

PCI-CAMPOS Program Coordinating Center
U.C. Davis Medical Center
Lawrence J. Ellison Ambulatory Care Center
4860 Y Street, Suite 2820
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November 20, 2013

Debby Rogers, RN, MS, FAEN
Deputy Director
California Department of Public Health
Licensing & Certification Program
1615 Capitol Avenue, MS #3401, P.O.Box 997377
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Dear Debby Rogers, RN, MS, FAEN:

The enclosed report was reviewed and approved for the PCI-CAMPOS program that was undertaken as a result of California Senate Bill 891.

This report was approved by the Advisory Oversight Committee (AOC) on November 19, 2013 at the public AOC meeting held at the U.C. Davis Medical Center (Lawrence J. Ellison Ambulatory Care Center 4860 Y Street, Suite 2820 Sacramento, CA 95817). The vote on approval was as follows:

1. Stephen Arnold MD- yes
2. Ralph Brindis MD- yes
3. Robert Davidson MD- yes
4. Mahmoud Eslami Farsani MD- absent
5. George Fehrenbacher MD- yes
6. Steven Forman MD- yes
7. William French MD- no
8. Dipti Itchhaporla MD- no response
9. Aditya Jain MD- yes
10. Sushil Karmarkar MD- yes
11. George Smith MD- absent
12. Rohit Sundrani MD- yes

On November 20, 2013 AOC members Dipti Itchhaporla, MD and George Smith, MD submitted their formal approval of the document electronically, as they were absent or unable to vote during the AOC meeting held on November 19, 2013.

On November 20, 2013 AOC member, William J. French MD, read and agreed with the AOC final report.

Enclosed is the complete AOC report on the PCI-CAMPOS program established by SB891 and hereby submitted to the California Department of Public Health.

Sincerely,

PCI-CAMPOS Program Coordinating Center

Advisory Oversight Committee

Report to the

California Department of Public Health

November 19, 2013

Pilot Hospital Investigators:

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At-Large Members:

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***PCI-California Audit Monitored Pilot with Offsite Surgery (PCI-CAMPOS) Principal Investigator

Percutaneous coronary intervention (PCI) has become a major component of the revascularization strategy for coronary artery disease. Primary PCI provides the lowest mortality rate and best outcomes for the treatment of ST elevation myocardial infarction (STEMI). Many regions in California have been underserved in the past in providing PCI as the best treatment for STEMI. The reason for this is multifactorial; however, many California rural and semi-rural communities don't have hospitals with cardiac surgery on-site. In spite of this, many smaller hospitals provide emergency PCI for STEMI patients, but not urgent or elective PCI, and some have been providing this emergency PCI service for over two decades. Urgent or elective PCIs are prohibited in hospitals without cardiac surgery on-site under Title 22 of the California Code of Regulations. Many have advocated allowing some hospitals without cardiac surgery to perform elective and urgent PCI in addition to primary PCI. This would boost the overall PCI experience at these hospitals to allow volume related improvements in clinical outcomes and cost-effectiveness.

Senate Bill 891(SB 891) was passed in 2008, and enacted January 1, 2009. SB 891 provided a three-year pilot program for PCI without on-site cardiac surgery, which was concluded in August 2013. This pilot program allowed six hospitals to perform elective PCI with cardiac surgery availability at a nearby hospital. The pilot program was patterned after suggestions from the expert consensus document from the Society for Cardiovascular Angiography and Interventions published in 2007 (1). The Advisory Oversight Committee (AOC), comprising 12 cardiologists from the State of California, is required by law to report its findings and recommendations to the California Department of Public Health (CDPH) regarding future changes in the law.

In the United States, PCI without on-site surgery has increased since 2008. 45 states allow both primary and elective PCI without onsite surgery, four states allow only primary PCI without on-site surgery, and one state prohibits all PCI without on-site surgery (2). PCI without on-site surgery is

regulated by the State Department of Health in 34 states but is unregulated in 16 states (2). PCI without on-site surgery is performed in 19 of the 65 cardiac catheterization laboratories within the Veterans Health Administration (2). In 2011 the ACC/AHA/SCAI guidelines for percutaneous coronary intervention assigned a class IIb (procedure may be considered, but additional studies are needed) indication to elective PCI with off-site surgery. (3) The guidelines stated it might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (3).

Since the original conception of the pilot program in California, there have been many studies in the United States on PCI without onsite surgery in addition to SB891 in California (4-16). Seven studies of primary PCI showed no difference for in hospital or 30 day mortality between off-site or on-site surgery. Additionally there was no difference in the seven studies in the occurrence of emergency coronary artery bypass surgery after primary PCI, between onsite or offsite surgery. There are eight studies that have examined urgent and elective PCI comparing PCI with on-site surgery and off-site surgery. There was no difference in mortality or a need for emergency coronary artery bypass surgery between the two sites, in these studies.

Two randomized trials have been performed in non-emergency PCI. The CPORT-E randomized 18,000 patients to undergo PCI with or without onsite cardiac surgery, and was published in 2012 (4). The MASS COMMM trial, which examined non-emergency PCI at hospitals with or without on-site cardiac surgery, was published in 2013 (5). Mortality and coronary artery bypass surgery did not differ significantly in the two groups in either study. Therefore, the results of the California PCI pilot program as outlined by SB 891 should be interpreted in the context of the substantial data that has accumulated over the last six years in observational registries and recently published randomized clinical trials.

Recommendations of the AOC will incorporate PCI guidelines from the AHA/ACC/SCAI, 6 years of multiple studies done outside of California, and the results of the California pilot program.

Methods

Design: The PCI California Audit Monitored Pilot with Offsite Surgery (PCI-CAMPOS) program is a prospective, multi-center pilot trial allowing elective PCIs at hospitals without on-site cardiovascular surgery in California. The pilot program was established by California Senate Bill No. 891 (SB 891) which was enacted in January 2009 authorizing the CDPH to set up a pilot program to allow California hospitals without surgery on-site to perform elective PCIs. The PCI-CAMPOS program was designed to compare PCI outcomes at the pilot hospitals with offsite cardiac surgery to PCI outcomes at established California hospitals with Onsite cardiac surgery.

The CDPH requested pilot hospital applications in December 2009, selected 6 hospitals out of over 30 applicant hospitals in May 2010 and contracted with University of California, Davis (UCD) to train, audit, and monitor the program. The CDPH appointed a 12 member Advisory Oversight Committee (AOC) with 6 at-large members nominated by the California American College of Cardiology (CAACC) and 6 members from the pilot hospitals (1 principal investigator from each participating pilot hospital). The pilot program was funded by CDPH from fee assessments of participating pilot hospitals. The study was approved by the Institutional Review Board (IRB) at each pilot hospital and at the University of California, Davis (UCD) coordinating center, and each patient was asked to provide written informed consent for pilot participation (unless unavailable in critically ill patients).

The National Cardiovascular Data Registry (NCDR[®]) CathPCI Registry (v. 4.3, 4.4) was selected as the data entry format for both pilot hospitals and non-pilot hospitals. The pilot PCI data was entered using the NCDR[®] CathPCI Registry v.4.3 and v.4.4 on an internet accessible UCD Velos server (Velos eResearch v9.1.2, Velos, Inc., Fremont, CA). The non-pilot hospitals entered their data using various NCDR[®] approved onsite software or the central NCDR[®] CathPCI v.4.3 and v.4.4 website. The pilot hospital

data was entered within 72 hours of each procedure and immediately available to the PCI-CAMPOS coordinating center. The non-pilot data was entered individually or obtained from quarterly data harvests submitted to NCDR[®]. After masking patient, operator, and hospital identity, this non-pilot California NCDR[®] CathPCI registry data was downloaded annually from the NCDR[®] center to the UCD PCI-CAMPOS coordinating center. The UCD coordinating center performed all pilot audits and had full access to the pilot information. The UCD coordinating center received only masked non-pilot data directly from the NCDR. The UCD coordinating center performed all pilot and comparative analyses. Interim data summaries and analyses were presented to the full AOC for review at 6-12 month intervals throughout the study.

Outcomes: The pilot hospital outcomes were compared with hospital outcomes from non-pilot California hospitals performing either elective PCIs with surgery on-site or STEMI only PCIs. Initially the non-pilot mortality data was obtained from all California hospitals using the California Patient Discharge Data (PDD) set collected by the Office of Statewide Healthcare Planning and Development (OSHPD). After October 2012, the non-pilot clinical data was obtained from the 116 California hospitals that submitted their clinical data directly to the NCDR[®] data center and was used for the final analysis of the data. Both the non-pilot and pilot data sets were analyzed and compared using SAS statistical software (version 9.3 for Windows, SAS Institute, Cary, NC).

