Appendix B

EVALUATION OF DATA COMPLETENESS

A reference dataset was constructed by identifying cases that were found in at least 1 of 3 data sources (CathPCI Registry®, EpicCare Billing, Merge Hemo™) and that were entered at Mercy Hospital St. Louis or Mercy Hospital Springfield over the timeframe from November 1, 2012, through March, 2013. This timeframe was chosen due to the availability of CathPCI data for comparison purposes. Data from OptiFlex™ CL were excluded from this analysis because OptiFlex™ CL scanned stents are not explicitly tied to a procedure within that system. Additionally, OptiFlex™ CL does not definitively distinguish between peripheral and coronary stents in its descriptions. Custom logic was developed to account for minor discrepancies in procedure dates between systems to maximize the accuracy of the comparison. The proportion of procedures in the reference dataset that were also present in the UDIR from each of the other data sources was calculated.

eTable 1 shows the results of our comparisons of procedure counts to the reference data sets. The UDIR EpicCare Billing and CathPCI Registry® data are in close agreement (95% of the procedures in the reference dataset) but a lower proportion (88%) is captured in Merge Hemo™. This is not a surprising result since Merge Hemo™ data capture requires a manually executed data export to the UDIR by Cath Lab personnel. Failure to export the data or technical failures in UDIR data import result in gaps in the Merge Hemo™ UDIR data. Indeed, heat maps of the procedure completeness across systems over time show what appear to be random missing cases in all three systems, and the presence of blocks of missing data in UDIR Merge Hemo™. eFigure 1 is the heat map for the St. Louis Cath Lab. Closer inspection of the raw data shows that there are blocks of missing data that represent weeks of time where no procedures were captured in the UDIR Merge Hemo™ tables. Although, we were unable to

determine the reason(s) for these gaps because our data completeness analysis was performed more than a year following data collection, a number of possibilities exist including a Merge Hemo™ system upgrade that occurred at the time and a failure of workers to export data. Ongoing concurrent monitoring for data gaps will not only improve data completeness by providing opportunities for workflow improvements and identifying training needs and system failures but it will also assure randomness of missing data.

eTable 1. Procedure Counts by Site and System

Data Source	St Louis	Springfield	(All Sites)
CathPCI Data	291 (95%)	566 (95%)	857 (95%)
Merge Data	267 (87%)	528 (89%)	795 (88%)
Epic Billing Data	290 (95%)	564 (95%)	854 (95%)
Reference Dataset	306	594	900

Interestingly, the same reference data set analysis performed on stent counts compared to procedure counts reveals different trends. (eTable 2) The stent counts in EpicCare Billing are the lowest of the three, a finding that was not unexpected since the stent numbers in that system are derived from billing codes rather than from stent counts. No billing code exists for distinguishing between procedures involving 4 versus more than 4 stents, so the number of stents will be undercounted in procedures where 5 or more stents were implanted. A more surprising result is that, despite having the lowest procedure counts among the three data sources, UDIR Merge Hemo™ tables have the highest stent counts overall. There are several possible reasons for this. One issue is contamination of the dataset

with peripheral stent procedures due to the failure of OptiFlex™ CL to distinguish between coronary and peripheral stents. (Even though peripheral stents are occasionally used in coronary arteries, they were not included in this analysis because their attributes were not available in GUDID or SUDID data.) Other issues include use of non-billed stents (e.g., stents used in clinical trials or supplied free of charge by vendors) and the many challenges to stent data entry integrity in the Merge Hemo™ software (e.g. manual editing of stent names).

eTable 2. Stent Counts by Site and System

Data Source	St Louis	Springfield	(All Sites)
CathPCI Data	514 (81%)	877 (87%)	1391 (85%)
Merge Data	549 (87%)	868 (86%)	1417 (86%)
Epic Billing Data	480 (76%)	767 (76%)	1247 (76%)
Reference Dataset	632	1013	1645

