

Executive Summary

The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions

Gregory J. Dehmer,^{1*} MD, James Blankenship,² MD, Thomas P. Wharton Jr.,³ MD, Ashok Seth,⁴ MD, MBBS, DSc, Douglass A. Morrison,⁵ MD, PhD, Carlo DiMario,⁶ MD, David Muller,⁷ MD, Mirle Kellett,⁸ MD, and Barry F. Uretsky,⁹ MD

The full-length version of this article can be found on the *Catheterization and Cardiovascular Interventions* website (<http://www.mrw.interscience.wiley.com/suppmat/1522-1946/suppmat/index.html>) and on the SCAI website at www.scai.org.

PREAMBLE

The Society for Cardiovascular Angiography and Interventions (SCAI) coauthored and cosponsored with the American College of Cardiology (ACC) and the American Heart Association (AHA) the percutaneous coronary intervention (PCI) guidelines update, released in November 2005 [1]. This guideline update continued to designate elective PCI without on-site surgery as a Class III indication, and primary PCI for ST-segment elevation myocardial infarction (STEMI) as a class IIb indication in the absence of on-site surgery. The performance of PCI without on-site surgical backup is currently the subject of debate. Although providing the highest quality of care and best outcomes to patients should always be the primary goal, debate on this topic has the potential to supersede quality of patient care issues. Within this context, SCAI developed this Expert Consensus document to determine the current status of PCI without on-site surgery not only in the United States, but globally, and make recommendations regarding the performance of PCI in this circumstance. The focus of this document is to provide a structure that provides the highest quality care to patients undergoing PCI in any circumstance.

¹Texas A&M School of Medicine, Scott & White Clinic, Temple, Texas

²Geisinger Medical Center, Danville, Pennsylvania

³Exeter Hospital and Exeter Cardiovascular Associates, Exeter, New Hampshire

⁴Max Devki Devi Heart & Vascular Institute, Saket, New Delhi, India

⁵Yakima Heart Center, Yakima, Washington

⁶Royal Brompton Hospital, London, United Kingdom

⁷St. Vincent's Hospital, Melbourne, Australia

⁸Maine Medical Center, Portland, Maine

⁹Sparks Health System, Fort Smith, Arkansas

See Appendix Table

Endorsed by the following societies: Asian Pacific Society of Interventional Cardiology, Belgian Working Group of Interventional Cardiology, Brazilian Society for Interventional Cardiology, British Cardiovascular Intervention Society, Working Group on Interventional Cardiology of the Bulgarian Cardiology Society, Cardiac Society of Australia and New Zealand, Egyptian Society of Cardiology Working Group on Interventional Cardiology, Interventional Council of the Cardiological Society of India, Italian Society of Interventional Cardiology, Working Group on Interventional Cardiology of the Latvian Society of Cardiology, Polish Working Group on Interventional Cardiology of the Polish Cardiology Society, Sociedad Venezolana de Cardiología Intervencionista (Venezuelan Society of Interventional Cardiology).

*Correspondence to: Gregory J. Dehmer, MD, FSCAI, Professor of Medicine, Texas A&M School of Medicine, Director, Cardiology Division, Scott & White Clinic, 2401 South 31st Street, Temple, Texas 76508. E-mail: president@scai.org

Received 18 January 2006; Accepted 20 January 2006

DOI 10.1002/ccd.21097

Published online in Wiley InterScience (www.interscience.wiley.com).

BACKGROUND

Over the past 20 years, the use and indications for PCI have greatly expanded. It is now well-recognized that PCI is safer and the need for urgent coronary artery bypass graft (CABG) surgery greatly reduced [2]. Primary PCI, when available, has eclipsed fibrinolytic therapy for reperfusion in the treatment of STEMI [3], but is adversely affected by time delays in initiating the PCI procedure [4]. Studies examining patient transport to PCI hospitals have shown suboptimal initial door-to-balloon times, especially in the United States [5]. Efforts to provide primary PCI services locally at community hospitals without on-site cardiac surgery have developed and demonstrate outcomes comparable to facilities that have on-site cardiac surgery [6]. Because it is difficult to sustain a PCI program solely on STEMI patients, elective PCIs are also being performed at facilities without on-site surgery [7], enhancing the debate regarding PCI without on-site surgery.

