encompass the process by which attributes are chosen and kept current (in the Demonstration Project, the work of the Expert Panel) along with the functionalities that make the attributes available to users for incorporation into EHRs, registries, and device databases. Governance of the SUDID and related services refers to the organizational structure and processes by which policy decisions are made regarding the content of the database and the scope and nature of SUDID services. The governing body has ultimate responsibility for and authority over the SUDID and would be established by the entity or entities that have ownership of the database.

The group identified four potential options for database governance. The first was establishing the Expert Panel as the governing body. The second was a multi-stakeholder executive committee or governing board derived from the Expert Work Group's participating organizations; and the third was a not-for-profit, possibly international entity. Finally, the FDA was discussed as the potential governing body, although it was felt that the Agency might be challenged in this capacity for reasons noted previously.

Financial Support of SUDID Services

Implementing SUDID services will not be without costs. Potential funding mechanisms considered were: cost sharing, public support, industry support, subscription fees, or a combination of these mechanisms. Arguably, costs should be shared by those who benefit from the SUDID service. Those entities would include hospitals, industry, FDA and other

governmental entities, and individual data consumers (e.g., clinicians, patients). The FDA is currently covering the costs of GUDID services, and a publically supported approach to SUDID services would seem to be a financially beneficial choice whereby FDA could facilitate the process of submitting and storing supplemental attribute data and coordinate it with global UDI data submission such that the incremental costs to industry of maintaining the SUDID could be minimized. Industry user fees or subscription user fees are also possible alternatives. It was proposed that subscriber user fees for those outside of the data sharing surveillance network could be implemented to support the SUDID services.

Industry Perspectives and Concerns

The discussions of the Expert Work Group meetings covered a number of related topics. Chief among these were 3 perspectives raised by the industry participants related to the requirements of the Demonstration Project itself, and comments about the future development of a device-based surveillance and research system.

Burden of Providing Data

While the *specific data for the 9 supplemental attributes* is in the public domain, the preparation of this material for submission and upload to an SUDID system *will* still entail cost and effort. Sustaining this process on a larger scale and in perpetuity will be potentially challenging and burdensome*.*

Methodology Concerns Related to Use of Device Data

Industry representatives and other Expert Work Group participants pointed out the need to establish a system of review to ensure the adequacy of methodologies employed in analyses of shared data that might be developed from a data sharing network. All of the challenges of using observational data, particularly bias and unrecognized confounding, were acknowledged

and will require thorough multi-stakeholder discussions when such a data sharing network is established. For example, a methodology for longitudinal follow-up using EHR data will be challenged by irregular follow-up and incomplete data capture, and could be supplemented with information from claims and other sources to reduce ascertainment bias.

Privacy Concerns

A data sharing network would also raise numerous ethical, legal, and medical concerns regarding the coronary data set and derivative databases designed for post-market surveillance and research. For instance, who should host or maintain these datasets and who should have access to them? All of these concerns will need to be addressed early in the course of network planning.

In addition to patient privacy concerns, the management of information considered proprietary by a manufacturer was discussed by the Work Group. The consensus was that all care should be taken to protect such information from discovery. Because this demonstration is being performed with a well established and studied technology like coronary stents, accessing proprietary information was not a significant issue with the exception of one attribute (stent to artery ratio). In the end, it was elected to remove this attribute from the list as the clinical relevance was unclear that would require substantial additional time and research to determine. Of note, this paradigm may not hold true for newer technologies where the need for post-market surveillance and research is even more pressing. An exemplar from the coronary stent arena is the impending application of bioabsorbable stents and bioabsorbable polymer drug eluting stents, where *a priori* knowledge of additional stent attributes may prove beneficial. The specific mechanisms for dealing with clinically important but proprietary device attributes will need to be discussed and resolved.

Next steps

All participants agreed that the Expert Work Group meetings provided a valuable platform to discuss emerging issues, openly and honestly share concerns, and brainstorm solutions. It was also apparent to all that, though much work had been accomplished, there was much more work to be done. Immediate deliverables arising from the meetings in support of the Demonstration Project include the following.

Manufacturers' Deliverables

In order to proceed, manufacturers of US marketed coronary stents were requested to collate and forward the data for the 10 (later reduced to 9 as noted above) selected supplemental attributes of their respective stents to populate the prototype SUDID. This included the creation of a constrained vocabulary of structural materials and coatings used to manufacture their stents to enable standardization of the collected data across all device manufacturers.

Building a Prototype SUDID

The Mercy Health technical team will be designing and building the prototype SUDID system for the Demonstration Project. Experience with this temporary database will help inform further discussions regarding operational, governance, accessibility, technical, and other issues related to the creation, maintenance, and utilization of an SUDID.

Development of Proprietary EHR Derived Data Sets Linking UDI Data

The Mercy Health technical team will link the GUDID and SUDID to a coronary stent data set containing UDIs and data from the Mercy EHR and other internal data sources. This will allow Mercy to work in coordination with Harvard epidemiologists to demonstrate the utility of such datasets in post-market surveillance, longitudinal comparative effectiveness research, and similar clinical projects pertaining to cardiac devices used at Mercy hospitals. The data set,

while remaining under the control of Mercy and containing "de-identified" data, is being designed to ultimately be part of a distributed data network in which it will be accessible to other network investigators and the FDA as part of a larger surveillance and research system (8). This approach should serve as a model for such data use at other participating centers--a key objective of the Demonstration Project. It was again recognized by the group that the generalizability of this approach will have to be investigated with other device types and in specialty areas other than cardiology.

Future Development of a UDI-based Device Surveillance System

At the end of the Expert Work Group face to face meeting, the participants took advantage of the opportunity to begin discussions about the creation of a robust system of post-market device surveillance and comparative effectiveness research utilizing UDI-associated attributes and clinical data from EHRs and national registries. Expanding the current work with coronary stents and the CathPCI Registry® to include all of the participating health systems was proposed by Mercy Health as a way of testing the potential strategy of establishing a distributed or federated network for data sharing (8).

Conceptual Model of a Distributed Network

The utility of the UDI system in post-market device surveillance and research would be significantly enhanced by development of a distributed network of health system databases that would contain both EHR and UDI-associated device data accessible to all interested parties (9). In the case of coronary stents, the network could be linked to the CathPCI Registry®, which would function as the hub [Figure 3]. The data generated by the network could be used for purposes of both post-market device surveillance and device related research. This could then serve as a model applicable not only to other cardiovascular devices but also to all implanted devices.

It was suggested that such a distributed network should leverage existing common data models and network approaches rather than building and implementing new solutions. Existing data models that may prove useful include the Observational Medical Outcomes Partnership (OMOP) Common Data Model (10). OMOP is public-private partnership established by the Foundation of the National Institutes of Health involving Pharmaceutical Research and Manufacturers of America (PhRMA) and FDA for the primary purpose of supporting pharmaceutical research by identifying the most reliable methods for analyzing huge volumes of data drawn from heterogeneous sources (11). 3M's Healthcare Data Dictionary (HDD) platform (12) or the data sharing model of the Agency for Healthcare Research and Quality (AHRQ) sponsored DEcIDE Network (13) are other options. Currently, there is not an obvious and robust network for device data sharing in place. The Work Group agreed to explore the possibility of establishing a data sharing network involving the health systems that are supporting the current Demonstration Project and to ensure that all pertinent information is incorporated in the common data model under construction. All realized that this work is out of scope for the Demonstration Project but is Mercy's proposed next step in the creation of a robust system of post-market surveillance using clinical and device specific data.

Summary

We have herein described the specifics of a Demonstration Project for the implementation of coronary stent UDI data in the information systems of a multi-hospital integrated delivery system. We anticipate that this system will provide for operational and supply chain efficiencies, facilitate the care of patients receiving these devices, and create a data set that can be linked to the CathPCI Registry® in order to enable post-market device surveillance and device related research. A key aspect of the Demonstration Project is the creation of a functioning partnership of key stakeholders, i.e., manufacturers, health systems, the NCDR, ACCF, and SCAI. Furthermore, we believe the model we are creating for this Demonstration

Project will have applicability across device types and not be limited only to cardiovascular devices, although this hypothesis will have to be tested with other devices and in specialties outside of cardiology.

Future proposed work following the Demonstration Project includes the following:

- Incorporation of coronary stent UDI data into the EHRs and associated coronary stent data sets of the other 4 large health systems that participated in the Expert Work Group

- Actualization of a distributed network of health system data sets with the CathPCI Registry® as the hub

- Development of appropriate methodologies for analyzing data generated by the distributed network

- Expansion of the work to other devices, e.g., implantable cardioverter-defibrillator and orthopedic devices

- Development of methodologies for capturing patient reported data on device performance

In conclusion, medical devices are among the most efficacious treatments of chronic disease that physicians have in their armamentarium. This efficacy has a financial cost, and disabling and occasionally fatal device-related adverse events can occur. The need to closely monitor device performance in "the real world" has never been greater and it is clear that our current methods are inefficient, cumbersome, and incomplete (14,15). The current Demonstration Project envisions the development of a more robust UDI-based post-market device surveillance system that can address many of these concerns and that can support the ongoing development of life-improving and life-saving technologies.

References

1. Normand SL, Hatfield L, Drozda J, Resnic FS. Postmarket surveillance for medical devices: America's new strategy. BMJ 2012;345:e6848.
2. Gross TP, Crowley J. Unique device identification in the service of public health. N Engl J Med 2012;367:1583-5.
3. Center for Devices and Radiological Health. Strengthening our National System for Medical Device Postmarket Surveillance. (2012). Available at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM301924.pdf. Accessed October 8, 2012.
4. Unique Device Identification System. (2012). Available at: http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0090-0001. Accessed October 8, 2012.
5. Center for Devices and Radiological Health. Medical Device Epidemiology Network Initiative (MDEpiNet). (2012). Available at: http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm. Accessed October 8, 2012.
6. Center for Devices and Radiological Health. Medical Device Epidemiology Network (MDEpiNet) - Work Streams and Projects. (2012). Available at: http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/ucm296428.htm. Accessed October 8, 2012.
7. American College of Cardiology. Principles for Relationships with Industry. (2012). Available at: http://www.cardiosource.org/~/media/Files/ACC/Relationships%20with%20Industry/Principles%20for%20Relationships%20with%20Industry.ashx. Accessed November 20,2012.
8. Brown J, Syat B, Lane K, Platt R. Blueprint for a Distributed Research Network To Conduct Population Studies and Safety Surveillance - Research Report - Final | AHRQ Effective Health Care Program. Effective Health Care Program Research Reports 2010;27.
9. Maro JC, Platt R, Holmes JH et al. Design of a national distributed health data network. Ann Intern Med 2009;151:341-4.
10. Observational Medical Outcomes Partnership. CDM and Standard Vocabularies (Version 4) | Observational Medical Outcomes Partnership. (2012). Available at: http://omop.fnih.org/CDMvocabV4. Accessed November 16, 2012.
11. Observational Medical Outcomes Partnership. Observational Medical Outcomes Partnership. (2012). Available at: http://omop.fnih.org/. Accessed November 16, 2012.
12. HDD Access. What is HDD Access?). Available at: http://www.hddaccess.com/. Accessed January 5, 2013.
13. Agency for Healthcare Research and Quality. Effective Healthcare Program. About the DEcIDE Network.). Available at: http://effectivehealthcare.ahrq.gov/index.cfm/who-is-involved-in-the-effective-health-care-program1/about-the-decide-network/. Accessed January 5, 2013.
14. FS R, ST N. Postmarketing surveillance of medical devices - filling in the gaps. N Engl J Med 2012;366:875-877.
15. Kramer DB, Xu S, Kesselheim AS. Regulation of medical devices in the United States and European Union. N Engl J Med 2012;366:848-55.