EVALUATION OF SCAN COMPLIANCE

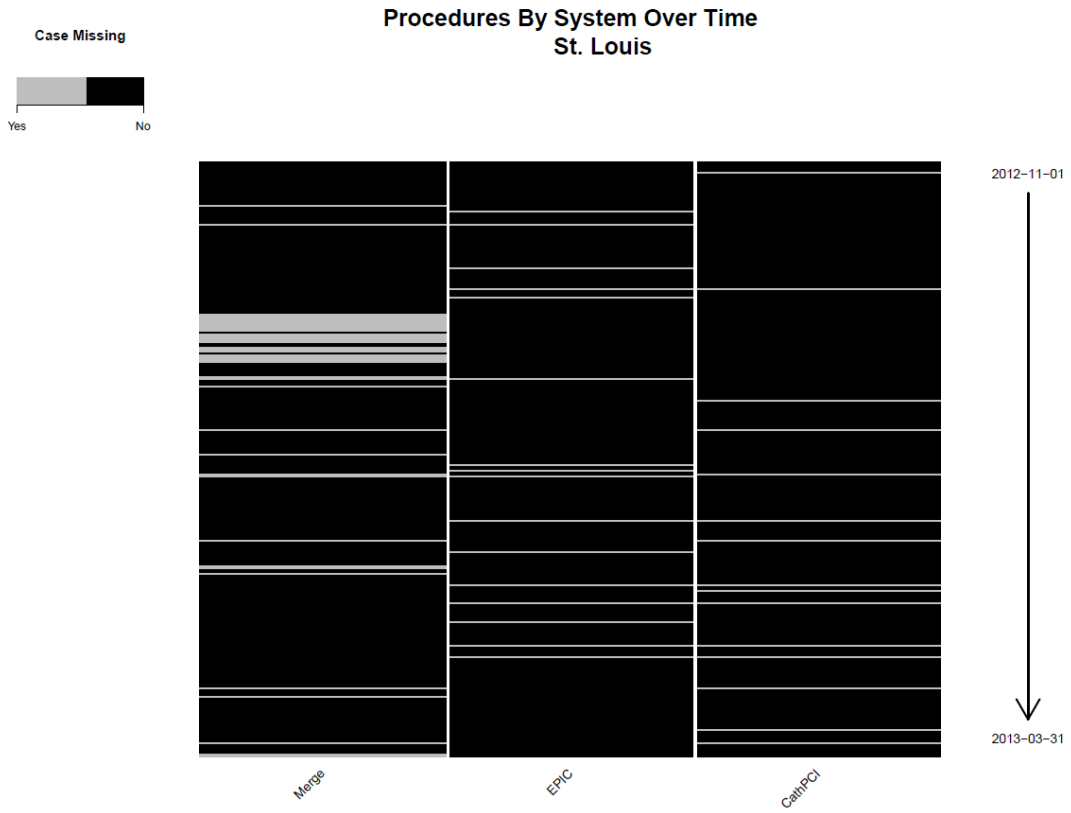
To assess Cath Lab personnel compliance with barcode scanning procedures, a larger dataset was assembled over a longer timeframe. Stents captured in Merge Hemo™ from November 1, 2012, through October 31, 2013, for procedures performed in Joplin, Springfield, St. Louis, and Rogers were

extracted. Records from OptiFlex™ CL of patients receiving these stents were then identified by matching patient medical record number (MRN) and scan date in the 2 systems. Each procedure was then labeled as occurring during 'Regular Hours' or 'Off Hours' and as 'Emergent' or 'Non-Emergent.' Regular Hours were defined as 7:00 a.m. to 7:00 p.m. Monday through Friday excluding holidays. All other hours were Off Hours. Emergent procedures were defined as those probably performed as an intervention for an acute myocardial infarction (AMI). For Emergent procedures, then, we included all PCIs performed on the same dates as patient admissions for ST segment elevation myocardial infarction (STEMI). We recognized that in these instances the AMI could either be a complication of a PCI or the reason for the procedure (primary PCI) but made the judgment that in the overwhelming majority of cases they would represent the latter situation.

Compliance was evaluated both at the case level and at the stent level. Case compliance is defined as the percent of cases in which the OptiFlex™ CL and Merge Hemo™ stent counts matched. Stent compliance is simply the percentage of total Merge Hemo™ stents scanned in OptiFlex™ CL.

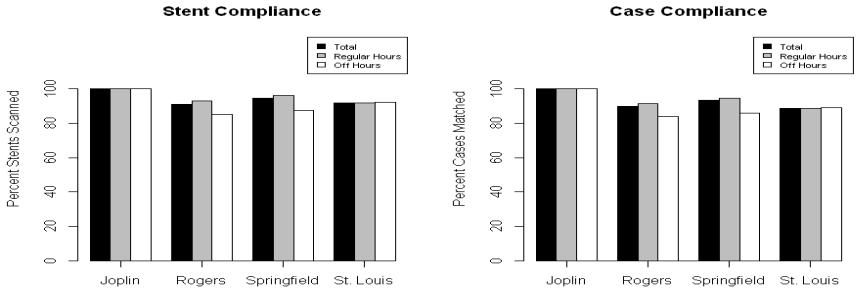
The results of this analysis are shown in eFigure 2. Overall, the Cath Labs showed similar compliance except for Joplin. However, the 100% compliance for the Joplin site represents only 11 cases. Additionally, compliance was not grossly affected by either the urgency of the procedure or the time of day the procedure was performed. Finally, case compliance and stent compliance were similar, suggesting that stent compliance is not distorted by failure to scan a small number of cases that have relatively high stent counts associated with them.

eFigure 1: Source system data in the UDIR over time



eFigure 2: UDI Scan Compliance

UDI Scan Compliance by Time of Day



UDI Scan Compliance by Procedure Type