Study Participants

Hospitals: The non-pilot hospital group consisted of all 116 California hospitals which submitted PCI data directly to the NCDR[®] central office between July 2010-July 2013 and had performed ≥ 1 PCI. For all elective PCIs, these hospitals had on-site surgery available for any post-PCI patients who required emergency coronary bypass surgery (CABG).

The pilot hospital group consisted of all 6 hospitals selected by the CDPH, which met the eligible hospital criteria as required by SB891 SEC.2. Section 1256.01 (c) (09/25/2008).

Operators: Operators were approved to perform procedures under the pilot program based on the operator criteria as required by SB891 SEC.2. Section 1256.01 (c) (09/25/2008). Pilot operators underwent training for the assessment of the operator, and the assessment of patient inclusion and exclusion requirements by UCD staff and were also were required to pass a competency exam. Non-pilot operators did not receive special training and their identity was masked to comply with NCDR[®] requirements.

Emergency (and salvage) pilot hospital PCI's were performed by any credentialed interventionalists at the pilot hospitals. Non-emergent (elective, urgent) PCI's were redirected to the pre-qualified pilot operators.

Coders: Data entry coders at each pilot hospital received an initial 1 day training session, followed by a competency exam. On-going training, telephone, and email access to the coordinating center were available throughout the program. Non-pilot coding was also performed by coders at each onsite hospital participating in the NCDR[®] CathPCI Registry.

Patients: All pilot hospital patients who met the SB891 SEC.2. Section 1256.01 (A through D) (09/25/2008) selection criteria for PCI at pilot hospitals were enrolled in the program. All patients with STEMI who presented to the pilot hospitals were included in the STEMI PCI group. STEMI-excluded patients who were low to moderate risk for complications were included in the STEMI-excluded group. Patients deemed high-risk (both high lesion and patient risk) for complications were excluded from the pilot program. These high-risk patients were either discharged or transferred to non-pilot hospitals with on-site surgery for revascularization with PCI or CABG.

Pilot Protocol

After completion of each PCI, the required information was entered online into the NCDR[®] CathPCI Registry v.4.3 and v.4.4 UCD server. All cases were then reviewed by the central coordinating site for data field completion and data consistency. All cases with complications (death, stroke, CABG,

shock, CHF, cardiac arrest, IABP, perforation, significant dissection, tamponade, and new requirement for dialysis) and a randomized 10% of non-complication cases were then selected for a pilot-site audit that included a review of all medical records and angiographic images. Audit reviews produced multiple queries that were transmitted to the hospital coders for discussion with operators. An iterative process eventually led to a consensus agreement in most cases. In rare cases, when auditor-operator agreement was not achieved, the case was referred to the angiographic committee or to the AOC for a final determination. The patient and procedure data was stored on the Velos Server; the angiographic images were saved on an Xcelera R3.3L1 Server (Koninklijke Philips Electronics N.V.); and the statistical analyses were stored and performed on SAS software, version 9.3 for Windows (SAS Institute, Cary, NC).

Non-pilot Audits: California hospital PCI data that was submitted individually or at 3 month harvests to the NCDR[®] central office was reviewed for completeness and data accuracy by NCDR[®] and received a red, yellow, or green light before acceptance. The vast majority of the hospitals in California that perform PCI participate in the NCDR CathPCI registry. The NCDR[®] in addition to employing robust data quality strategies for its participating hospitals also performs a limited number of site audits to directly assess data accuracy. The NCDR[®] complete non-pilot California data was downloaded annually to the UCD central site for comparison analysis. The downloaded data was masked to protect patient, operator, and hospital identity.

Pilot Program End Points: The primary outcome was the post-PCI composite of in-hospital death and/or transfer for emergency CABG during the initial hospitalization for: STEMI excluded and all patients. Key secondary individual post-PCI clinical outcomes included: death and transfer for emergency CABG. The primary and secondary events were entered by hospital coders into the pilot or non-pilot data registry. Pilot primary and secondary events were included in the hospital pilot-site audits. Additional secondary outcomes included successful PCI (a composite of <20% residual stenosis and post PCI TIMI-III flow or each individually). Additional secondary metrics included appropriate use

criteria, discharge medications, length of stay, creatinine assessed, biomarkers assessed, transfusion, door-to-balloon time, acute kidney injury, and post PCI biomarker positive MI. Supplemental data fields related to compassionate use were added to the pilot website on July 1, 2011. These data fields included the presence of any compassionate use criteria, pre-PCI coma, CPR, or LV assist device. This compassionate use data was not available for the non-pilot patients.

Statistical analysis: A PCI risk model was developed and risk-adjusted primary outcomes were compared for the 6 pilot and 116 non-pilot hospital PCI procedures. To compare the demographic and clinical profiles and observed outcomes between CA-NCDR[®] (non-pilot) and PCI-CAMPOS (pilot), all continuous and categorical variables were reported as mean \pm standard deviation (SD) or percentages, and compared with the *t* test or chi-square test (two tailed), respectively. The primary outcome was a composite event which included in-hospital death, regardless of length of stay and/or patients who were transferred for an emergent CABG. The non-pilot data and the pilot data were merged as a single data source for development of the risk adjustment models for the composite outcome. With the combined data, we performed a bi-variable analysis to identify significant demographic and clinical risk factors for the composite outcome and serve as candidate risk factors for the multivariable logistic risk models. We developed both parsimonious and refined risk models with the combined data and used only non-pilot data for model validation purpose. All models were evaluated with the Hosmer-Lemeshow goodness-of-fit statistic. The c- statistic was reported as a measure of predictive power. The refined model was then used for computation of provider's expected and risk-adjusted composite event rates. A general linear model for analysis of variance (GLM/ANOVA) was used to compare observed, expected and risk-adjusted composite event rates between CA-NCDR[®] and PCI-CAMPOS hospitals. We further computed 95% confidence interval (CI) of provider's risk-adjusted composite event rate using the Poisson exact probability method for pilot and non-pilot hospitals and pilot operators. We determined provider's performance rating based on a comparison of the 95%CI of provider's risk-

adjusted composite event rates and to the California average composite event rate that includes both CABG on-site and off-site hospitals. Two performance rating analyses were conducted for hospitals (or operators in pilot hospitals): (1) based on all PCIs and (2) based on PCIs with STEMI excluded. We also assessed the correlation between provider's total and STEMI excluded PCI volume and risk-adjusted composite event rate among hospitals and operators in pilot hospitals. All reported p-values were 2-sided, and p-value < 0.05 were considered to be statistically significant. All statistical analyses were conducted at the UCD with the use of SAS software, version 9.3 for Windows (SAS Institute, Cary, NC).

Results

A total of 6 pilot hospitals were selected by the CDPH from the initial applicant pool. The numbers of PCI procedures performed during the first 3 years of the enrollment period for the 6 pilot site hospitals with off-site surgery from 08/01/2010 to 07/31/2013 (36 months) was 3773 (Appendix B:Table 1). The number of procedures per pilot site during this period ranged from 86-390 per year (Appendix B: Table 2). The pilot enrollment goal was 1200PCIs/year and this was achieved in years 1 and 2, but dropped slightly in year 3(Appendix B: Table 1). The largest numbers of patients were seen in the STEMI group (Appendix B: Table 1). Figure 1 (Appendix B) shows the monthly enrollment variation for each of the 6 pilot hospitals. Tables 3-8 (Appendix B) show the numbers of total and STEMI patients enrolled for each pilot hospital. Pilot hospitals 1 and 2 met the minimum goals of 36 STEMI and 200 total patients for all 3 years and pilot hospital 6 achieved 602/3 years (avg. 200 per year) (Appendix B: Table 3 & 4). Pilot hospitals 3, 5, and 6 met the minimum STEMI goals but did not meet the total volume goal (Appendix B: Table 5, 7 & 8). Pilot hospital 4 did not meet either the STEMI or the total volume goals (Appendix B: Table 6). Tables 3-8 (Appendix B) also show the admitting diagnosis enrollments for each pilot hospital with peak numbers for NSTEMI for hospitals 1, 4, 5 and STEMI for hospitals 2, 3, and 6.