List of Tables

Table 1: Device Attributes in the GUDID

Field Name	Description
Device Identifier (DI) Information	
Issuing Agency	Organization accredited by FDA to operate a system for the issuance of UDIs
Primary DI Number	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI # will be located on the base package, which is the lowest level of a medical device containing a full UDI.
Unit of Use DI Number	An identifier assigned to associate the use of a device on a patient. This is for use when a base package contains more than one device and there is a reason to identify the single device, i.e., a UDI is not labeled on the individual device at the level of its Unit of Use. For example, a Unit of Use DI would be assigned to an individual electrode when the electrode is distributed in a package of 10. The Unit of Use DI # is not the same as the Primary DI #
Device subject to Direct Marking (DM), but Exempt	The Labeler can claim their device is exempt from Direct Marking
DM DI different from Primary DI	Indicates that the DM DI is different than the Primary DI
DM DI Number	An identifier that is marked directly on the medical device and is different than the Primary DI
Issuing Agency of Secondary DI	Name of Secondary Device Identifier (DI) Issuing agency
Secondary DI Number	An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI
COMPANY INFORMATION	
Labeler DUNS Number	Business number issued by Dun & Bradstreet that matches the Labeler (Company) name on device label

Field Name	Description
Company Name	Company name associated with the labeler DUNS # entered in the DI Record. This name should match the company name on the device label
Company Physical Address	Company physical address associated with the DUNS # entered in the DI. This address should match the address on the device label
Contact Type	The type of contact indicates if the contact is the regulatory contact (internal use only - this is a person that can be contacted by the FDA) or support contact (for public use - this is a consumer or provider contact information for the public) for the medical device
First Name	First Name of the contact
Last Name	Last Name of the contact
Contact Email	Email for the contact
Contact Phone	Phone number for the contact
DEVICE INFORMATION	
Brand Name	The Proprietary/Trade/Brand name of the medical device as used in device labeling or in the catalog. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device
Model/Version Number	The model or version number found on the device label or accompanying packaging used to identify a category or design of a device
Catalog Number	The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product
Device Description	Additional descriptor information found on label of device to help users identify and use the device appropriately
MARKETING STATUS	
Marketing Status	Indicates if device is currently being marketed or is no longer marketed
DI Record Publish Date	Indicates the date the DI Record gets published and is available via Public Search

Field Name	Description
Date Device Discontinued	Indicates the date the device is discontinued from being actively marketed by the labeler
DEVICE STATUS – Product Codes	
Product Code	Classification for pre-market devices issued by the FDA; three letter code
Product Code Name	Name associated with the three-letter Product Code
DEVICE STATUS - GMDN	
GMDN Preferred Term Code	Unique numerical five-digit code used to generically identify medical devices and related health care products
GMDN Preferred Term Name	Name associated with the GMDN Preferred Term Code
GMDN Preferred Term Definition	Description associated with the GMDN Preferred Term Code
SNOMED ConceptID	Unique numeric identifier that identifies a SNOMED Clinical Term (CT)
SNOMED Clinical Term	Comprehensive clinical terminology used for the effective clinical recording of data
DEVICE STATUS - Premarket	
Device Exempt from Premarket Authorization	Device is exempt from FDA Premarket regulations
FDA Premarket Submission Number	Number associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA, and NDA
Supplement Number	Number associated with the regulatory decision regarding the applicant's legal right to market a medical device for PMA supplements
DEVICE STATUS - FDA Listing	
FDA Listing Number	Unique number used to list medical devices that are marketed in the United States
DEVICE CHARACTERISTICS - Clinically Relevant Device Dimensions	
Size Type	Dimension type for the clinically relevant measurement of the medical device

Field Name	Description
Value	Numeric value for the clinically relevant size measurement of the medical device
Unit of Measure	The unit of measure associated with each Clinically Relevant Size. The unit of measure must conform to UCUM standards
Size Text	This will capture an undefined size type and its value, size type and unit of measure as free text
DEVICE CHARACTERISTICS - Storage and Handling Requirements	
Storage and Handling Type	Indicates storage requirements that are required for the device, including: temperature, humidity, etc.
Low Value	Indicates the low value for storage requirements, such as temperature, humidity, etc.
High Value	Indicates the high value for storage requirements, such as temperature, humidity, etc.
Unit of Measure	The unit of measure associated with the Storage and Handling Conditions. The unit of measure must conform to UCUM standards
Special Storage Conditions	Indicates any special storage requirements for the device
DEVICE CHARACTERISTICS - Production Identifiers as specified on the medical device package/label	
Controlled By Lot or Batch Number	Flag to indicate the device is managed by lot or batch number. This number can be found on the device label or packaging. Lot or Batch means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits
Controlled By Serial Number	Flag to indicate the device is managed by serial number. This number can be found on the device label or packaging. The serial number is assigned by the labeler and should be specific to each device

Field Name	Description
Controlled By Manufacturing Date	Flag to indicate the device is managed by date of manufacture, the date a specific device was manufactured
Controlled By Expiration Date	Flag to indicate the device is managed by expiration date, the date by which the label of a device states that the device must or should be used
DEVICE CHARACTERISTICS - Device Characteristics	
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	Indicates that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. Choosing yes indicates that the device is labeled with one of the following statements: (1) "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions", (2) This Product Contains Dry Natural Rubber", (3) Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions" or (4) "The Packaging of This Product Contains Dry Natural Rubber"
Device labeled as "Not made with natural rubber latex"	Indicates that natural rubber latex was not used as materials in the manufacture of the medical product and container. Only applicable to devices not subject to the requirements under 21 CFR 801.437 (i.e., only if the response to "Device required to be labeled as containing natural rubber latex or dry natural rubber" was "No")
For single-use	Indicates that the device is intended for one use or on a single patient during a single procedure
Kit	Indicates that the device is a convenience, combination, IVD, or medical procedure kit.
Combination Product	Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity; packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the products in the combination product must be a device in this case

Field Name	Description
HCT/P	Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3
Prescription Use (Rx)	Indicates that the device requires a prescription to use
Over the Counter (OTC)	Indicates that the device does not require a prescription to use and can be purchased over the counter (OTC)
Has the device been evaluated for MR Safety?	Indicates that sufficient testing has been conducted to characterize the behavior of the device in the MR environment.
If yes, choose the standardized term that applies	The three drop down values will be MR Safe, MR Conditional, and MR Unsafe. Please see the ASTM F2503 standard for more information on these three values
DEVICE CHARACTERISTICS - Sterilization	
Device packaged as Sterile	Indicates the medical device is devoid of living organisms
Requires Sterilization prior to use	Indicates that the device requires sterilization prior to use if the response to Device packaged as Sterile is "No"
Sterilization Method	Indicates the method(s) of sterilization that can be used for this device
DEVICE CHARACTERISTICS - Package	
Device Count	Number of medical devices in the base package. For example, Base Package = Box of 100 gloves, Primary DI = 001; Device Count = 100

Field Name	Description
Package DI Number	A device identifier for the package configuration that contains multiple units of the base package (does not include shipping packages). For example: 4 glove boxes in a Case -- Package DI =002 (the UDI on the Case) 10 glove boxes in a Carton -- Package DI=003 (the UDI on the Carton) 5 Cartons in Pallet -- Package DI=004 (the UDI on the Pallet) contains a 5 cartons with 10 glove boxes in a carton
Quantity per Package	The number of packages with a unique primary DI within a given packaging configuration For example: Package configuration Case with Package DI=002 contains 4 boxes of the base package DI=001, the quantity per package is 4; Package configuration Carton with Package DI=003 contains 10 boxes of the base package DI=001; the quantity per package is 10; Package configuration Pallet with Package DI=004 contains 5 cases of Package DI=003, the quantity per package is 5.
Contains DI Package	The primary DI for the base package or any lower level package configuration contained within a given package configuration For example: Package DI=002 and Package DI=003 contain the base package Case with primary DI=001; Package DI=004 contains lower level package configuration of a Carton with Package DI=003
Package Type	Text to describe the outer packaging of the product and enables users understand higher level packaging configurations

Table 2: Demonstration Project Work Group Members

Expert Panel Members
James Tcheng, MD (*Chair*), Duke University Medical Center
Kirk Garratt MSc, MD, Lenox Hill Heart and Vascular Institute of New York
Kalon K.L. Ho, MD, MSc,, Beth Israel Deaconess Medical Center
John McB. Hodgson, MD, FACC, Agora Group
J. Brent Muhlestein, MD, FACC, Intermountain Medical Center Cardiology

FDA
Jay Crowley, Senior Advisor for Patient Safety
Behnaz Minaei, Public Policy Analyst
Terrie L. Reed, MSIE, Director of Informatics
Madris Tomes,UDI External Program Manager

Health System Representatives
Mercy Health
Joseph P. Drozda, Jr., MD (**Principal Investigator**)Director of Outcomes Research
Curtis Dudley, Vice President, Integration Technology Solutions and Account Implementation
Paul Helmering, Executive Director, Enterprise Architecture
Priscilla Smith, Project Development Specialist
Mitzi Sutton, Director, Operations Mercy Health Research
Mayo Clinic
Joseph Dudas, Vice Chair, Category Management

Robert F. Rea, MD, Cardiology

Intermountain Healthcare

J. Brent Muhlestein, MD, FACC, Intermountain Medical Center Cardiology

Geisinger Medical Center

James Blankenship, MD, Director, Cardiology

Kevin Capatch, Director of Supply Chain Technology and Process Engineering

Deborah Templeton, R.Ph, MHA, Vice President, Supply Chain Services

Kaiser Permanente

Scott Adelman, MD, FACC, Chair, Cardiology Technology Committee, Northern California

Laurel Junk, Vice President, Supply Chain

Manufacturer Representatives

Abbott Vascular

Judith Fairchild, Director, AV Quality

Krishna Sudhir, MD, PhD, FRACP, FACC , Divisional VP, Medical Affairs and Product Performance

Boston Scientific Corporation

Dominic Allocco, MD, FACC, Vice President, Clinical, Division of Interventional Cardiology