PREVALENCE AND TRENDS OF PCI WITHOUT ON-SITE SURGERY

Data on the prevalence of PCI performed without on-site surgical backup in the United States are not easily found and are changing rapidly. Data gathered from several sources and believed accurate as of July 2006 indicate primary PCI programs without on-site surgical backup exist in all but 10 states (Alaska, Arkansas, Delaware, Georgia, Mississippi, North Dakota, Rhode Island, South Dakota, Vermont, and Wyoming) plus the District of Columbia. Facilities performing both primary and elective PCI without on-site surgery currently exist in 28 states. A large ($n = 18,000$) randomized trial of elective PCI without on-site surgery (The Atlantic Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study) is currently enrolling patients and includes facilities in several states where elective PCI without on-site backup has been prohibited.

The exact number of patients receiving PCI at facilities without on-site surgery is unknown. Data from facilities reporting to the CathPCI RegistryTM of the ACC-National Cardiovascular Data Registry (ACC-NCDR[®]) show an increase in the number of both primary and elective PCIs performed without on-site surgical backup [8]. In 2005, 75 of the 463 facilities reporting to the ACC-NCDR were performing PCI without on-site surgical backup.

PCI without on-site surgical backup is being performed in 35 of 39 (90%) countries responding to requests for information and appears to be increasing. For example, 7% of PCI procedures performed in the

United Kingdom in 1996 were at facilities without on-site cardiac surgery. By 2004, this increased to 15% with 26% of the PCI centers in the United Kingdom operating without on-site cardiac surgery.

EXISTING GUIDELINES AND COMPETENCY DOCUMENTS

ACC/AHA/SCAI Guidelines

In the 2005 update of this guideline, primary PCI without on-site surgical backup remained a Class IIb indication, and elective PCI without on-site surgery remained a Class III indication. Many other programmatic recommendations were made [1].

European Society of Cardiology Guidelines

In contrast to the ACC/AHA/SCAI guidelines, the 2005 European Society of Cardiology (ESC) guidelines do not comment on PCI without on-site cardiac surgery or issues related to institutional or operator competency [9].

British Cardiac Society and British Cardiovascular Intervention Society Guidelines

The British Cardiac Society and British Cardiovascular Intervention Society (BCIS) guideline, published in 2005, acknowledges and approves PCI without on-site surgical backup and emphasizes a common standard applied across facilities with and without on-site surgical backup so as to avoid two levels of service provision [10].

German Guidelines

The only German guidelines found were published in 1987 [11] and thus may not be relevant today. However, there is substantial evidence that PCI without on-site surgical backup is widely performed in Germany.

The Cardiac Society of Australia and New Zealand Guidelines

Policy statements on support facilities and on the performance of coronary angiography and PCI at rural sites in Australia and New Zealand were published (online) in 2003 and 2005, respectively [12,13]. The Cardiac Society of Australia and New Zealand (CSANZ) guidelines state that PCI is preferably performed in hospitals with on-site surgical support, but acknowledge that the requirements for on-site cardiac surgical facilities may be omitted in certain circumstances, and that appropriately trained individuals can perform coronary interventional procedures safely in hospitals without on-site surgical

backup. Furthermore, these documents acknowledge that rural patients have reduced access to diagnostic angiography and interventional procedures and further state that providing these services as close to the patient's place of residence as possible facilitates equity of access, which should result in improved quality of care.

Spanish Society of Cardiology Guidelines

Published in 1999 [14], these guidelines are specific for PCI at hospitals without on-site cardiac surgery. PCI performance without on-site cardiac surgery is not prohibited, provided a program meets certain requirements.

Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista

Guidelines from the Brazilian Society of Cardiac Hemodynamics and Intervention (Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista) [15] were published in 2003. They use a scheme similar to the ACC/AHA/SCAI guidelines [1] and classify elective PCI without on-site surgical backup as Class III. Primary PCI for STEMI in the absence of on-site surgery is a Class IIa indication; their guidelines do not have a IIb category.

Belgian Working Group on Invasive Cardiology Guidelines

Published in 2003, these guidelines acknowledge the increasing safety and diminishing risk of PCI but conclude that "the current standard practice for elective PCI remains the presence of on-site surgical standby" [16].