The two year pilot site data was compared to an equivalent two year non-pilot site data set obtained from the NCDR[®] CathPCI data registry. The 2 year non-pilot PCI data was obtained from 116 hospitals (almost all with on-site surgery) which performed 99,332 PCIs from July 1, 2010 to June 30, 2012. The matching 2 year pilot PCI data was collected from the 6 pilot hospitals which performed 2601 PCIs from August 1, 2010 to July 31, 2012 (Appendix C: Table 1). In comparing these two data sets we found a significant difference in the STEMI incidence. The pilot sites had a 32.2% STEMI incidence compared to a 17.7% STEMI incidence among the non-pilot sites (Appendix C: Table 2). Since patients with an acute myocardial infarction (STEMI) are at a higher risk of death, the pilot hospitals appeared to enroll a higher proportion of these high-risk patients than the non-pilot hospitals. Additional comparisons of demographic, clinical, and laboratory parameters are shown in Appendix C (Tables 2-4). Since the risk profiles of pilot and non-pilot PCIs appeared to differ, a risk adjustment model was developed to allow a more accurate comparison of these two groups (Appendix D: Tables 1-3).

The primary composite PCI end point (death and/or transfer for emergency CABG) was observed in 2.5% of the pilot patients (Appendix C: Table 5) for the first two years. These observed pilot end points were not significantly different from non-pilot end points for both composite outcome and in-hospital mortality (Appendix C: Table 5). However, there was a significant difference in transfer for emergent CABG between pilot and non-pilot groups (0.35%, 0.29%; $p < 0.0001$) (Appendix C: Table 5). Secondary observed outcomes also showed significant differences for post PCI biomarker positive MI, cardiogenic shock, heart failure, and bleeding within 72 hours (Appendix C: Table 6).

Statistical analysis using multivariate logistic regression resulted in an excellent risk model with 21 refined variables and with a high predictive value (C-statistic of 0.902) (Appendix D: Figures 1-3). Using this refined model, the risk-adjusted composite event rates were determined for both pilot and non-pilot overall and STEMI-excluded groups. The risk-adjusted comparison shows similar elective

(STEMI-excluded) composite events (1.15% vs. 1.16%) and overall composite events (1.58% vs. 2.11%) for both groups. There was no statistically significant difference in composite events between pilot and non-pilot hospital PCIs for either elective (STEMI-excluded) or all patients (Table 1 below).

Table 1. Risk-adjusted Results Summary			
	Pilot	Non-pilot	p-value
Risk-adjusted Overall Composite Event Rate	1.58%	2.11%	NS*
Risk-adjusted STEMI-excluded Composite Event Rate	1.15%	1.16%	NS*

*NS – Not Significant

Thus, after complete risk adjustment, pilot hospitals PCIs had the same composite mortality and emergency CABG rate as non-pilot hospital PCIs.

Hospital and operator ratings were also assessed for both groups (Table 2). Results of hospital ratings for risk-adjusted overall composite events showed 7 worse outliers in the non-pilot group but no worse outliers in the pilot group. Ratings for risk-adjusted STEMI-excluded composite events, showed 5 worse outliers in the non-pilot group and no worse outliers for the pilot group. There were no worse outliers for operators in the pilot group; operator data was not available for the non-pilot group. Thus, outliers with higher than expected mortality and emergency CABG rates were only encountered in the Non-pilot hospitals almost all of which had CABG surgery onsite.

Table 2. Outliers		
	Better outlier	Worse outlier*
Risk-Adjusted Overall-composite Event Outliers		
Hospitals		
Pilot (N=6)	1	0
Non-Pilot (N=116)	4	7
Operators		
Pilot (N=47)	1	0
Non-Pilot (N=116)	NA	NA
Risk-Adjusted STEMI-excluded Composite Event Outliers		
Hospitals		
Pilot (N=6)	0	0
Non-pilot (N=106)	4	5
Operators		
Pilot (N=41)	0	0
Non-pilot	NA	NA

*The performance rating is based on a comparison of each hospital's risk-adjusted end-points rate (RAER) to the California (Non-Pilot+Pilot) observed end-points rate. A hospital is classified as "**Better**" if the upper 95% confidence limit of its RAER falls below the California observed end-point rate. A hospital is classified as "**Worse**" if the lower 95% confidence limit of its RAER is higher than the California observed end-points rate.

A Pearson correlation analysis showed no significant relationships between hospital or operator PCI volume and risk-adjusted composite event (Appendix D: Figures 11, 12). Thus, PCI hospital volume did not seem to affect PCI mortality or need for emergency CABG.

Summary

A comprehensive rigorous pilot program establishing elective PCIs in 6 California hospitals without onsite surgery demonstrated similar safety and efficacy results for elective and non-elective PCIs when compared to 116 hospitals with onsite Surgery. No strong relationship was noted between hospital volumes and overall safety and efficacy. Potential worse outliers were identified only in the Onsite Non-pilot Hospital Group. We note that one pilot site did not meet the STEMI or total volume goals and that three hospitals did not meet total volume goals but met the STEMI volume goals. In spite of not meeting total volume goals, outcomes were not statistically different.

Across the U.S. PCI without onsite surgery has been increasing since the year 2007. We have described two randomized trials of Non-Primary PCI in the United States have been published- the CPORT-E (4) and MASS –COMM (5) trials. They found no increase in mortality or greater need for emergency CABG for either primary or non-primary PCI at sites without cardiac surgery.

Discussion and Recommendations

Similar to larger US randomized control trials, the PCI-CAMPOS observational pilot study also demonstrated both safety and feasibility of primary and elective PCI in centers without surgical back up. Most would agree that the argument for these centers is the strongest in regards to geographically isolated patients, with the aim of improving access to care. We strongly recommend that any hospital that performs PCI, regardless of whether cardiac surgery is onsite or offsite, have the intent of providing primary PCI in all STEMI patients 24 hours a day, 7 days a week, and 365 days per year.

The existence of labs performing a low volume of PCIs, which are not serving isolated or underserved populations, should be questioned and any labs that cannot maintain satisfactory clinical outcomes should be closed. We concur with the 2011 ACCF/AHA/SCAI PCI guidelines statement that “desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI program without onsite cardiac surgery.”

The annual volume of PCI in California peaked in 2006 and has declined by over 30% (California Patient Discharge Data-OSHPD). Many reasons have been cited for this volume decline including the reduction in the restenosis rates with the use of drug eluting stents, improved primary and secondary prevention (decreased smoking, cholesterol and hypertension control) along with greater emphasis on medical therapy, particularly for stable coronary disease. Primary and secondary prevention measures have resulted in decreasing the incidence of STEMI. Greater utilization of Fractional Flow Reserve (FFR-

catheterization lab assessments for ischemia producing coronary lesions) along with stricter adherence to the ACC/AHA Appropriate Use Criteria has also led to decreases in inappropriate PCI procedures.

In PCI-CAMPOS, each hospital had close monitoring of the clinical outcomes. What should be the ongoing process to maintain stringent systems and process protocols with close monitoring for clinical outcomes? The committee believes that an ongoing statewide quality assurance program as outlined below would be recommended for all PCI sites, regardless whether coronary bypass is available onsite or not. It would be important to include all PCI hospitals, as the worse outliers were found only in the PCI hospitals with bypass surgery onsite. Additionally, it is reasonable to say that in the current era, volume outcome relationships are not as robust as in the era of balloon angioplasty. How do we proceed forward with the issue of volume?

Institutional and Operator Volume

Institutional Volume: The 2013 ACCF/AHA/SCAI 2013 PCI Competency Document identified a signal suggesting that an institutional volume threshold of <200 PCIs/year was associated with worse outcomes. Therefore, the 2013 Competency Document recommended that the continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned and that any laboratory that cannot maintain satisfactory outcomes should be closed. There is currently no national definition for “satisfactory outcomes”. Satisfactory outcomes could be defined by each PCI center initially, (both in programs with or without on-site surgery) as part of their quality review process using national benchmark data, with oversight by a California Interventional Cardiology Advisory Panel reporting to the California Department of Public Health. Programs failing to meet established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve their performance, engaging outside experts if necessary. Failure to improve quality metrics should lead to program closure. To ensure proper assessment and monitoring,

laboratories should be required to submit data to a national data registry, have regular meetings to discuss key performance metrics and develop plans for the correction of any deficiencies. Clinical data from 1298 U.S. facilities reporting to the National Cardiovascular Data Registry (NCDR) show that 49% of facilities performed ≤ 400 PCIs and 26% performed ≤ 200 PCIs annually (17, Table 3). Approximately 33% of facilities had no on-site surgery, and among these, 65% (282 facilities) had an annual case volume of ≤ 200 PCI procedures.

Recommendations for Institutional Volume (18)

STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary PCI. Primary PCI should not be performed at facilities unless it is provided on a 24/7 schedule. The cardiac catheterization laboratory staff and interventional cardiologist should arrive within 30 minutes of a STEMI activation call. Facilities should have a plan for triage and treatment of simultaneous presentation of STEMI patients. Ideally STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually (19), and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.