Medtronic

Roberta Dressen, Vice President, Global Post-Approval Network

Kweli P. Thompson, MD, MPH, Group Vice President of Clinical Research for the Cardiac and Vascular Group

Professional Societies

American College of Cardiology

Kathleen Hewitt, Associate Vice President

Society for Cardiovascular Angiography and interventions

Joel Harder, Director for Quality Initiatives and Clinical Documents

NCDR

Nichole Kallas   Associate Director, IT Business Analyst

Table 3: SUDID Clinical Attributes and Parameters

Attribute	Definition	Parameter	Data Type
Length	Nominal length per manufacture specification	Fractional dimension in mm	4 significant digits, w/1 precision
Diameter	Nominal (inner) diameter per manufacturer specification	Fractional dimension in mm	4 significant digits, w/2 precision
Non-conventional Property	Stent having nonconventional design, variable or multiple length/diameter parameters	Covered stent Bifurcation Stent Tapered Stent	Alphanumeric
Structural Material	Composition of principal structural element	Constrained list e.g. L605 cobalt chromium -- Constrained list to be developed	Alphanumeric
Coating(s)	Non-Structural material covering surface of structural element	Constrained list -- Constrained list to be developed -- Need to handle multiples --name that would be mostly referenced --start with what is in the IFU --accommodate multiple coatings	Alphanumeric
Drug(s)	Active agent released from stent	NDC code (National Drug code) directory (default) --Use name if no applicable NDC code—do it uniformly	Alphanumeric
Strut Thickness	Maximum nominal thickness of stent struts on a radius from the center of the stent	Dimension in microns	4 integer digits
Surface to Artery Ratio*	Percentage of the surface area of the artery covered by the stent at nominal expansion of the stent		3 significant digits, w/1 precision
Expansion Method	Method used to achieve nominal stent deployment	Balloon Self	Alphanumeric
MRI Compatibility	MRI compatibility category per testing	4 categories per existing standard: --Safe --Conditional --Unsafe --Not tested	4 Categories

*This attribute was originally selected by the Expert Panel but subsequently withdrawn.

Table 4: Examples of SUDID Clinical Attribute Data

Manufacturer	Product	Length	Diameter	Non-conventional Property	Structural Material	Coating(s)	Drug(s)	Strut Thickness	Expansion Method
Abbott	Xience V Everolimus Eluting Coronary Stent System	8mm	2.5mm	N/A	L-605 Cobalt Chromium Alloy	Everolimus and Polymers	Everolimus	0.0032'' 81 µm	Balloon
Boston Scientific	Taxus Express Monorail	8mm	2.50mm	N/A	316L SS	Translute Polymer (SIBS)	Paclitaxel	132 µm	Balloon
Medtronic	Resolute Integrity Zotarolimus-Eluting Coronary Stent System	8mm	2.50mm	N/A	MP35N Cobalt Alloy	Biolynxpolymer & Parylene	Zotarolimus	88.9 µm	Balloon

Table 5: Use Case Attributes

Use Case Name	Description	Attributes Needed (GUDID/SUDID)
Point of Care UDI Scan	Query device attributes immediately prior to use	GUDID & SUDID
Catalog/device ordering	Ordering by attribute, device, substitution, tracking devices in disasters	GUDID & SUDID
Medical Documentation	Procedure reporting, health care communication	GUDID & SUDID
EHR/Patient Portal	Attributes stored as data outside of procedure report, patient education	GUDID & SUDID
Queries (by attribute)	Support for process measurement, QI projects	GUDID & SUDID
Extending indications for use	Support of alternative processes for device labeling	GUDID & SUDID
Comparative effectiveness research	Support of comparative effectiveness	GUDID & SUDID
Registries	Process, performance, quality outcomes, education, performance improvement Continuing Medical Education	GUDID & SUDID
PHR/Consumer	Information to patient, education, public communication, healthcare advocates	GUDID & SUDID
Supply chain management	Competitive bidding by attributes	GUDID & SUDID
Advance notice of expiration	Inventory management	GUDID
Administrative uses	Asset and financial management	GUDID
Device Recall	Easily identify patients who received the affected lots and locate unused product in clinical use areas	GUDID
Federated Data Exchange	Increased ability to report outcomes across products	GUDID
Adverse Event Reporting	Increased ability to report adverse events and outcomes	GUDID
Anti-counterfeiting	Increased protection against fraud	GUDID
Tracking of patients with multiple devices	Allow providers to learn information about prior device implantation, even when prior medical records are not available	GUDID
Federal (post-market surveillance)	Specify device exposure and usage for linkage with safety and research outcomes	GUDID

List of Figures

Figure 1: Coronary Stent UDI Tracking System

Key:

EHR = Electronic Health Record

ERP = Enterprise Resource Processing Software

SUDID = Supplemental Unique Device Identifier Database

ROi = Mercy's supply chain company

EDI = Electronic Data Interchange

GUDID = FDA's Global Unique Device Identifier Database

GHX = A multi-stakeholder owned company whose purpose is to optimize healthcare supply chain efficiency (http://www.ghx.com/)

GS1 = One of the companies that set standards for the display of device identifiers including bar codes (http://www.gs1.org/)

GDSN = Global Data Sychronisation Network: A network of companies and suppliers built around the GS1

Global Registry that allows for sharing device identification data (http://www.gs1.org/gdsn)

Figure 2: Single EHR UDI Tracking System Data Flow
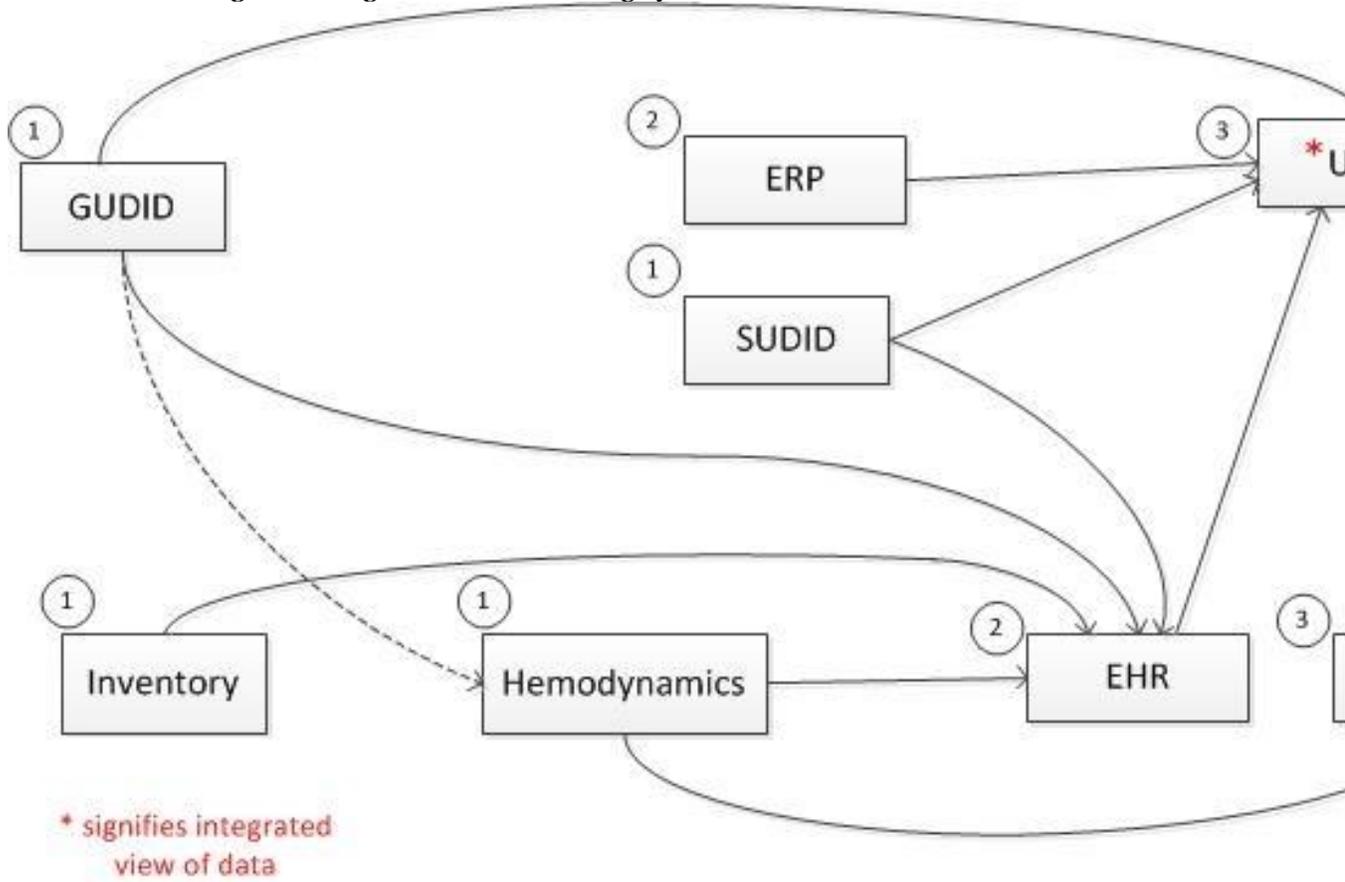
Global Unique Device Identification Database (GUDID)   Electronic Health Record (EHR)
Enterprise Resource Processing (ERP)   Unique Device Identification Research (UDIR)
Supplemental Unique Device Identification Database   Enterprise Data Warehouse (EDW)
(SUDID)

