



RON CHAPMAN, MD, MPH
Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN, JR.
Governor

The Elective Percutaneous Coronary Intervention (PCI) Pilot Program

Report to the Legislature

California Department of Public Health
Center for Health Care Quality
Licensing & Certification Program

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Executive Summary

Senate Bill 891 (Chapter 295, Statutes of 2008) authorized a pilot program for elective percutaneous coronary intervention (PCI) without on-site cardiac surgery. This pilot program allows six hospitals to perform elective PCI with cardiac surgery availability at a nearby hospital. The six participating pilot hospitals are authorized to continue offering elective PCI until January 1, 2015. The pilot project requires the development of a report analyzing patient outcomes between the pilot hospitals and the outcomes at hospitals with cardiac surgery. Except as authorized by the pilot project, existing law prohibits elective PCIs in hospitals without on-site cardiac surgery.

SB 357 (Chapter 202, Statutes of 2013) extended the sunset date for the PCI Pilot Program to January 1, 2015, allowing the pilot sites' PCI services to continue for an additional year. SB 357 also required the program's Advisory Oversight Committee (AOC) to conduct its final report by November 30, 2013 and made CDPH's report to the Legislature due 90 days after receipt of the AOC report (February 28, 2014)

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. There was no statistically significant difference in composite events between pilot and non-pilot hospital PCIs for either elective (STEMI-excluded) or all patients. Thus, after complete risk adjustment, pilot hospital PCI had the same composite mortality and emergency Coronary Artery Bypass Grafting (CABG) rate as non-pilot hospitals. The AOC report made recommendations in the following areas:

- Institutional Volume
- Operator Volume
- Recommendations for Hospitals
- Quality Assurance

Purpose

This report communicates CDPH's findings from the PCI Pilot Program, as mandated by Health & Safety Code section 1256.01(h):

“Notwithstanding Section 10231.5 of the Government Code, within 90 days of receiving the final report of the oversight committee, the department shall prepare and submit a report to the Legislature, pursuant to Section 9795 of the Government Code, on the initial results of the Elective PCI Pilot Program. The report shall include, but not be limited to, an evaluation of the pilot program's cost, safety, and quality of care. The report shall also include a comparison of elective PCI performed in connection with the Elective PCI Pilot Program, and elective PCI performed in hospitals with on-site cardiac surgery services. The report shall further recommend whether elective PCI without on-site cardiac surgery should be continued in California, and if so, under what conditions.”

Background

Senate Bill (SB) 891 (Chapter 296, Statutes of 2008) established the Elective PCI Pilot Program in Health & Safety Code (HSC) section 1256.01 allowing CDPH to authorize up to six general acute care hospitals to perform elective PCI without having on-site cardiac surgery services. This bill established an advisory committee to provide oversight for the pilot project and to make recommendations to CDPH and required CDPH to submit a report to the Legislature that evaluates the pilot program, compares outcomes in hospitals with and without cardiac surgery services, and recommends whether elective PCI without on-site cardiac surgery should be continued in California. SB 891 included a sunset date for the pilot of January 1, 2014.

SB 357 (Chapter 202, Statutes of 2013) extended the sunset date for the PCI Pilot Program to January 1, 2015, allowing the pilot sites' PCI services to continue for an additional year. SB 357 also required the program's Advisory Oversight Committee (AOC) to conduct its final report by November 30, 2013 and made CDPH's report to the Legislature due 90 days after receipt of the AOC report (February 28, 2014). The AOC report is attached as Appendix A and is available on CDPH's website at:

http://www.cdph.ca.gov/programs/LnC/Documents/PCI_CAMPOS_AOC_Report.pdf

PCI Program Evaluation

A comprehensive rigorous pilot program establishing elective PCIs in six California hospitals without on-site cardiac surgery demonstrated similar safety and efficacy results for elective and non-elective PCIs compared with 116 hospitals with on-site cardiac surgery. No strong relationship was noted between the safety or efficacy of outcomes achieved and the volumes of patients treated. Potential worse outcomes were not identified when comparing the pilot hospitals with non-pilot hospitals. The AOC noted that one pilot site did not meet the STEMI or total volume goals and 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 United States, PCI without on-site cardiac surgery has been increasing since 2007. The AOC report described two randomized trials of non-emergency PCI in the United States that have been published- the CPORT-E¹ and MASS-COMM² trials. Similarly, they found no increase in

¹ Aversano T, Lemmon CC, Liu L; Atlantic CPORT Investigators. Outcomes of PCI at hospitals with or without on-site cardiac surgery N Eng J Med 2012;366:1792-802.

mortality or greater need for emergency coronary artery bypass grafting (CABG) for either primary or non-primary PCI at sites without cardiac surgery.