Special Recommendations for Low Volume PCI Centers (<200 cases/year) (18)

Full service laboratories (both primary and elective PCI, with and without on-site cardiac surgery) performing <200 cases annually (averaged over 2 years) must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. Both physicians and staff should have the opportunity to work at a high volume center to enhance their skills. The operation of laboratories performing <200 procedures annually that cannot maintain satisfactory clinical outcomes should be closed.

Satisfactory outcomes should be initially defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. We recommend an oversight body statewide to help define satisfactory outcomes. Programs that fail to meet their established criteria for satisfactory performance for 2 consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location. As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.

Operator Requirements: The 2007 SCAI Expert Consensus Document included a recommendation that operators at PCI programs without on-site surgery perform at least 100 total and 18 primary PCIs annually, a recommendation that might not be achievable in the current environment (1). The 2013 PCI Competency Document moves away from strict volume requirements to focus more on achieving quality metrics for facilities and individual operators.

The 2013 Competency document recommends that operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200 total and >36 primary PCI procedures annually. The 2007 SCAI Expert Consensus Document suggested that initial operators at a new program without on-site surgery should have a lifetime experience of >500 PCIs as primary operator after completing a fellowship. In the current environment of decreasing PCI volumes and in view of the recommendations of the 2013 PCI competence document, this number would be difficult to achieve. Nevertheless, it is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by more experienced physicians until it is determined that the skills, judgment and outcomes of these new

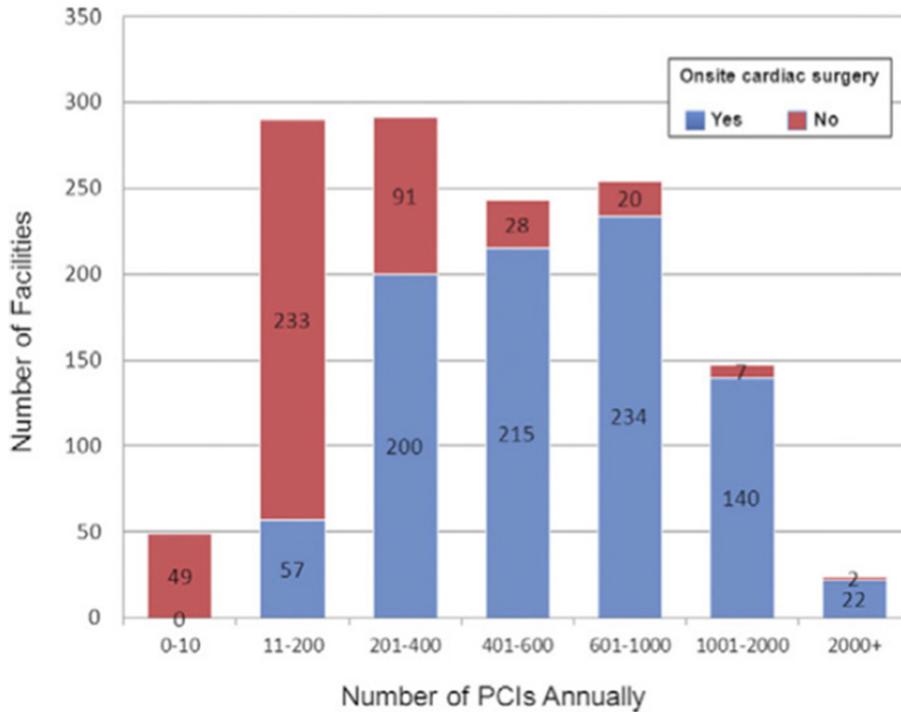
cardiologists are acceptable, but at least 500 lifetime procedures (including interventional fellowship) in total must be performed.

Operator Recommendations (17): Interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency.

Primary PCI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 primary PCI procedures per year. Ideally, these procedures should be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year. Facilities should develop internal review processes to assess operators performing <50 PCIs annually. Individual operator level volume is one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, individual operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance.

It is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by existing physicians until it is determined their skills, judgment and outcomes are acceptable.

Table 3 Dehmer, et al J Am Coll Cardiol 2012;60:2017-31.



Legend: PCI volume at facilities with and without cardiac surgery

Recommendations for Hospitals in California who Wish to Perform Elective and Urgent PCI with Offsite Surgery

The recommendations for infrastructure, communication, hospital services (both ancillary services, nursing services, and physician subspecialty services) are based on a combination of the experience of the advisory oversight committee members and the hospital criteria for entering the CPORT (4) and MASSCOM randomized trials (5), and the original 2007 SCAI recommendations (1) Some of these recommendations are fluid, based on the local facility, and the facility’s relationship with the cardiac surgical receiving center . Many of the sicker patients, particularly the STEMI patients in shock, require expert cardiac nursing care, expert critical care physicians in addition to expert interventional

cardiologists. Additionally, great emphasis should be placed on the relationship between the cardiac surgical receiving facility and the PCI with off-site surgery center.

General Recommendations for hospitals that wish to establish an elective or urgent PCI program without cardiac surgery on-site:

- Cardiac Cath Lab Medical Director or equivalent and the Hospital administration must work together to review and approve these recommendations at their respective facilities prior to establishing the program.
- The on-call schedule will provide operators for the cardiac catheterization laboratory 24 hours-a-day, 365 days-a-year.
- The institution is dedicated to perform primary PCI as the treatment of first choice for STEMI, and has policies and procedures in place that require tracking of door-to-device times, with the goal of 90 minutes or less, and requires that outlier cases be carefully reviewed for process improvement opportunities.
- The hospital employs experienced nursing and technical cath lab staff with training in interventional procedures. Cardiac Catheterization Laboratory (CCL) personnel should have the competency in treating acutely ill patients with hemodynamic and/or electrical instability. It employs experienced CCL and intensive care unit nursing staff who have competency with invasive hemodynamic monitoring, temporary pacemaker, and IABP management. Nursing and other ancillary providers such as respiratory therapy must be capable of managing endotracheal intubation and mechanical ventilators both on-site and during transfer, if necessary.
- The eligible hospital shall have 24/7/365 acute care ER and ICU with sufficient staffing capacity in the Intensive care Unit (ICU), Cardiac Care Unit (CCU or equivalent), or Cardiac Telemetry Unit for providing post-procedure care for patients undergoing PCI.

- An appropriate inventory of interventional and supportive care equipment must be maintained, including a full spectrum of guide catheters, guide wires, balloons and stents, thrombectomy and distal protection devices, flow wires for FFR assessment, Intra-Vascular Ultrasound, Pericardiocentesis tray, ability to perform STAT bedside echocardiography, temporary pacemakers, and Intra-Aortic Balloon pump support compatible with transport vehicles.
- Support from hospital administration will be provided in fulfilling the necessary institutional requirements including, but not limited to OSHPD space issues, regulatory compliance, and support services such blood banking, respiratory care, spiritual care etc. There should also be the availability of the full spectrum of medical specialties consultative services on-site, that include but are not limited to pulmonary/critical care, vascular surgery, Interventional Radiology, Neurology, STAT ultrasound and CT-imaging, and nephrology/dialysis.
- The hospital has on-site rigorous QA system that includes but is not limited to, data collection, outcomes analysis, benchmarking, quality improvement/performance improvement process, and formal case review of all complications or unexpected occurrences.
- The PCI hospital with offsite surgery eligible hospital must participate in the ACC-NCDR CathPCI registry.
- The eligible hospital and participating interventional cardiologists must employ rigorously appropriate patient selection criteria. These criteria should be widely posted and distributed and periodically reviewed. The patient selection criteria are based on SCAI/ACC/AHA recommendations and may evolve.

Patient selection shall be based on the interventional cardiologist's professional judgment which considers the patient's risk, lesion risk, and overall health, and emergent or urgent nature of the patient's condition.

- If the PCI hospital with offsite surgery uses a single Interventional/CCL, or has a combo lab or shared lab, a “bump” protocol detailing which emergency patient has the priority must be established and followed. It is recommended that all services and providers using the shared CCL discuss and come up with service agreements that make patient safety a top priority.