Figure 3: Coronary Stent Distributed Data Sharing Network
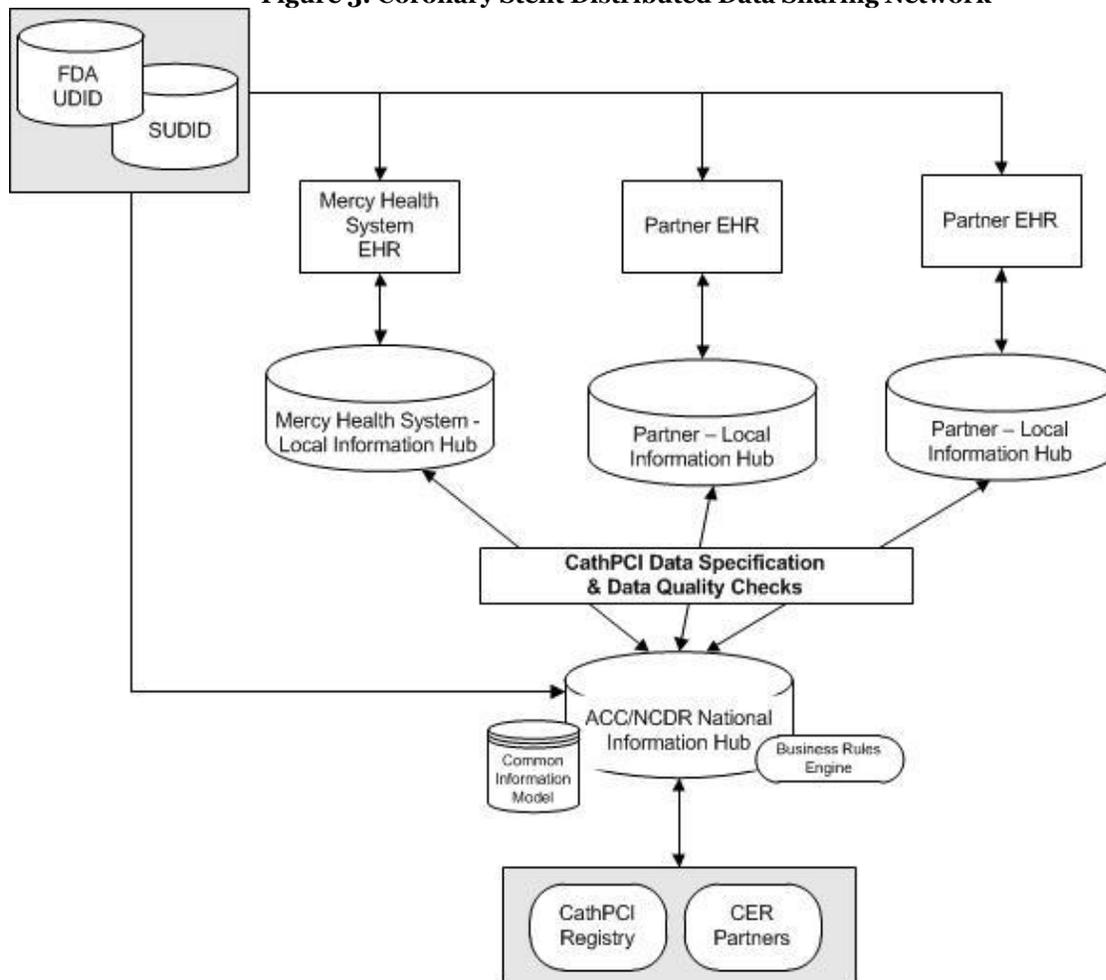
Electronic Health Record (EHR)
American College of Cardiology (ACC)
Comparative Effectiveness Research (CER)

Unique Device Identification – Architecture Study

MTS Data Engineering & Analytics - Architecture Study

Title:	UDI Phase 2
Stakeholders:	Dr. Joe Drozda
EA Contact:	Jim Roach
Contributors:	Paul Helmering, Tom Forsyth
Version:	1.0

Version History

Version	Date (mm/dd/yy)	Changed By	Change Log Description
0.0	04/08/13	J. Roach	Initial Draft
1.0	04/10/13	J. Roach	Additional content, updates based on initial reviews
2.0	05/23/2013	J. Roach	Revisions based on review
2.5	06/05/2013	J.Roach	Incorporated Architecture 'option B' along with additional revisions based on feedback.
3.0	06/25/2013	J. Roach	Modified diagrams to properly reflect IPD (instead of EDW), added gaps between demonstration pilot and phase 2 pilot.
3.5	07/09/2013	J. Roach	Restructured sections and updated diagrams
3.7	08/23/2013	J. Roach	Final edits

Business Study

Contents

Glossary

Term	Definition and/or Description
EHR (or EMR)	Mercy's 'Electronic Health Record' application which is utilized for patient, procedure, and clinical documentation
ERP	'Enterprise Resource Planning' application utilized for ordering of medical supplies and devices.
GDSN	GS1 Global Data Synchronization Network
GLN	GS1's Global Location Number which uniquely identifies a facility/location.
GMDN	Global Medical Device Nomenclature
GS1	International non-profit association which defines global specifications for management of supply chain identifiers and barcode standards
GTIN	GS1 assigned product-identifier for 'Global Trade Item Number'
GUDID	The FDA's "Global Unique Device Identification" reference database of manufacturer provided device attributes
HEMO	Hemodynamics application which is utilized by Mercy for the clinical documentation during a catheterization / PCI procedure
HMDYN	Prefix for database tables within UDIR which contain Hemodynamics procedure data
INVNTRY	'Inventory' application which is utilized by Mercy for 'point of use/point of care' supply and medical-device selection and utilization accounting
IPD	Abbreviation for the Mercy 'Integrated Patient Data-Mart'
OMOP	Clinical data-model standard developed by the Observational Medical Outcomes Partnership (OMOP)

SPLY	'Supply Chain' application which is utilized by Mercy for ordering medical supplies and devices; provides electronic 'Item Master' for all items purchased
SUDID	"Supplemental Unique Device Identification" reference database of clinically meaningful device attributes; currently hosted by Mercy
UDIR	Abbreviation for the UDI Demonstration Project 'Research' database, supporting device identification, surveillance, and comparative effectiveness research capabilities

Executive Summary

The primary aim of the 'Unique Device Identification (UDI)' Demonstration Project was to develop an integrated solution which would serve as a 'pilot' of a national system for the baseline capture of UDI-associated device data on coronary stents and EHR-derived clinical data for the purposes of post-market surveillance and research using those data elements. The Demonstration, while ongoing, is achieving its goals and planning has begun on a strategy to enhance the solution architecture so that multiple healthcare organizations can use the model for capturing the same data and create a national system of surveillance and research data sets and ultimately incorporate additional device types and/or classes into the processing model.

The purpose of this document is twofold:
1. To describe in some detail the design and implementation of the information system solutions used in the UDI Demonstration Project, and
2. To make some preliminary observations regarding the system design to support the distributed data network envisioned in the proposed UDI Phase 2 project.

As determined by the Healthcare Transformation Group (HTG) Research and Development (R&D) team the goals of the UDI 'Phase 2' project are as follows,:

- To implement a coronary stent UDI based surveillance system in the EHRs of 4 of the health system members of HTG and in the NCDR's CathPCI Registry

- To establish a distributed network of the 4 HTG systems' UDI-based device databases with the CathPCI Registry as the hub

- To assess the validity and utility of data obtained from the distributed network for purposes of post-market surveillance

The UDI Demonstration Project

The UDI Demonstration Project was constrained to focus on coronary stents implanted within a Cardiac Catheterization Laboratory (Caht Lab) setting, and involved five Mercy Hospitals (St. Louis, Springfield, Washington, and Joplin MO, as well as Rogers AR). The resulting solution architecture for the project is depicted below in Figure 1 - 'Mercy UDI Pilot Architecture':
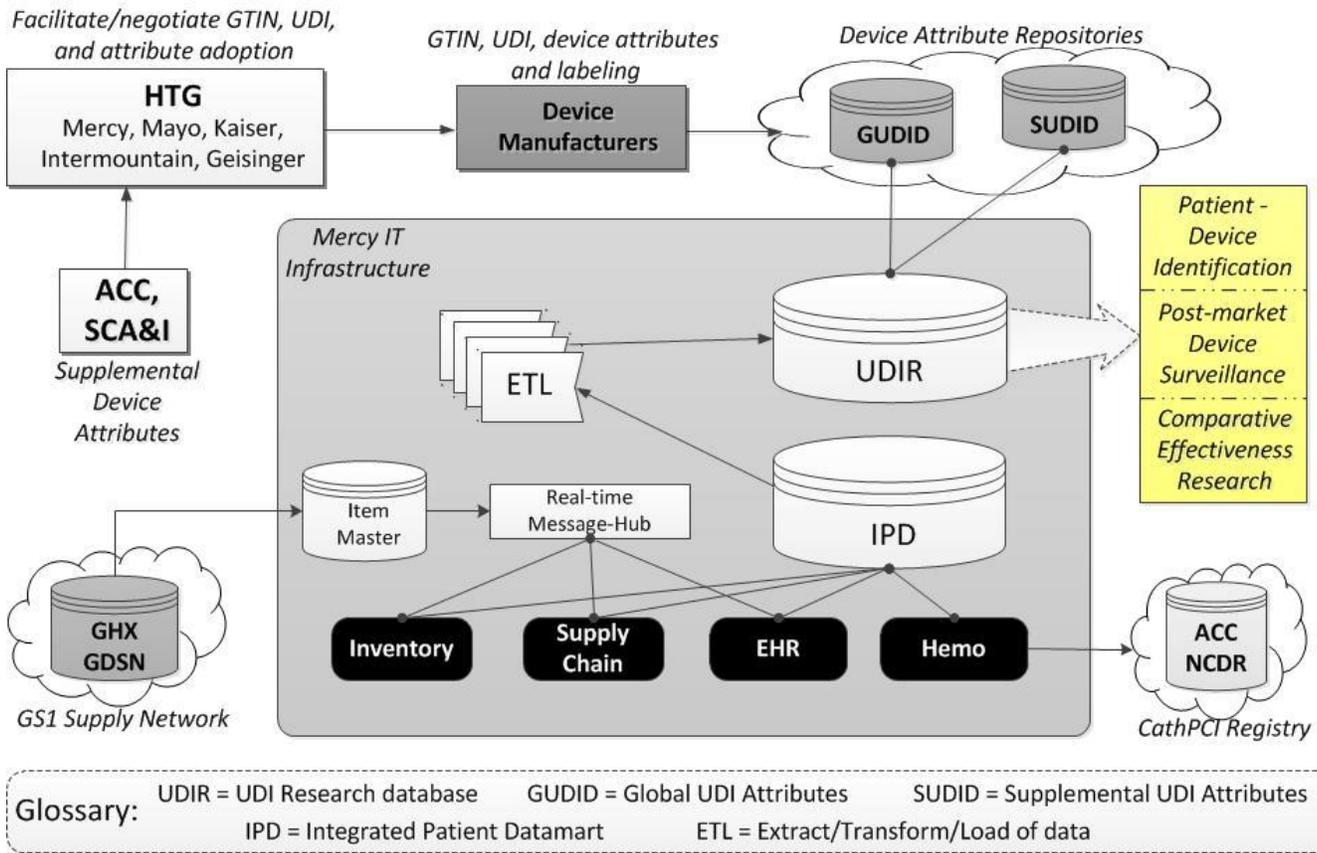
Figure 1: Mercy UDI Pilot Architecture