PEER-REVIEWED LITERATURE OF PCI WITHOUT ON-SITE SURGERY

There are over 30 published papers or abstracts reporting PCI results without on-site surgical backup. All published data for both primary and elective PCI were derived from retrospective reviews or registries, and thus are subject to unintentional bias and other methodological concerns. These are summarized and referenced in the on-line version of this document. These studies span a time period from 1990 to 2006, and thus incorporate changing treatment paradigms, including fibrinolytic therapy before PCI, glycoprotein IIb/IIIa inhibitors, and coronary artery stents. The total patient number within some of these reports is not easily derived because the studies listed are expanding experiences within the same registry; thus, simple aggregation of outcome data is not appropriate or meaningful. The more recent reports show that both primary and elective PCI without on-site surgical backup are performed with a high success rate,

low in-hospital mortality rate, and a low rate of urgent cardiac surgery.

BEST PRACTICES FOR PCI WITHOUT ON-SITE SURGERY

Although no randomized or controlled studies exist and despite the current ACC/AHA/SCAI guideline recommendation, PCI without on-site surgery is being performed in many states and is accepted in many countries throughout the world. Moreover, data from many countries, including the United States, indicate that the use of PCI without on-site surgery is growing [8]. The purpose of this document is neither to challenge the ACC/AHA/SCAI guideline recommendations nor to support PCI without on-site surgery backup. However, with the reality that PCI without on-site surgery is growing, it is both appropriate and necessary to define the best standards of practice such that facilities and physicians operate within the highest possible quality standards.

Qualifications of the Physician

Simply performing a high volume of cases does not guarantee technical expertise or sound judgment on the part of the physician. More important than a specific case volume threshold is the accurate assessment of complication rates and patient outcomes. Recommendations for physicians performing PCI at facilities without on-site surgery include the following:

- a. Only operators with complication rates and outcomes equivalent or superior to national benchmarks should perform PCI procedures with or without on-site surgery. The operator also must actively participate in a facility's quality improvement program. In addition to involvement in local continuous quality improvement efforts, participation in a national data registry if available and appropriate continuing medical education is mandatory.
- b. A proven record of satisfactory outcomes is of greater importance than simply meeting an arbitrary case volume requirement. However, operators must have sufficient prior experience to allow assessment of their judgment and quality. The initial operators at a facility without on-site backup should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Interventional cardiologists joining those already engaged in PCI without on-site surgery with <500 cases of lifetime experience should be mentored and monitored by existing physicians until it is determined and certi-

4 Executive Summary

TABLE I. Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup

Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.

On-call schedule with operation of laboratory 24 hr/day, 365 days/year^a.

Experienced coronary care unit nursing staff, comfortable with invasive hemodynamic monitoring, temporary pacemaker operation, and intraaortic balloon pump management. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.

Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (e.g., respiratory care, blood bank, etc.).

Written agreements for the emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of twice per year.

Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability and intraaortic balloon pump equipment compatible with transport vehicles. The ability for the real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is ideal.

Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes, thrombectomy and distal protection devices, covered stents, temporary pacemakers, pericardiocentesis trays. Pressure wire device and intravascular ultrasound equipment are optimal but not mandatory. Rotational or other atherectomy devices should be used cautiously in these facilities due to the greater risk of perforation.

Meticulous clinical and angiographic selection criteria for PCI (Tables II and III).

Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door-to-balloon times should be tracked and be ≤ 90 min. Outlier cases should be carefully reviewed for process improvement opportunities.

On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.

Participation in a national data registry where available, such as the American College of Cardiology-National Cardiovascular Data Registry[®] in the United States.

CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation acute myocardial infarction.

^aRequired for the United States facilities, but this may not be possible for all facilities world-wide.

Adapted from Ref. 6.

fied formally by that hospital that their skills and judgment are excellent and outcomes equivalent or superior to the national benchmarks.