The importance of the relationship and distance, between the elective PCI with off-site surgery, and the cardiac surgical receiving facility cannot be over emphasized. The cardiac surgeons and the hospital administration at the cardiac surgical receiving facility should be willful and active participants. Each PCI offsite surgery capable hospital should consider local topography, traffic patterns, and identify potential obstacles to emergency transport within 25-50 mile radius, and designate a cardiac surgery center (receiving hospital) with whom transfer agreements have been established. The PCI hospital with offsite surgery should have an alternative plan regarding emergency patient transfer in place, if the first option is not available. The hospital should have a well-equipped and maintained CCL with high resolution digital imaging and storage capability, including the ability to transfer images and hemodynamic data via high speed transmission line to review terminals at the CV surgery capable receiving hospital. The MD performing the PCI procedure must have the ability to consult with CV surgery MD at the receiving hospital via real-time phone conversation. The patient should be transferred with CD copy of the images and printed copies of hemodynamics and other clinical information critical for good patient care (copies of History & Physical exam, lab results, ECGs, prior pertinent medical history, etc.).

It is mandatory to have a written transfer agreement for the emergency transfer of patients to a facility with cardiac surgery. The transfer agreement must ensure that emergent patients will be accepted at the receiving hospital regardless of whether the receiving hospital is at full capacity or not. Transfer protocols should be developed and tested periodically (at least once-a-year). The transfer

should ensure immediate and efficient transfer of such patients within 60 minutes of identified need, 24 hours-a-day, 7 days-a-week. In person, periodic meetings between PCI hospital with offsite surgery cardiologists and administrators and their counterparts at CV surgery-capable receiving hospital is recommended to foster smooth working relationships. Finally, the eligible hospital should have a process for obtaining a formal written consent from the patient prior to undergoing PCI detailing the possibility of transfer for emergent CABG.

Quality Assurance

The advisory oversight committee members strongly believe that participation in the NCDR CathPCI registry is imperative for all PCI with offsite surgery programs. Additionally the committee believes that all PCI programs in California should participate in the NCDR CathPCI registry for direct comparisons of clinical outcomes between outlier hospitals, and non-outliers. This is partially based on our study results demonstrating that the poor performing outlier hospitals in the state of California were actually cardiac surgical hospitals, not members of the PCI-CAMPOS pilot program.

Our recommendations for the state of California is to require all hospitals that perform PCI, regardless of whether surgery is onsite or offsite, to participate in quality assurance programs that benchmarks facilities to other hospitals in the state. Currently the most practical and most widely used PCI quality assurance program is the NCDR CathPCI registry.

It is proposed that an advisory panel of cardiologists skilled in interventional cardiology quality assurance would assist the California Department of Public Health in interpreting and monitoring the quarterly reports from the NCDR. This would be a non-compensated Interventional Cardiology Advisory Panel, of perhaps four to six cardiologists. This panel should include outcomes experts. In order to provide a diverse opinion without bias, it would be reasonable for the California chapter of the American College of Cardiology and/or American Heart Association to appoint half of the members of the voluntary advisory panel, and for the CDPH to appoint half of the members from hospitals that are

performing PCI with off-site surgery. A consumer representative and cardiac surgeon should also be considered. This committee could meet quarterly, or semi-annual, depending on the need. The task of the committee could be to help CDPH identify criteria for outlier hospitals, and assist in quality improvement, or if the quality cannot be improved, then to recommend closure.

Conclusion

The advisory oversight committee believes that PCI centers with offsite surgical back up are reasonable. We have demonstrated in California that they can provide the highest quality timely primary PCI for STEMI, and elective or urgent PCIs. PCI centers provide local care to patients who are not willing or cannot travel significant distance, and provide continuity of care with the patient's regular physicians.

The existence of small volume cardiac surgical programs in California that exist solely to provide PCI backup is not necessarily in the best interest of patients. These medium-size hospitals may be able to serve their community better by having PCI programs with offsite surgical backup, thereby concentrating the surgical experience at a larger hospital. When the surgical experience is larger and concentrated, a greater variety of technologies are available. The committee believes that there may be a significant number of small cardiac surgery programs in medium-size hospitals that may wish to convert their PCI program to an off-site surgical program. Although many smaller hospitals not currently performing PCI may wish to perform elective PCI with offsite surgery, it is unclear how many hospitals will be able to meet the criteria as outlined above.

What is clear is that it is important to provide access to elective and emergency timely PCI for STEMI that would otherwise not be available. Thus we need to do this with the emphasis on quality care and patient safety. PCI programs should be evaluated on the ability to sustain adequate quality metrics for all PCI procedures with skilled operators.

The field of percutaneous coronary intervention is rapidly evolving. We anticipate that some of the recommendations may change over the years as new data becomes available. The Interventional

Cardiology Advisory Panel as described in the quality assurance section, may advise the California Department of Public Health to alter these recommendations based on future research, and as technology evolves in the future. We would recommend the California Department of Public Health work closely with such an advisory panel to provide state of the art quality metrics that are expected to change as more research adds to our knowledge.

In conclusion the AOC recommends that this Pilot program regarding elective PCI without on-site cardiac surgery program be continued in the 6 hospitals until California law can be changed such that elective PCI without on-site cardiac surgery can be performed under the above recommendations. We recommend that other hospitals which meet the specified criteria, and wish to perform PCI with offsite surgery may do so, but only after the California law is changed.

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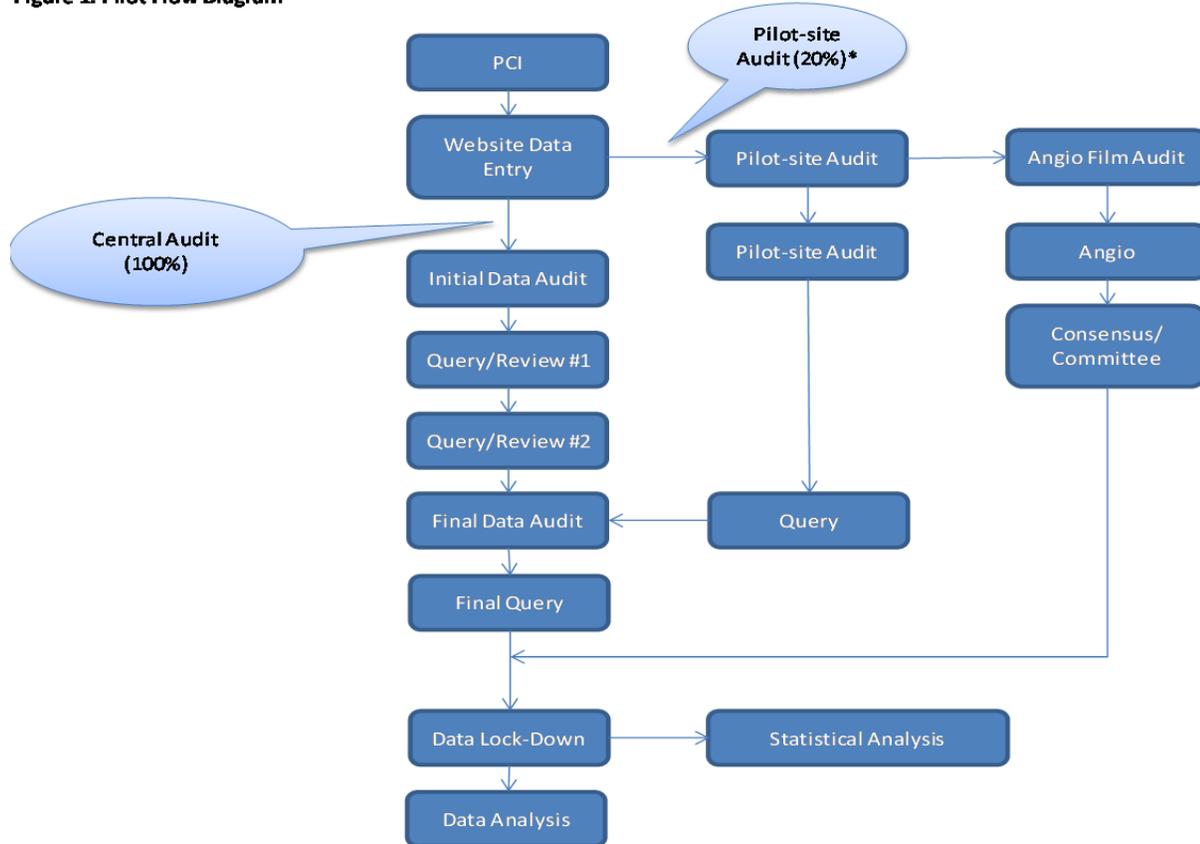
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Appendix A: Pilot Flow Diagram

Figure 1. Pilot Flow Diagram



*Includes 10% random cases, all complications, and all deaths.