As part of the Demonstration Project Mercy partnered with several cardiology, manufacturer, and supply-chain experts in the definition and implementation of 9 'supplemental' coronary stent device attributes intended to meet the needs of safety surveillance and research. All data that were incorporated into the UDIR were first electronically captured and stored in Mercy's EHR; Mercy's Enterprise Resource Planning (ERP)/supply chain software; as well as ancillary supporting systems and databases. In addition to supporting surveillance and research, incorporation of UDI information into the EHR in this fashion has enabled integrated adverse-event reporting at the point of care, as well as more reliable safety and recall notifications and tracking of medical devices. Data capture is integrated into Mercy's clinical and business processes, and will be utilized for analysis, reporting, and research purposes. The post-market device surveillance and research will be carried out in conjunction with the 'National Cardiovascular Data Registry (NCDR)' through its CathPCI Registry. A key

deliverable for the initial UDI Demonstration Project was the creation and hosting of an integrated UDI 'research' database (the "UDIR"), which is a repository of clinical, device, and other data that is intended for post-market medical device surveillance, and research. The following diagram (Figure 2) provides a high-level dataflow depicting the major data sources incorporated into the resulting integrated UDIR repository:
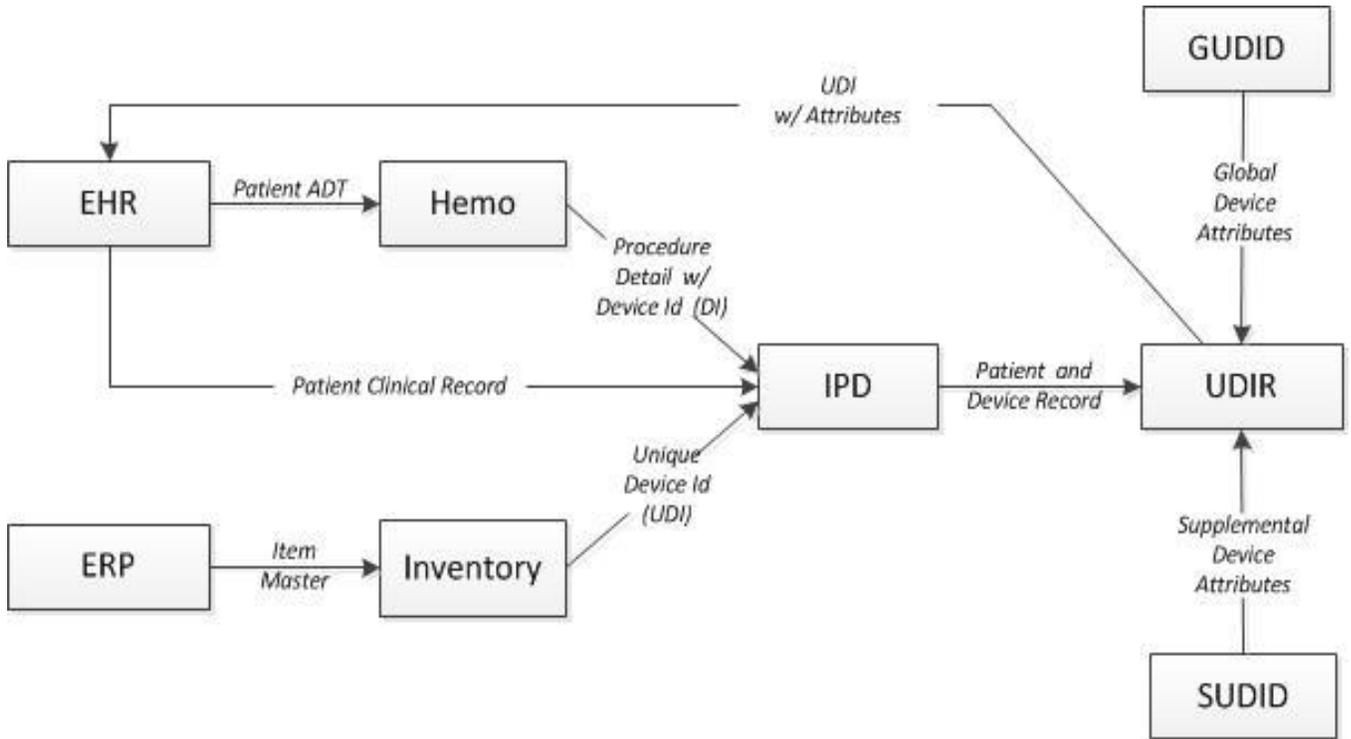
Figure 2: Mercy UDI Pilot Data Sources

Figure 3 depicts a model containing the various data architecture 'layers' which comprise the infrastructure of the UDI Demonstration Project. The model calls for the progression of data from multiple, non-integrated, source applications and systems through the transformed and combined patient/device integration data layer to the enhanced, enriched, and clinically-oriented research and surveillance layer.
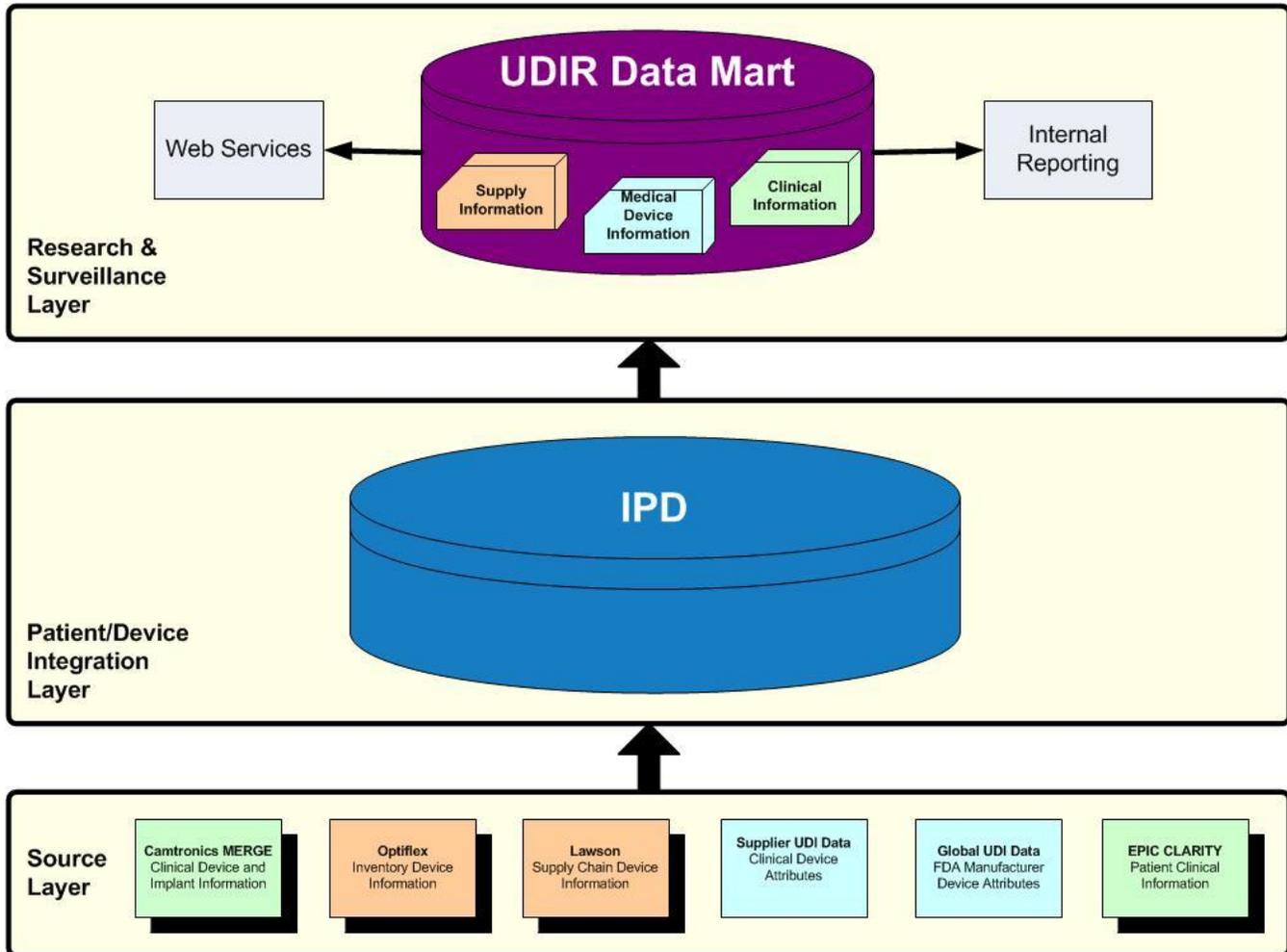
Figure 3: UDI Pilot – Data Architecture Layers

UDI Phase 2

The system development in Phase 1 of the UDI work at Mercy was designed to provide a solid foundation for UDI Phase 2 in which Mercy's partner health systems will create their own mechanisms for capturing UDI data and will build UDIRs for inclusion in a distributed data network.

The roadmap presented herein is proposed as an architecture that supports the efficient transmission and exchange of relevant electronic content amongst the UDIRs of the organizations participating in the UDI 'Phase 2' project. The proposed design will enable a data research framework which will not only accommodate additional categories of medical device surveillance and comparative research, but also research across multiple participating organizations. The desired model facilitates near real-time communication and exchange of data from the UDIRs of each organization. .