- c. Operators performing PCI without on-site surgery should perform ≥ 100 total PCIs per year, including ≥ 18 primary PCIs per year. These numbers exceed those currently recommended in the ACC/AHA/SCAI guidelines to reflect the opinion of this writing group that a greater experience level is appropriate for PCI in this setting.
- d. In the United States, board certification in interventional cardiology by the American Board of Internal

TABLE II. Recommendations for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in:

- Patients with $>50\%$ stenosis of left main artery proximal to infarct-related lesion especially if the area in jeopardy is relatively small and the overall LV function is not severely impaired.
- Long, calcified or severely angulated target lesions at high-risk for PCI failure with TIMI grade 3 flow present during initial diagnostic angiography.
- Lesions in other than the infarct artery (unless they appeared to be flow-limiting in patients with hemodynamic instability or ongoing symptoms).
- Lesions with TIMI grade 3 flow that are not amenable to stenting in patients with left main or three-vessel disease that will require coronary bypass surgery.
- Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention.

Transfer emergently for coronary bypass surgery patients with:

- High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with intra-aortic balloon pump support.
- Failed or unstable PCI result and ongoing ischemia, with intra-aortic balloon pump support during transfer.

LV, left ventricular; PCI, percutaneous coronary intervention; TIMI, Thrombolysis in Myocardial Infarction.

Adapted from Ref. 6.

Medicine is strongly recommended for all physicians performing PCI.

Facilities and Support Personnel

It is essential that all support personnel have adequate education regarding the management of PCI patients before, during, and after the procedure. This knowledge should include potential procedural complications and their management and the drug therapies used in PCI patients (Table I).

Facilities performing both primary and elective procedures without on-site surgery should perform a minimum of 200 PCI/year. Programs with <200 PCI/year should be reviewed on an individual basis. They should remain open only if they are in geographically isolated or under-served areas and their performance metrics are equivalent to accepted benchmarks. We recommend that each country or state review this issue, and establish an absolute minimum annual case volume below which a PCI program must close under any circumstance. In the United States, this minimum should be 150 PCI/year for a program offering both primary and elective PCIs and this must include a minimum of 36 primary PCI/year. Programs offering only primary PCIs must perform a minimum of 36 primary PCIs/year to remain operational. At the present time in the United States, there is no justification for a PCI

TABLE III. Recommendations for Patient and Lesion Selection and Backup Strategy for Nonemergent PCI at Hospitals Without On-site Cardiac Surgery and by Operators Performing ≥ 100 PCIs/Year

Patient Risk: expected clinical risk in case of occlusion caused by procedure.

High Patient Risk: Patients with any of the following:

- decompensated congestive heart failure (Killip Class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders;
- left ventricular ejection fraction $\leq 25\%$;
- left main stenosis ($\geq 50\%$) or three-vessel disease unprotected by prior bypass surgery ($>70\%$ stenoses in the proximal segment of all major epicardial coronary arteries);
- single target lesion that jeopardizes over 50% of remaining viable myocardium.

Lesion Risk: probability that procedure will cause acute vessel occlusion.

Increased Lesion Risk: lesions in open vessels with any of the following characteristics:

- diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments;
- more than moderate calcification of a stenosis or proximal segment;
- location in an extremely angulated segment ($>90^\circ$);
- inability to protect major side branches;
- degenerated older vein grafts with friable lesions;
- substantial thrombus in the vessel or at the lesion site;
- any other feature that may, in the operator's judgment, impede successful stent deployment.
- aggressive measures to open chronic total occlusions are also discouraged due to an increased risk of perforation.

Strategy for Surgical Backup Based on Lesion and Patient Risk:

High-Risk Patient with High-Risk Lesion should not undergo nonemergent PCI at a facility without on-site surgery.

High-Risk Patient with Not High-Risk Lesion: nonemergent patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room is immediately available is necessary.

Not High-Risk Patient with High-Risk Lesion requires no additional precautions.

Not High-Risk Patient with Not High-Risk Lesion requires no additional precautions. Best scenario for PCI without on-site surgery.

CVA, cerebrovascular accident; PCI, percutaneous coronary intervention. Adapted from Ref. 6.

program without on-site surgery to perform only elective procedures or not provide availability to primary PCI 24 hr/day, but such a situation may exist in other countries and be appropriate. New programs should have 2 years to reach the absolute minimum volume, but after that programs failing to reach this volume for 2 consecutive years should not remain open under any circumstance.