PCI Program Cost

Based on the actual costs in prior years, the remaining encumbrances in fiscal year (FY) 2013/14, and the budget for FY 2014/15, we estimate the PCI Pilot Program costs to be \$2,425,680. All costs were borne by the participating hospital's themselves and not by the State of California or CDPH.

Final Recommendations

Institutional and Operator Volume

The AOC recommends:

“The 2013 ACCF/AHA/SCAI 2013 PCI Competency Document³ 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. Oversight by a California Interventional Cardiology Advisory Panel reporting to the California Department of Public Health may be utilized in reviewing the outcomes and data. 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.” (Appendix A, pg. 13)

CDPH concurs with the AOC report's final recommendation regarding institutional and operator volume.

Recommendations for Institutional Volume

The AOC recommends:

² Jacobs AK, Normand SL, Massaro JM, Cutlip DE, Carrozza JP Jr, Marks AD, Murphy N, Romm IK, Biondolillo M, Mauri L; the MASS COMM Investigators. Nonemergency PCI at hospitals with or without on-site cardiac surgery. *New Eng J Med* 2013;368:1498-508.

³ Harold J.G., Bass TA, Bashore TM, Brindis RG, et.al. ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Cardiovascular Interventional Procedures: a report of the American College of Cardiology Foundation/American Heart Association /American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Update the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). *J Am Coll Cardiol* 2013;62:357- 396.

“STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary (emergency) 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.” (Appendix A, pg. 14)

CDPH concurs with the AOC report’s final recommendation regarding institutional volume.

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

The AOC recommends:

“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.” (Appendix A, pg. 14)

CDPH concurs with the AOC report’s final recommendation regarding low volume PCI centers and the use of facility quality review to determine satisfactory outcomes.

Operator Requirements: The AOC recommends:

“The 2007 Society of Cardiovascular Angiography and Interventions (SCAI) Expert Consensus Document⁴ 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. The 2013 PCI Competency Document moves away from strict volume requirements to focus more on achieving quality metrics for facilities and individual operators.

⁴ Dehmer GJ, Blankenship J, Wharton TP Jr, Seth A, Morrison DA, DMario C, Muller D, Kellett M, Uretsky BF. The current status and future direction of percutaneous coronary intervention without on-site surgical backup an expert consensus document from the Society of Cardiovascular Angiography and Interventions. *Catheter Cardiovasc Interv* 2007;69:471-8

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.” (Appendix A, pg. 15)

Operator Recommendations: The AOC recommends:

“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.” (Appendix A, pg. 16)

CDPH concurs with the AOC report’s final recommendation regarding operator requirements and operator recommendations; however, under current law the privileging and credentialing of physicians is the responsibility of the hospital, and not CDPH. Hospitals have the responsibility for ensuring appropriate privileging and credentialing of their staff and this should continue for any hospital performing elective PCI.

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

The AOC recommends:

“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 as 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 an 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, Electrocardiogram (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." (Appendix A, pg. 17)

CDPH concurs with the AOC report's final recommendations regarding hospitals in California who wish to perform elective and urgent PCI with offsite surgery.

Quality Assurance

The AOC recommends:

“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 on-site 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.” (Appendix A, pg. 21)

CDPH concurs with the AOC report’s final recommendation regarding participation in the NCDR CathPCI registry and requiring all hospitals that perform PCI, regardless of whether surgery is on-site or off-site, to participate in quality assurance programs that benchmark facilities to other hospitals in the state. Further, CDPH sees the benefit of ongoing consultation with cardiology experts as part of a voluntary advisory committee.

AOC 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 six 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.” (Appendix A, pg. 22)

CDPH Conclusion

There was no statistically significant difference in composite events between pilot and non-pilot hospital PCIs for either elective (STEMI-excluded) or all patients. After complete risk adjustment, pilot hospital PCIs had the same composite mortality and emergency Coronary Artery Bypass Grafting (CABG) rate as non-pilot hospitals.

Consequently, CDPH concurs with the AOC report’s final recommendations regarding:

- institutional and operator volume
- low volume PCI centers and the use of facility quality review to determine satisfactory outcomes
- operator requirements and recommendations (though the privileging and credentialing of physicians is the responsibility of hospitals, and this should continue for any hospital performing elective PCI)
- hospitals in California that wish to perform elective and urgent PCI with offsite surgery
- participation in the NCDR CathPCI registry and requiring all hospitals that perform PCI to participate in quality assurance programs that benchmark facilities to other hospitals in the state.