Appendix B: Pilot Program Enrollment Tables and Figures

Table 1. Pilot Total 3 Year Enrollment

Pilot	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 07/31/2013	Totals
STEMI	436	401	371	1208
NSTEMI	322	365	338	1025
Unstable Angina	269	326	270	865
Stable Angina	199	174	154	527
No symptoms, No Angina	46	53	35	134
Symptoms Unlikely to be Ischemic	1	9	4	14
Total	1273	1328	1172	3773

Figure 1. Pilot Monthly Enrollment

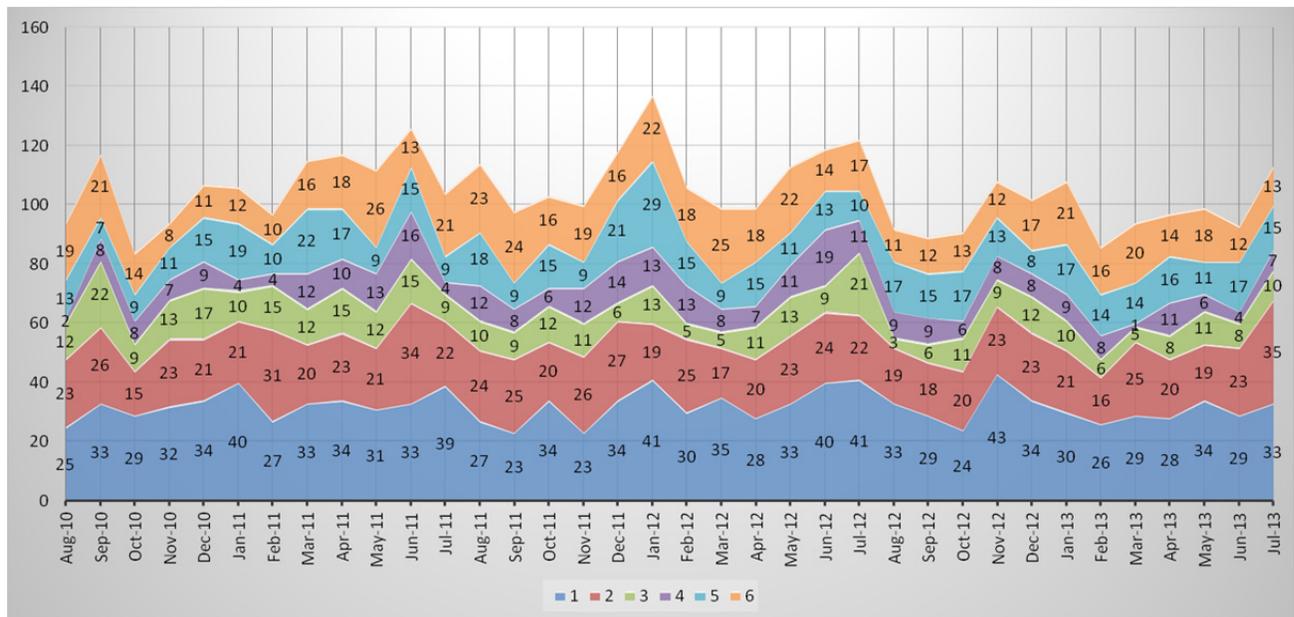


Table 2. Pilot Site Annual Enrollment

Site	Year 1		Year 2		Year 3 (*preliminary)	
	Total PCIs 08/01/2010- 07/31/2011	STEMI's 08/01/2010- 07/31/2011	Total PCIs 08/01/2011- 07/31/2012	STEMI's 08/01/2011- 07/31/2012	Total PCIs 08/01/2012- 07/31/2013	STEMI's 08/01/2012- 07/31/2013
Pilot-Hospital 1	390	73	389	56	372	66
Pilot-Hospital 2	280	108	272	86	262	93
Pilot Hospital 3	161	69	125	62	99	42
Pilot-Hospital 4	97	22	134	29	86	24
Pilot Hospital 5	156	49	174	54	175	43
Pilot-Hospital 6	189	115	234	114	179	103

Table 3. Pilot Hospital 1 Annual enrollment, CAD presentation

Hospital 1	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 07/31/2013	Totals
STEMI	73	56	66	195
NSTEMI	106	97	102	305
Unstable Angina	91	117	93	301
Stable Angina	97	91	91	279
No Sxs, No Angina	23	25	17	65
Sxs Unlikely to be Ischemic	0	3	3	6
Total Procedures	390	389	372	1151

Table 4. Pilot Hospital 2 Annual enrollment, CAD presentation

Hospital 2	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 07/31/2013	Totals
STEMI	108	86	93	287
NSTEMI	61	97	75	233
Unstable Angina	72	73	66	211
Stable Angina	28	11	17	56
No Sxs, No Angina	11	5	11	27
Sxs Unlikely to be Ischemic	0	0	0	0
Total Procedures	280	272	262	814

Table 5. Pilot Hospital 3 Annual enrollment, CAD presentation

Hospital 3	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 07/31/2013	Totals
STEMI	69	62	42	173
NSTEMI	40	25	27	92
Unstable Angina	37	24	19	80
Stable Angina	12	10	9	31
No Sxs, No Angina	3	4	1	8
Sxs Unlikely to be Ischemic	0	0	1	1
Total Procedures	161	125	99	385

Table 6. Pilot Hospital 4 Annual enrollment, CAD presentation

Hospital 4	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 07/31/2013	Totals
STEMI	22	29	24	75
NSTEMI	32	47	36	115
Unstable Angina	19	33	24	76
Stable Angina	19	10	1	30
No Sxs, No Angina	4	9	1	14
Sxs Unlikely to be Ischemic	1	6	0	7
Total Procedures	97	134	86	317

Table 7. Pilot Hospital 5 Annual enrollment, CAD presentation

Hospital 5	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 07/31/2013	Totals
STEMI	49	54	43	146
NSTEMI	47	49	67	163
Unstable Angina	25	46	41	112
Stable Angina	30	16	19	65
No Sxs, No Angina	5	9	4	18
Sxs Unlikely to be Ischemic	0	0	0	0
Total Procedures	156	174	174	504

Table 8. Pilot Hospital 6 Annual enrollment, CAD presentation

Hospital 6	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 07/31/2013	Total
STEMI	115	114	103	332
NSTEMI	36	50	31	117
Unstable Angina	25	33	27	85
Stable Angina	13	36	17	66
No Sxs, No Angina	0	1	1	2
Sxs Unlikely to be Ischemic	0	0	0	0
Total Procedures	189	234	179	602

Appendix C: Data Group Comparison Tables and Figures

Table 1. Data Groups

	Non-pilot	Pilot
Time Period	24 months (07/01/2010-06/30/2012)	24 months (08/01/2010-07/31/2012)
Hospitals	116	6
Operators	Unknown	47
Total PCIs	99,332	2,601
Primary PCIs (STEMI)	17,577 (17.7%)	837(32.2%)

Table 2. Risk Factors Comparison (Non-pilot < Pilot)

Risk Factor	Non-pilot (N=99,332)	Pilot (N=2,601)	p-value
STEMI	17.7%	32.2%	<.0001
Caucasian	68.3%	72.4%	<.0001
Emergent PCI	19.7%	35.4%	<.0001
Recent smoker	19.6%	22.1%	0.002
Dyslipidemia	78.5%	83.5%	<.0001
Family CAD history	17.4%	19.0%	0.037
NYHA IV	3.7%	5.0%	0.001
Heart failure	12.8%	23.3%	<.0001
Chronic lung disease	11.7%	13.8%	0.001
Cardiogenic shock	3.0%	3.7%	0.022
Thrombosis	17.3%	31.4%	<0.0001
TIMI-0	21.1%	28.9%	<0.0001
RCA/RPDA/RPL/A M stenosis, Mean (SD)	58.0% (40.3%)	60.0% (39.5%)	0.016

Table 3. Risk Factors Comparison (Non-pilot > Pilot)

Risk Factor	Non-pilot (N=99,332)	Pilot (N=2,601)	p-value
Hypertension	81.3%	78.5%	0.001
Diabetes	38.1%	32.9%	<.0001
Prior MI	28.0%	26.2%	0.047
Prior valve surgery	1.6%	1.0%	0.009
Prior PCI	36.8%	28.7%	<.0001
Prior CABG	16.5%	12.0%	<0.0001
Dialysis	3.9%	2.0%	<0.0001
GFR stage 3-5	27.5%	25.2%	0.010
Left Main stenosis>75%	3.5%	2.6%	0.009
Ejection fraction<40%	8.6%	5.7%	<0.0001
High/C lesion	55.9%	34.1%	<0.0001

Table 4. Risk Factors Comparison (Non-pilot ~Pilot)