Figure 3 depicts the high-level architecture of the proposed solution for this exchange of UDIR data across the HTG partners, in which a 'hub and spoke' model is implemented with the NCDR serving as a "national information hub" providing the network with a number of services including the processing of inquiries among the systems' networked UDIRs and maintaining the network's business rules engine and common data model. This model would enable pattern recognition within data sets allowing extraction of information from social interactions (e.g., heightened communication about a particular device); notification "triggers" to "follow" topics of interest; and identification of significant clinical events. The model also maintains the CathPCI Registry data specifications and calls for NCDR to perform data quality checks for the network. The NCDR will also link the CathPCI Registry with the network and pull in data from other sources, e.g., claims databases. This model provides each participating partner the capability of submitting a UDI-based query to the central 'hub' for broadcasting to the shared research network, which would in-turn interrogate 'other' participating data repositories for the requested data.
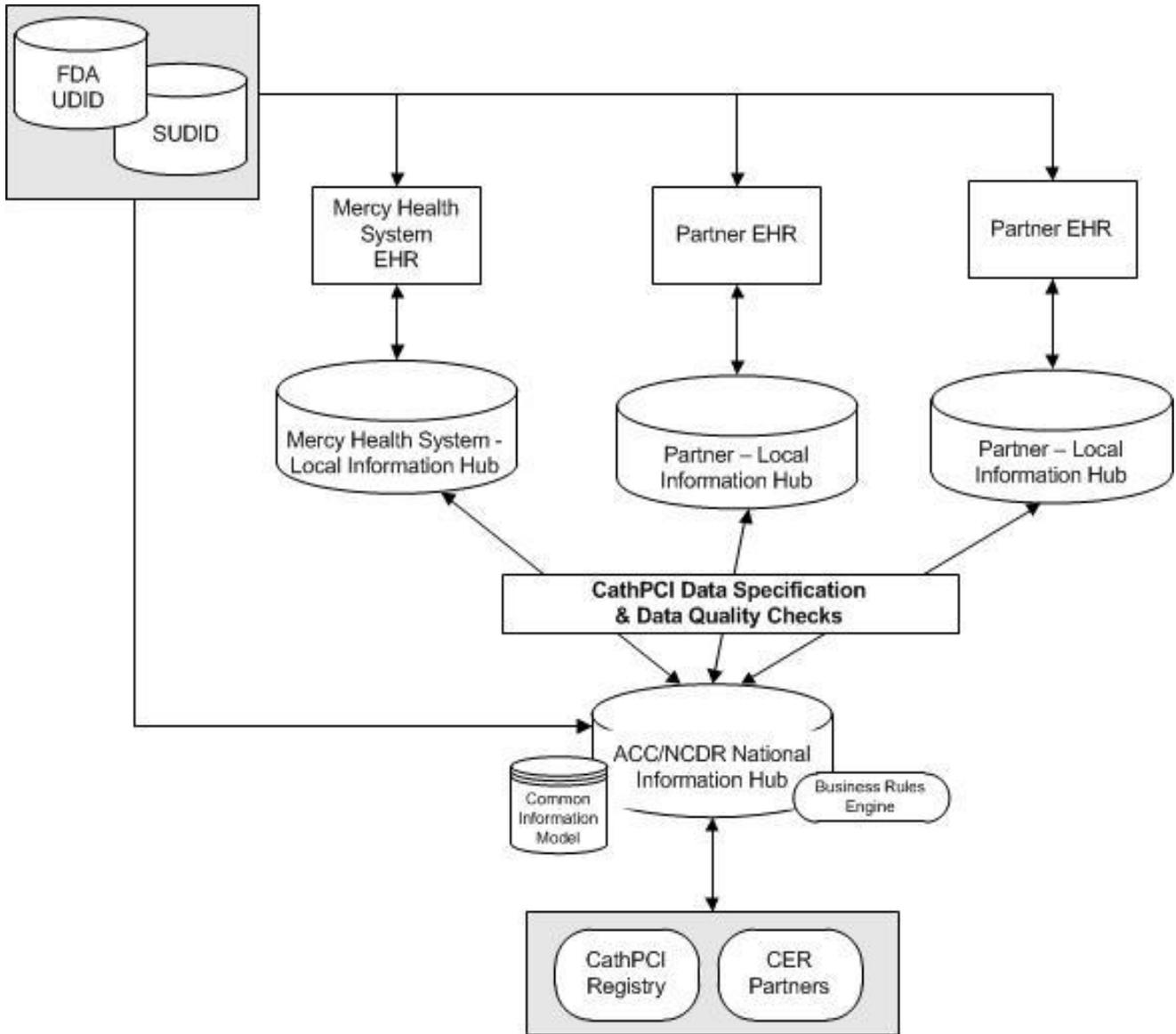
Figure 4: UDI Phase 2 - 'Hub and Spoke' Model

In order to enhance and expand the existing Demonstration Project architecture to meet the needs of the UDI Phase 2 project, the following IT architecture 'gaps' have been identified and will need to be addressed in a subsequent design document with technological solutions which are acceptable to the healthcare organizations involved.

The architecture gaps identified thus far are as follows:

1. Definition and development of a common, shared surveillance and research database architecture and standardized data-model (potentially OMOP) which will allow partners to share large data sets and common data elements in research and surveillance and which will additionally enable efficient data storage and the development and sharing of common queries and research models across partners

2. Definition and development of a UDI HL7-based messaging format which will allow shared exchange of common information sets across partners, efficient data processing, and the development and sharing of common software components

3. Identification and agreement for the messaging model involved in the transmission of UDI data which will standardize how systems "talk" to one another, how they communicate technically, error processing, and monitoring and logging of activity through the national hub for performance and auditing functions

4. Determination of several key 'Master Data Management' data-sources to be utilized by all participating organizations, including, but not limited to:

   a. Standard industry source for Medical Device descriptions such-as GMDN or GS1
   b. Standard source for Medical and Manufacturing facilities location identification

5. Definition and development of data quality checks which will serve as "filters" for data passing through the national hub, ensuring standard values and clean data to the greatest extent possible
6. Definition and development of security architecture to protect all data and interactions from unauthorized use
7. Definition and development of business rules engine which will recognize patterns in communication and data sets allowing extraction of information from social interactions (e.g., heightened communication about a particular device); notification "triggers" to "follow" topics of interest; identification of significant clinical events; as well as detection of common/uncommon patterns of care
8. Device recall capabilities which will provide the architecture and pre-defined communication patterns for sharing recall notifications from the national hub to partners, and partner data content back to the national hub

Appendix A: UDI Demonstration Pilot - Key Observations

These observations do not constitute a full lessons-learned review. They are based upon 'lessons learned' as a result of the current UDI Demonstration Project.

ID #	Observations (Key Findings)	Recommendations
1	Mercy discovered that coronary stents are not "serialized" by device manufacturers and are instead tracked at the "Lot" level. Mercy was required to generate a unique serial number and affix to device packaging upon receipt because of inventory software restrictions.	In order to completely exercise UDI definition, a different type of medical device should be piloted which does have manufacturer provided production identifiers.
2	Slow adoption of clinical software vendors to comply with the UDI rule caused Mercy to change the original demonstration solution architecture, based on near real-time messaging, to that of a batch-oriented daily integration of data.	Acquire firm commitment from all software vendors, involved in subsequent projects that they will enable/accept HL-7 based messaging of patient & device data.
3	Mercy discovered that the clinical hemodynamic software vendor intentionally modifies the device packaging barcode by replacing the 'check-sum' digit with an arbitrary value of "X". This negated the original design to utilize the hemodynamic software as a reliable 'source' of the device barcode and instead switch to the Inventory Management software.	Acquire commitment from clinical software vendors that they will not intentionally modify the barcode data when storing in their proprietary databases.
4	Majority of the UDI pilot data-sources provide a localized version of a device description; in order to define a 'standard' description, Mercy decided to utilize that provided by the GMDN. Since GMDN data are yet to be provided by the FDA GUDID, a decision was made to include ALL device descriptions in the research database, until such time that the GMDN can be sourced as the 'standard'.	Determine a healthcare standard for medical device descriptions, to be referenced in subsequent UDI-based system development long term the GMDN will be available in the GUDID, until then we will provide an interim solution.
5	Mercy utilizes a GDSN from GS1 as a "master" data source for all medical supplies, including GS1 GLN facility id, however, this does not align with the FDA since they utilize the 'Dun and Bradstreet' DUNS number as location id.	Develop a 'GLN to DUNS' crosswalk database.

Appendix B: UDI Demonstration Pilot - Data Model

Two versions of the data-model were developed as part of the UDI Demonstration Project; both are attached as links to PDF files: The "UDI Physical Data Model" pdf and the UDI Patient Clinical Data Submodel pdf, which contains a 'Logical' view of the patient clinical data elements. Accompanying these is a third link to an Excel file entitled "UDI Data Model Metadata," which contains the full metadata dictionary for the entire UDI data-model.

These thinks are provided below:

UDI Physical Data
Model

UDI Patient
Clinical-Data Submodel

UDI Data Model
Metadata

Appendix C: UDI Demonstration Pilot - Data-Dictionary

Catheterization Primary Key Identifiers (HEMO)

Domain	Datatype	Length	Definition
PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).
ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "CATH_IMPLNT_MSTR"
HEMODYNAMIC CATHETERIZATION IMPLANT MASTER IDENTIFIER	NUMBER	20	BUS DESCR: Unique, sequential number generated as the key for the Camtronics MERGE system master record.

Medical Device Supply Data (HEMO)

Domain	Datatype	Length	Definition
PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).

ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "CATH_SUPLY"
ITEM IDENTIFICATION NUMBER	NUMBER	10	
DEVICE IDENTIFICATION NUMBER	NUMBER	10	
MANUFACTURER BARCODE NUMBER	VARCHAR2	125	
ITEM CATEGORY NAME	VARCHAR2	60	
ITEM DESCRIPTION	VARCHAR2	60	
DEVICE LENGTH MEASURE	NUMBER	10	
DEVICE DIAMETER MEASURE	NUMBER	10	
DEVICE IDENTIFICATION NUMBER	NUMBER	10	

Patient Clinical Data Surveillance Elements (EHR Subset)

Domain	Datatype	Length	Definition
PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).
ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "PTNT_CLNCL_INFO"

PATIENT ENCOUNTER CONTACT SERIAL NUMBER IDENTIFIER	NUMBER	18	BUS DESCR: The serial number for the patient contact of the patient record. This number is unique across all patient contacts in the system.
EPIC PATIENT IDENTIFICATION NUMBER	VARCHAR2	10	BUS DESCR: The unique ID assigned to the patient record (EPT .1). This ID may be hidden in a public view of the PATIENT table.
ZIP CODE	VARCHAR2	50	BUS DESCR: The ZIP Code area in which the patient lives.
PATIENT BIRTH DATE	DATE		BUS DESCR: The date on which the patient was born. (formatted as MM/DD/YYYY).
PATIENT GENDER ABBREVIATION	VARCHAR2	254	BUS DESCR: The abbreviation identifying the patient's sex/gender.
PATIENT ENCOUNTER CONTACT DATE	DATE		BUS DESCR: The date of a patient encounter contact in calendar format. (formatted as MM/DD/YYYY).
CURRENT PRIMARY CARE PHYSICIAN IDENTIFICATION NUMBER	VARCHAR2	18	BUS DESCR: The unique ID of the provider record for the PCP. This ID may be encrypted if you have elected to use enterprise reporting's security utility.
CURRENT PRIMARY CARE PHYSICIAN NAME	VARCHAR2	254	BUS DESCR: The name of the patient's current primary care physician.
VISIT PROVIDER IDENTIFIER	VARCHAR2	18	BUS DESCR: The unique internal identifier assigned to the service provider for the patient's most recent visit.
VISIT PROVIDER NAME	VARCHAR2	254	BUS DESCR: The name of the servicing provider for the patient's most recent visit.
EPIC PROVIDER IDENTIFICATION NUMBER	VARCHAR2	18	BUS DESCR: The unique EPIC ID assigned to the provider record.
DEPARTMENT NAME	VARCHAR2	254	BUS DESCR: The text name of the unit for the most recent location of the patient for this patient contact.
ZIP CODE	VARCHAR2	50	BUS DESCR: The ZIP/postal code of the address for the department.

….multiple additional elements removed for clarity…

Medical Device Master (Inventory)

Domain	Datatype	Length	Definition
PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).
ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "INVTRY_SER_ITEM_MSTR"
ITEM IDENTIFICATION NUMBER (VARCHAR)	VARCHAR2	25	
ITEM DESCRIPTION	VARCHAR2	60	BUS DESCR: The name/description of a supply chain inventory item.
PAR LOCATION NAME	VARCHAR2	50	
FACILITY IDENTIFICATION NUMBER	VARCHAR2	10	
MANUFACTURER ITEM NUMBER	VARCHAR2	25	
EPIC CHARGE NUMBER	VARCHAR2	15	BUS DESCR: The charge number from Mercy's EPIC clinical information system.
ISSUE UNIT OF MEASURE CODE	VARCHAR2	3	
ON HAND QUANTITY	NUMBER	10	
LOT NUMBER	VARCHAR2	50	
SERIAL NUMBER	VARCHAR2	50	
EXPIRATION DATE	DATE		
DISPOSITION NAME	VARCHAR2	20	
STATUS NAME	VARCHAR2	20	
SERIALIZED ITEM PAR LOCATION NAME	VARCHAR2	13	

Domain	Datatype	Length	Definition
VENDOR ITEM NUMBER	VARCHAR2	25	BUS DESCR: The item number as supplied by the vendor from Mercy's supply chain system (Lawson). This might be null if the Vendor is not available at the time the Contract is bound.
TISSUE ITEM INDICATOR	VARCHAR2	1	
SERIALIZED ITEM INDICATOR	VARCHAR2	1	
INVENTORY DETAIL KEY NUMBER	VARCHAR2	38	
MANUFACTURER BARCODE NUMBER	VARCHAR2	125	

Medical Device Utilization (Inventory)

Domain	Datatype	Length	Definition
PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).
ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "INVTRY_SER_ITEM_TRANS"
ITEM IDENTIFICATION NUMBER (VARCHAR)	VARCHAR2	25	
ITEM DESCRIPTION	VARCHAR2	60	BUS DESCR: The name/description of a supply chain inventory item.
PAR LOCATION NAME	VARCHAR2	50	
FACILITY IDENTIFICATION NUMBER	VARCHAR2	10	
TRANSACTION CODE	VARCHAR2	10	
TRANSACTION DATE	DATE		
TRANSACTION QUANTITY	NUMBER	10	
PATIENT ACCOUNT IDENTIFICATION NUMBER	VARCHAR2	20	

PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
TERMINAL IDENTIFICATION NUMBER	VARCHAR2	15	
TERMINAL PAR LOCATION NAME	VARCHAR2	50	
ISSUE COMMENT TEXT	VARCHAR2	255	
SERIAL NUMBER	VARCHAR2	50	
LOT NUMBER	VARCHAR2	50	
EXPIRATION DATE	DATE		
EPIC CHARGE NUMBER	VARCHAR2	15	BUS DESCR: The charge number from Mercy's EPIC clinical information system.
DOCTOR NUMBER	VARCHAR2	15	
LAST NAME	VARCHAR2	80	
FIRST NAME	VARCHAR2	80	
VENDOR ITEM NUMBER	VARCHAR2	25	BUS DESCR: The item number as supplied by the vendor from Mercy's supply chain system (Lawson). This might be null if the Vendor is not available at the time the Contract is bound.
TISSUE ITEM INDICATOR	VARCHAR2	1	
SERIALIZED ITEM INDICATOR	VARCHAR2	1	
MANUFACTURER BARCODE NUMBER	VARCHAR2	125	
ISSUE COST AMOUNT	NUMBER	15	
UNIT OF MEASURE CODE	VARCHAR2	20	BUS DESCR: The unit of measure associated with each Clinically Relevant Size. The unit of measure must conform to UCUM standards.

Purchasing Item Master (Supply-Chain)

Domain	Datatype	Length	Definition
PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).

ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "MV_SUPLY_ITEM_MSTR_INFO"
VENDOR IDENTIFICATION NUMBER	VARCHAR2	9	BUS DESCR: The unique identifier for a vendor in the Lawson system.
VENDOR ITEM NUMBER	VARCHAR2	25	BUS DESCR: The item number as supplied by the vendor from Mercy's supply chain system (Lawson). This might be null if the Vendor is not available at the time the Contract is bound.
VENDOR NAME	VARCHAR2	30	BUS DESCR: The name of a Vendor who distributes merchandise.
ITEM DESCRIPTION	VARCHAR2	60	BUS DESCR: The name/description of a supply chain inventory item.
ITEM DESCRIPTION	VARCHAR2	60	BUS DESCR: The name/description of a supply chain inventory item.
VENDOR CATALOG NUMBER	VARCHAR2	32	

UNITED NATIONS STANDARD PRODUCTS AND SERVICES CODE NUMBER	VARCHAR2	8	BUS DESCR: A code number identifying a product according to the United Nations Standard Produces and Services Code system. The United Nations Standard Products and Services Code® (UNSPSC®) provides an open, global multi-sector standard for efficient, accurate classification of products and services. The UNSPSC offers a single global classification system that can be used for:
			    Company-wide visibility of spend analysis
			    Cost-effective procurement optimization
			    Full exploitation of electronic commerce capabilities
			UNSPSC is a member funded and supported initiative.

Domain	Datatype	Length	Definition
UNITED NATIONS STANDARD PRODUCTS AND SERVICES CODE DESCRIPTION	VARCHAR2	255	BUS DESCR: A text description of a product or service in the UNSPSC system.
UNIT OF MEASURE CODE STRING TEXT	VARCHAR2	250	BUS DESCR: Pipe-delimited string of Global Trade Identification Numbers. The sequence of these numbers coincides with the sequence of UOM codes in the related UOM_STRING_TXT column.
GLOBAL TRADE IDENTIFICATION NUMBER STRING TEXT	VARCHAR2	500	BUS DESCR: Pipe-delimited string of unit of measure codes. The sequence of these numbers coincides with the sequence of GTIN codes in the related GTIN_STRING_TXT column.
ITEM IDENTIFICATION NUMBER (VARCHAR)	VARCHAR2	25	
MANUFACTURING CATALOG NUMBER	VARCHAR2	35	
MANUFACTURER CODE	VARCHAR2	4	BUS DESCR: Unique identifier for a manufacturer.
MANUFACTURER DIVISION ABBREVIATION	VARCHAR2	4	BUS DESCR: Text abbreviation for the name of a manufacturing division.

Medical Device Primary Key Identifiers

Domain	Datatype	Length	Definition
PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).
ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "DVC_MASTER"
MEDICAL DEVICE MASTER IDENTIFIER	NUMBER	20	BUS DESCR: Unique, surrogate key assigned to each medical device in this table.

PRIMARY DEVICE IDENTIFICATION NUMBER	VARCHAR2	25	BUS DESCR: An identifier that is the main (primary) lookup for a medical device product and meets the requirements to uniquely identify a device through its distribution and use.
ISSUING AGENCY NAME	VARCHAR2	30	BUS DESCR: Name of Device Identifier (DI) Issuing agency.
HAVE CLINICAL DEVICE PROFILE INDICATOR	VARCHAR2	1	BUS DESCR: Indicator flag that identifies whether the CLNCL_DVC_PRFL table has been populated for the device master record.
HAVE MEDICAL DEVICE PROFILE INDICATOR	VARCHAR2	1	BUS DESCR: Indicator flag that identifies whether the MED_DVC_PRFL table has been populated for the device master record.

Medical Device Profile

Domain	Datatype	Length	Definition
PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).
ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "MED_DVC_PRFL"

UNIT OF USE DEVICE IDENTIFICATION NUMBER	VARCHAR2	25	BUS DESCR: An identifier assigned to associate the use of a device on a patient. This is for use when a UDI is not assigned to the individual device at the level of its Unit of Use. For example, a Unit of Use DI would be assigned to an individual electrode when the electrode is distributed in a package of 10.
DIRECT PART MARKETING EXEMPTION INDICATOR	VARCHAR2	1	BUS DESCR: The Labeler can claim their product is exempt from Direct Part Marking.
DIRECT PART MARKETING EXEMPTION REASON CODE	VARCHAR2	1	BUS DESCR: The Labeler can claim their product is exempt from Direct Part Marking and this data element will collect one of the values allowable by the Proposed Rule for Exemption from the UDID system.
DIFFERENT DIRECT PART MARKETING DEVICE IDENTIFIER INDICATOR	VARCHAR2	1	BUS DESCR: Indicates that the DPM DI is different than the Primary DI.
DIRECT PART MARKETING DEVICE IDENTIFICATION NUMBER	VARCHAR2	25	BUS DESCR: An identifier that is marked directly on the medical device and is different than the Primary DI.
DUN AND BRADSTREET NUMBER	VARCHAR2	9	BUS DESCR: Data Universal Number System (DUNS) business identifier issued by Dun & Bradstreet that matches the Labeler (Company) name on device.
COMPANY NAME	VARCHAR2	100	BUS DESCR: Company name associated with the DUNS number entered in the DI Records Management module.
COMPANY PHYSICAL ADDRESS TEXT	VARCHAR2	1000	BUS DESCR: Company physical address associated with the DUNS # entered in the DI Records Management module.

BRAND NAME	VARCHAR2	80	BUS DESCR: The Proprietary/Brand name of the medical device as used in product labeling or in the catalog (e.g., Flo-Easy Catheter, Reliable Heart Pacemaker, etc.). This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device.
PRODUCT PART OF BRAND NAME INDICATOR	VARCHAR2	1	BUS DESCR: This brand name indicator identifies when the product is part of a brand name family.
MODEL OR VERSION NUMBER	VARCHAR2	256	BUS DESCR: The exact model number or version number found on the device label or accompanying packaging.
PRODUCT PART OF MODEL FAMILY INDICATOR	VARCHAR2	1	BUS DESCR: This model family indicator identifies when the product is part of a model family.
DEVICE DESCRIPTION	VARCHAR2	2500	BUS DESCR: Detailed text description of device.
MARKETING STATUS CODE	VARCHAR2	8	BUS DESCR: Indicates if device is currently being marketed or is no longer marketed.
DEVICE IDENTIFICATION RECORD PUBLISH DATE	DATE		BUS DESCR: Indicates the date the DI Record should be published in the public search module.
DEVICE DISCONTINUED DATE	DATE		BUS DESCR: Indicates the date the Device is discontinued from being actively marketed.
GLOBAL MEDICAL DEVICE NOMENCLATURE PREFERRED TERM INDICATOR	VARCHAR2	5	BUS DESCR: Unique numerical five-digit number used to generically identify medical devices and related health care products.
GLOBAL MEDICAL DEVICE NOMENCLATURE PREFERRED TERM NAME	VARCHAR2	360	BUS DESCR: Name associated with the GMDN Preferred Term Code.
GLOBAL MEDICAL DEVICE NOMENCLATURE PREFERRED TERM DESCRIPTION	VARCHAR2	4000	BUS DESCR: Description associated with the GMDN Preferred Term Code.
PACKAGED STERILE INDICATOR	VARCHAR2	1	BUS DESCR: This is to indicate the medical device is free from viable microorganisms.
REQUIRE STERILIZATION INDICATOR	VARCHAR2	1	BUS DESCR: If No, does it require sterilization prior to use?