Risk Factor	Non-pilot (N=99,332)	Pilot (N=2,601)	p-value
Age>70	37.9%	37.3%	0.567
Female	30.3%	30.5%	0.793
BMI, Mean (SD)	29.1 (7.7)	29.3 (6.8)	0.232
CVD	11.3%	11.0%	0.570
Peripheral arterial disease	11.3%	10.3%	0.142
ProxLAD stenosis, Mean (SD)	36.9% (39.8%)	36.1% (38.2%)	0.311
IABP	3.3%	3.8%	0.134

Table 5. Observed Outcomes Statistics

	Non-pilot	Pilot	p value
Composite Outcome (in-hospital death or emergency CABG)	1,989 (2.00%)	65 (2.50%)	0.075
In-hospital mortality	1,734 (1.75%)	56 (2.15%)	0.118
Emergent CABG	289 (0.29%)	9 (0.35%)	<0.0001

Table 6. Post PCI Factors Comparison (Non-pilot vs. Pilot)

Risk Factor	Non-pilot (N=99,332)	Pilot (N=2,601)	p-value
MI biomarkers	2.66%	3.38%	0.0234
Cardiogenic shock	1.25%	3.31%	<0.0001
Heart failure	1.02%	1.92%	<0.0001
CVD/Stroke	0.26%	0.27%	0.918
Hemorrhagic stroke	0.04%	0.04%	0.9251
Tamponade	0.13%	0.08%	0.4848
New required dialysis	0.38%	0.50%	0.3456
Other vascular complications	0.40%	0.27%	0.2894
RBC/Whole blood transfusion	3.27%	3.69%	0.2364
Bleeding within 72 hrs	1.51%	4.42%	<0.0001
Bleeding at access site	0.38%	0.46%	0.4983
Hematoma at access site	0.62%	1.31%	<0.0001
Hematoma Size>5cm	0.27%	0.50%	0.0002
Retroperitoneal bleeding	0.19%	0.08%	0.1954
GI bleeding	0.29%	0.50%	0.0471
GU bleeding	0.07%	0.19%	0.0164
Other (suspected) bleeding	0.29%	2.42%	<0.0001

Appendix D: Statistical Analysis Tables and Figures

Table 1. Bivariate Significant Variables

Significant variables (p<0.05): n=22	
Age	IABP
female	Cardiogenic shock
BMI<18.5	GFR stage
PCI status	Left main stenosis
CAD	Ejection fraction
Insulin Diabetes	Lesion complexity
NYHA IV	Thrombosis
Prior HF	PrePCI TIMI
Dialysis	ProxLAD stenosis
CVD	RCA/RPDA/RPL/AM stenosis
PAD	
CLD	

Table 2. Bivariate Insignificant Variables

Insignificant variables (p<0.05): n=4
Race
Recent smoker
Prior valve surgery
Pilot status

Table 3. Bivariate Counterintuitive Variables

Significant but "protective/counterintuitive" Variables (p<0.05): n=6
Hypertension
Dyslipidemia
Family CAD history
Prior MI
Prior PCI
Prior CABG

Figure 1. Odds Ratios

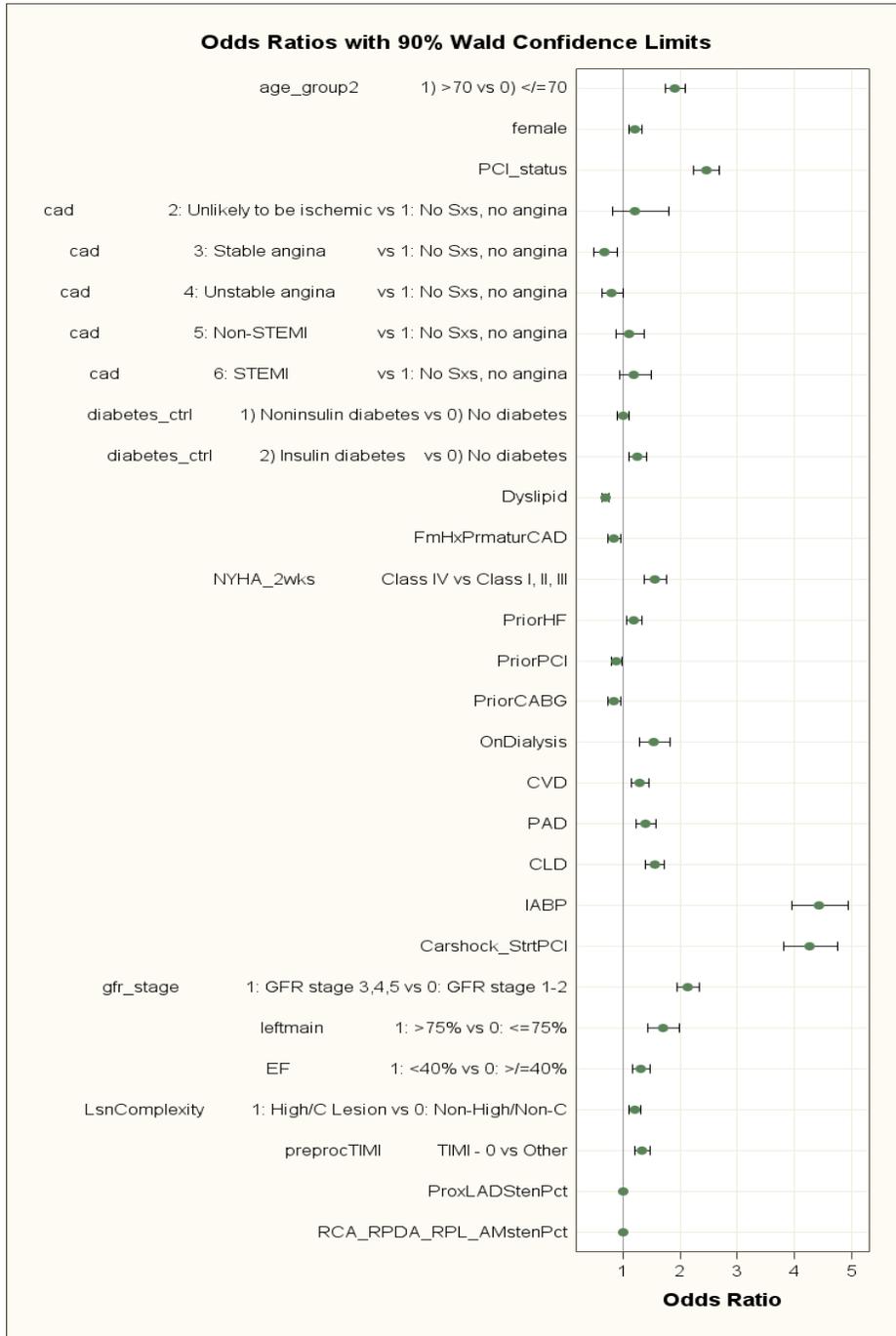
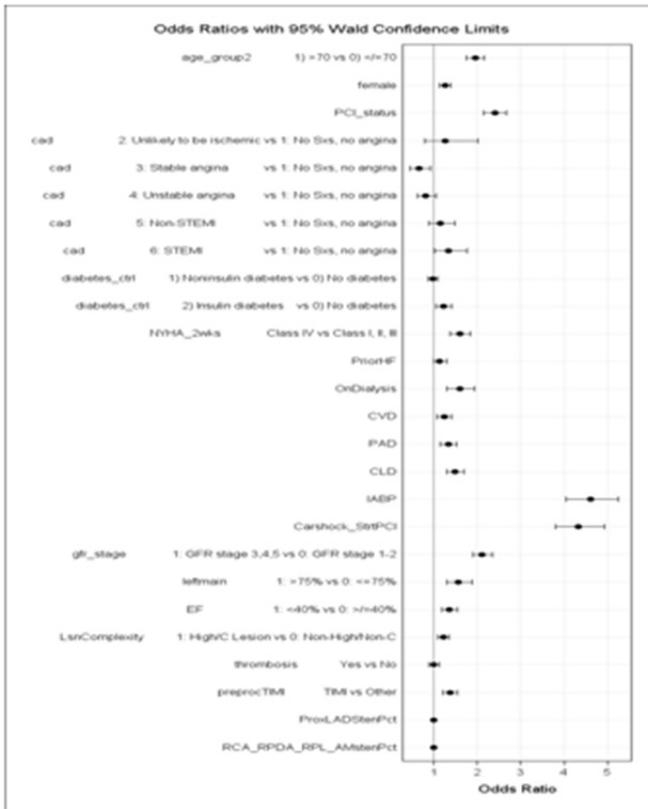
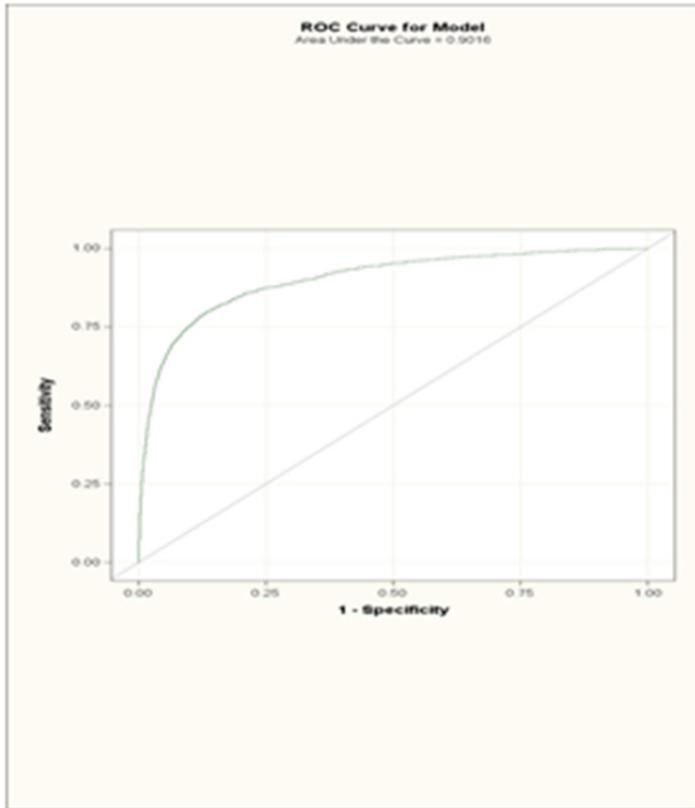