STERILIZATION METHOD DESCRIPTION	VARCHAR2	200	BUS DESCR: Method(s) of sterilization that can be used for this device.
CONTAIN LATEX INDICATOR	VARCHAR2	1	BUS DESCR: This is to indicate the medical device contains allergens specifically natural rubber.
NO NATURAL RUBBER LATEX INDICATOR	VARCHAR2	1	BUS DESCR: Indicates that the device was not manufactured with natural rubber latex. Note that this indicator is only relevant if the value of related attribute "Contains Latex" is "No".)
FOR SINGLE USE INDICATOR	VARCHAR2	1	BUS DESCR: Indicates whether product is a single-use (consumable/disposable) product.
CONTAIN HUMAN TISSUE INDICATOR	VARCHAR2	1	BUS DESCR: Flag indicating the device contains human tissue.
KIT PRODUCT INDICATOR	VARCHAR2	1	BUS DESCR: Indicates that the product is a kit.
COMBINATION PRODUCT INDICATOR	VARCHAR2	1	BUS DESCR: Indicates that the product is a combination product.
PRESCRIPTION USE PRODUCT INDICATOR	VARCHAR2	1	BUS DESCR: Indicates the device is a prescribed product.
OVER THE COUNTER USE PRODUCT INDICATOR	VARCHAR2	1	BUS DESCR: Indicates the device is a non-prescription product and can be obtained over the counter.
CONTROLLED BY LOT NUMBER INDICATOR	VARCHAR2	1	BUS DESCR: Flag to indicate the device is managed by lot number. This number can be found on the label or packaging material. Lot or Batch means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.
CONTROLLED BY SERIAL NUMBER INDICATOR	VARCHAR2	1	BUS DESCR: Flag to indicate the device is managed by serial number. This number can be found on the device label or accompanying packaging; it is assigned by the labeler and should be specific to each device.

CONTROLLED BY MANUFACTURE DATE INDICATOR	VARCHAR2	1	BUS DESCR: Flag to indicate the device is managed by date of manufacture. The date a specific device was manufactured.
CONTROLLED BY EXPIRATION DATE INDICATOR	VARCHAR2	1	BUS DESCR: Flag to indicate the device is managed by expiration date. The date by which the label of a device states that the device must or should be used.

Medical Device Global Attributes (GUDID)

Domain	Datatype	Length	Definition
PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).
ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "FDA_PROD"
PRODUCT CODE	VARCHAR2	3	BUS DESCR: Classification for pre-market devices issued by the FDA; three letter code.
PRODUCT NAME	VARCHAR2	360	BUS DESCR: Name associated with the three-letter PROCODE.
PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).
ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "FDA_PROD_LIST"
FOOD AND DRUG ADMINISTRATION LISTING NUMBER	VARCHAR2	7	BUS DESCR: Unique number used to list medical devices that are marketed in the United States.

PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).
ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "PROD_PKG"
BASE PACKAGE DEVICE QUANTITY	NUMBER	10	BUS DESCR: Number of medical devices in the base package (i.e., the base package is the package configuration as labeled with and identified by the DI Record's primary DI number). For example, Base Package = Box of 100 gloves, Primary DI = 001; Device Count = 100.
PACKAGE DEVICE IDENTIFICATION NUMBER	VARCHAR2	25	BUS DESCR: A device identifier for the package configuration that contains multiple units of the base package (does not include shipping packages). For example: 4 glove boxes in a Case -- Package DI =002 (the UDI on the Case) 10 glove boxes in a Carton -- Package DI=003 (the UDI on the Carton) 5 Cartons in Pallet -- Package DI=004 (the UDI on the Pallet) contains a 5 cartons with 10 glove boxes in a carton.

PER PACKAGE QUANTITY	NUMBER	10	BUS DESCR: The number of packages with a unique primary DI within a given packaging configuration" For example: Package configuration Case with Package DI=002 contains 4 boxes of the base package DI=001, the quantity per package is 4; Package configuration Carton with Package DI=003 contains 10 boxes of the base package DI=001; the quantity per package is 10; Package configuration Pallet with Package DI=004 contains 5 cases of Package DI=003, the quantity per package is 5.
CONTAINED PACKAGE DEVICE IDENTIFICATION NUMBER	VARCHAR2	25	BUS DESCR: The primary DI for the base package or any lower level package configuration contained within a given package configuration" For example: Package DI=002 and Package DI=003 contain the base package Case with primary DI=001; Package DI=004 contains lower level package configuration of a Carton with Package DI=003.
PACKAGE DESCRIPTION	VARCHAR2	20	BUS DESCR: A type of package (i.e., a text value to describe the outer packaging of the product).

Coronary Stent Supplemental Attributes (SUDID)

Domain	Datatype	Length	Definition
PATIENT MEDICAL RECORD NUMBER	VARCHAR2	18	BUS DESCR: The Mercy Medical Record Number associated with the patient's hospital account. This is the Epic identifier for the Patient.
PATIENT IDENTIFIER	NUMBER	18	BUS DESCR: The unique ID assigned to the patient record (EPT .1).

ENCOUNTER IDENTIFICATION NUMBER	VARCHAR2	60	BUS DESCR: The unique serial number for this encounter in the Camtronics MERGE system. This number is unique across all patients and encounters in that system.
RECORD TYPE IDENTIFIER	VARCHAR2	30	BUS DESCR: An identifier which distinguishes the data contents of the data record from any other data record. Constant value: "CLNCL_DVC_PRFL"
DEVICE DESCRIPTION	VARCHAR2	2500	BUS DESCR: Detailed text description of device.
STENTLENGTH	NUMBER	10	BUS DESCR: The numeric value of a clinical device measurement (for example, width or length). This value should always be qualified with a clinical device measurement unit code.
CLINICAL DEVICE MEASUREMENT UNIT CODE	VARCHAR2	20	BUS DESCR: Code value identifying a measurement unit associated with a measurement value.
STENT DIAMETER	NUMBER	10	BUS DESCR: The numeric value of a clinical device measurement (for example, width or length). This value should always be qualified with a clinical device measurement unit code.
CLINICAL DEVICE MEASUREMENT UNIT CODE	VARCHAR2	20	BUS DESCR: Code value identifying a measurement unit associated with a measurement value.
UNCONVENTIONAL PROPERTY NAME	VARCHAR2	50	BUS DESCR: With respect to medical devices (such as coronary stents), this is the text name of a non-conventional device design. This may involve having variable or multiple length/diameter parameters. EX: Covered Stent, Bifurcation Stent, Tapered Stent, etc.
PRINCIPAL STRUCTURAL MATERIAL NAME	VARCHAR2	50	BUS DESCR: Composition of principle structural element of a medical device. EX: L605 Chromium

ELUTENT NATIONAL DRUG CODE	VARCHAR2	20	BUS DESCR: National Drug Code for the active agent released from a DES (i.e. drug-eluting coronary stent).
ELUTENT NATIONAL DRUG CODE DESCRIPTION	VARCHAR2	250	BUS DESCR: Text description of the active agent released from a DES (i.e. drug-eluting coronary stent).
STENT MATERIAL COATING NAME	VARCHAR2	250	BUS DESCR: Non-structural material covering structural surface of a medical device.
STENT STRUT THICKNESS	NUMBER	10	BUS DESCR: The numeric value of a clinical device measurement (for example, width or length). This value should always be qualified with a clinical device measurement unit code.
CLINICAL DEVICE MEASUREMENT UNIT CODE	VARCHAR2	20	BUS DESCR: Code value identifying a measurement unit associated with a measurement value.
EXPANSION METHOD NAME	VARCHAR2	50	DESCR: Method used to achieve nominal stent deployment. EX: Balloon, Self, etc.
MAGNETIC RESONANCE IMAGING COMPATIBLE STATUS NAME	VARCHAR2	50	BUS DESCR: Text classification of whether the medical device is compatible with Magnetic Resonance Imaging (i.e., MRI) based upon testing. EX: Safe, Conditional, Unsafe, Not Tested.

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[TM] 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^{TM} 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^{TM} 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^{TM} 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^{TM} CL **Functions**
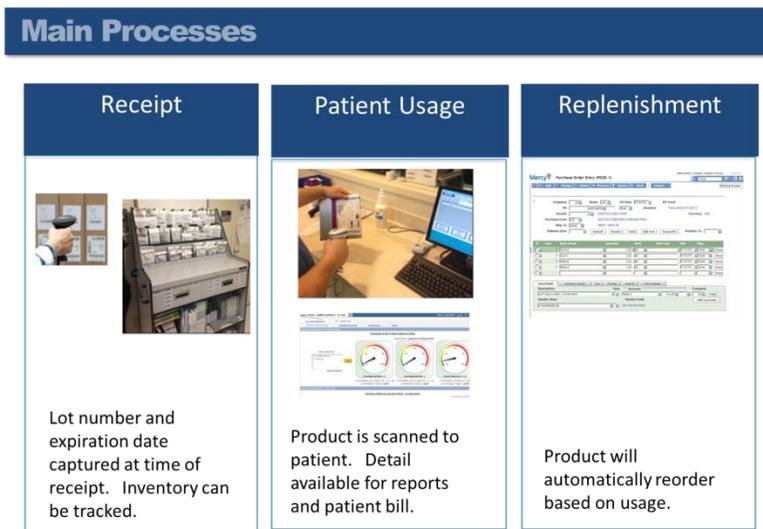
Obstacles and Solutions

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^{TM} CL. Due to

the lack of integration between OptiFlex^{TM} 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^{TM} 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^{TM} 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^{TM} 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

4

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^{TM}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^{TM} 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^{TM} 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^{TM} 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^{TM} 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^{TM} 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^{TM} 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^{TM} 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^{TM} 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^{TM} 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

Time Spent* Pre-Implementation
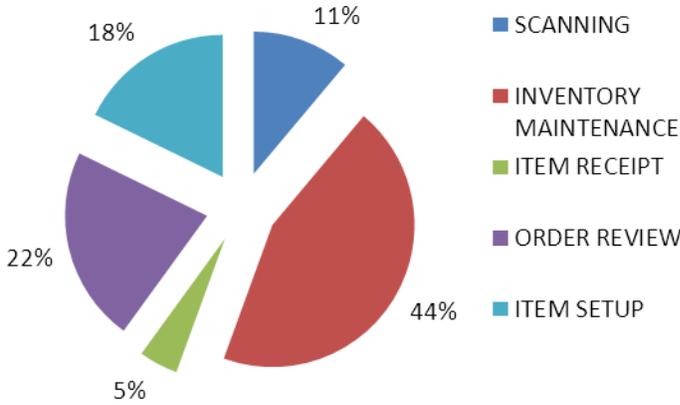
Time Spent* Post-Implementation
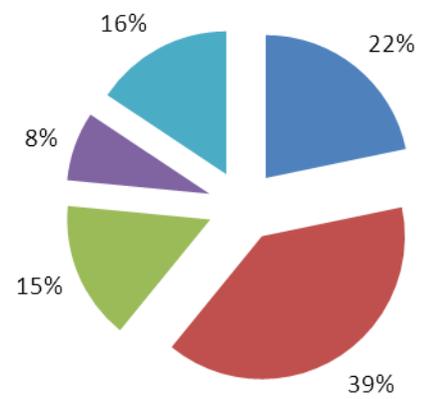
*Includes all inventory processes as well as charging and documentation of items

Table 3. Breakdown by Hours

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

POST-OPTIFLEX^{TM}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.