Figure 2. Odds Ratios (Refined Model)



- Refined model:
 - Removed 4 counterintuitive risk factors
 - Added Thrombosis
 - 21 risk factors
- AOR > 2.0 predictors:
 - PCI status
 - IABP
 - Cardiogenic shock
 - GFR stage 3-5

Figure 3: Odds Ratios (Refined Model)



- ▶ Refined Model: 21 variables
- ▶ C-statistic= 0.902
- ▶ Hosmer-Lemeshow test:
p-value <0.0001

Table 4. Hospital Ratings (Non-pilot)**

	Performance rating	Number of hospitals	Measure	Mean	Std Dev	Median	Minimum	Maximum
Non-pilot	As Expected	105	Volume	779	592	658	1	3344
			Observed event rate	3.23	9.66	2.07	0.00	100.00
			Expected event rate	2.58	3.06	2.01	0.39	31.33
			Risk adjusted event rate	2.04	0.88	2.00	0.00	6.43
	Better	4	Volume	2428	1544	2972	157	3613
			Observed event rate	1.12	0.50	1.11	0.54	1.72
			Expected event rate	2.80	2.24	2.11	0.94	6.03
			Risk adjusted event rate	1.02	0.43	1.10	0.43	1.44
	Worse	7	Volume	1119	1105	649	277	3027
			Observed event rate	3.60	1.24	3.52	2.17	6.14
			Expected event rate	1.98	0.57	1.80	1.59	3.25
			Risk adjusted event rate	3.65	0.62	3.91	2.75	4.29

Table 5. Hospital Ratings (Pilot)**

	Performance rating	Number of hospitals	Measure	Mean	Std Dev	Median	Minimum	Maximum
Pilot	As Expected	5	Volume	410	217	330	231	778
			Observed event rate	2.54	1.85	2.44	0.43	5.44
			Expected event rate	2.89	1.58	2.33	1.87	5.66
			Risk adjusted event rate	1.67	0.68	1.94	0.47	2.11
	Better	1	Volume	552	.	552	552	552
			Observed event rate	2.17	.	2.17	2.17	2.17
			Expected event rate	3.80	.	3.80	3.80	3.80
			Risk adjusted event rate	1.15	.	1.15	1.15	1.15

Table 6. Hospital Ratings, STEMI-Excluded (Non-pilot)**

	Performance rating	Number of hospitals	Measure	Mean	Std Dev	Median	Minimum	Maximum
Non-pilot	As Expected	106	Volume	665	562	530	1	2942
			Observed event rate	3.06	12.39	1.05	0.00	100.00
			Expected event rate	1.81	4.19	1.01	0.37	31.33
			Risk adjusted event rate	1.11	0.69	1.06	0.00	4.41
	Better	4	Volume	2421	929	2847	1032	2959
			Observed event rate	0.64	0.18	0.64	0.48	0.81
			Expected event rate	1.20	0.29	1.23	0.82	1.52
			Risk adjusted event rate	0.58	0.10	0.60	0.45	0.68
	Worse	5	Volume	325	122	269	219	522
			Observed event rate	3.35	0.88	3.58	1.92	4.09
			Expected event rate	1.42	0.38	1.66	0.91	1.72
			Risk adjusted event rate	2.55	0.31	2.49	2.27	3.04

Table 7. Hospital Ratings, STEMI-Excluded (Pilot)**

	Performance rating	Number of hospitals	Measure	Mean	Std Dev	Median	Minimum	Maximum
Pilot	As Expected	6	Volume	294	188	211	156	649
			Observed event rate	1.28	0.91	1.10	0.00	2.56
			Expected event rate	1.38	0.74	1.17	0.78	2.68
			Risk adjusted event rate	1.15	1.15	0.78	0.00	3.33

Table 8. Total Physician Ratings (Pilot)**

	Number of Operator	Measure	Mean	Std Dev	Median	Minimum	Maximum
As Expected	46	Volume	46	52	19	1	179
		Observed event rate	3.84	8.44	0.78	0.00	50.00
		Expected event rate	3.50	2.39	2.70	0.62	12.09
		Risk adjusted event rate	2.09	4.69	0.96	0.00	28.73
Better	1	Volume	491	.	491	491	491
		Observed event rate	1.83	.	1.83	1.83	1.83
		Expected event rate	3.73	.	3.73	3.73	3.73
		Risk adjusted event rate	0.99	.	0.99	0.99	0.99

Table 9. Physician Ratings, STEMI-Excluded (Pilot)**

	Number of Operator	Measure	Mean	Std Dev	Median	Minimum	Maximum
As Expected	41	Volume	43	64	15	1	336
		Observed event rate	1.80	5.57	0.00	0.00	33.33
		Expected event rate	2.05	3.65	1.10	0.43	23.02
		Risk adjusted event rate	0.88	1.85	0.00	0.00	9.64

Figure 10. Total PCI Volume and Composite Event

Hospital		Operator	
Pearson Correlation Coefficients, N = 122 Prob > r under H0: Rho=0		Pearson Correlation Coefficients, N = 47 Prob > r under H0: Rho=0	
	PCI Volume		PCI volume
rawrate	r=-0.14724	rawrate	r=-0.1063
Observed Event Rate (%)	p=0.1056	Observed Event Rate (%)	p=0.477
exprate	r=-0.22463	exprate	r=-0.1276
Expected Event Rate (%)	p=0.0129	Expected Event Rate (%)	p=0.3927
adjrate	r=-0.03996	adjrate	r=-0.05951
Risk-Adjusted Event Rate (% RAER)	p=0.6621	Risk-Adjusted Event Rate (% RAER)	p=0.6911

* Non-pilot and Pilot

*Pilot data only

Figure 11. PCI Volume and Composite Event, STEMI-Excluded

Hospital		Operator	
Pearson Correlation Coefficients, N = 121 Prob > r under H0: Rho=0		Pearson Correlation Coefficients, N = 41 Prob > r under H0: Rho=0	
	PCI Volume		PCI volume
rawrate	r=-0.17	<u>rawrate</u>	r=-0.07575
Observed Event Rate (%)	p=0.0623	Observed Event Rate (%)	p=0.6378
exprate	r=-0.18499	exprate	r=-0.14349
Expected Event Rate (%)	p=0.0422	Expected Event Rate (%)	p=0.3708
adjrate	r=-0.09628	adjrate	r=0.10083
Risk-Adjusted Event Rate (% RAER)	p=0.2935	Risk-Adjusted Event Rate (% RAER)	p=0.5305

* Non-pilot and Pilot

*Pilot data only

The performance rating is based on a comparison of each hospital's risk-adjusted end-points rate (RAER) to the California (Non-Pilot + Pilot) observed end-points rate. A hospital is classified as "Better**" if the upper 95% confidence limit of its RAER falls below the California observed end-point rate. A hospital is classified as "**Worse**" if the lower 95% confidence limit of its RAER is higher than the California observed end-points rate. A hospital is classified as "**Average**" (As Expected) if the California end-points rate falls within the confidence interval of the hospital's risk-adjusted end-point rate.