Patient and Lesion Selection

Rigorous clinical and angiographic selection criteria are essential for programs performing PCI without on-site surgery. Since the clinical situation and risk-to-benefit ratio are different for primary versus elective PCI, different criteria and standards should apply (Table II). In elective PCI without on-site surgery, it is

TABLE IV. Requirements for Off-Site Surgical Backup

1. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility.
2. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.
3. Cardiac surgeons and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours
4. Surgeon and receiving facility assure that patient will be accepted based on medical condition, capacity of surgeons to provide services at the time of request and availability of resources. If this cannot be assured before starting an elective procedure, the case should not be done at that time.
5. Interventional cardiologist must review with the surgeon the immediate needs and status of any patient transferred for urgent surgery.
6. Hospital administrations from both facilities endorse transfer agreement.
7. Transferring and receiving facility establish a rigorous protocol for the rapid transfer of patients, including the proper personnel with appropriate experience.
8. Transport provider is available to begin transport within 20 min of the request and provide vehicle/helicopter with necessary life-sustaining equipment, including IABP and monitoring capability.
9. Transferring physician obtains consent for surgery from patient or appropriate surrogate.
10. Initial informed consent for PCI discloses that procedure is being done without on-site surgical backup and acknowledges possibility of risks related to transfer. The consent process should include the risk of urgent surgery ($\sim 0.3\%$) and state that a written plan for transfer exists.
11. As part of the local continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.

IABP, intraaortic balloon pump; PCI, percutaneous coronary intervention.

necessary to assess not only the likelihood of PCI failure, but also the potential patient risk if complications occur since it is possible to have a low-risk lesion in a high-risk patient and vice versa. It is important to consider both the patient and lesion risk when developing criteria for selection of appropriate patients for treatment in facilities without on-site surgery (Table III).

Requirements for Off-Site Surgery

A close alliance and cross-communication with cardiovascular surgeons with formalized agreements and periodically tested protocols for the emergency transfer of patients are essential (Table IV). Interventional cardiologists and cardiac surgeons must be actively involved in the program with attendance at regularly scheduled cardiac catheterization conferences and participation in risk management activities.

In hospitals with on-site surgery, it is no longer standard for a surgical suite to be held open awaiting the completion of a PCI. Because the need for urgent

6 Executive Summary

surgery is so infrequent, there are no current data regarding the actual time required to transport a patient to the operating room and initiate cardiopulmonary bypass should the need arise. Should a patient undergoing PCI at a facility without on-site surgery develop a complication requiring urgent transfer for surgery, it is unclear whether or by how much the facility-to-facility transport would add an additional delay in the current practice environment where operating rooms are not held open at on-site facilities. Minimizing the time to the initiation of cardiopulmonary bypass is the goal in this situation and more likely is feasible with on-site cardiac surgery if that surgery is immediately available. There is no acknowledged goal with supporting data similar to a door-to-balloon time for the initiation of cardiopulmonary bypass in this situation, but this should always be accomplished as rapidly as possible, with the goal of <120 min. Operators at facilities without on-site surgical backup should activate the emergency transport system at the first clear signs of a complication even if they attempt to salvage the situation using percutaneous techniques.

Monitoring of Programs

Providing the highest quality PCI services to patients mandates the collection of outcome data and comparison of these data to established benchmarks. Regardless of the mechanism, all PCI programs, with or without on-site surgical backup, must collect appropriate outcome data and compare their data to state, national or their country's performance standards. Data submitted must be audited by an independent authority periodically to insure integrity of the entire process.

UNRESOLVED ISSUES AND FUTURE DIRECTIONS

PCI without on-site surgery is a polarizing and emotional issue for many individuals both within and external to the interventional community. Although debate has focused on whether facilities that offer PCI without on-site surgery should exist, a more meaningful approach would focus on the goal of providing the best possible care to patients who require PCI, regardless of the setting. Recent publications suggest this goal is not being consistently met. Data indicate that the number of coronary artery bypass operations is declining. This trend is likely to continue, resulting in the closing of smaller surgical programs and the coalescence of cardiac surgical services to more centralized locations. If cardiac surgery programs begin to shrink, it will become more difficult for all PCI facilities to have on-site cardiac surgery.

It is inappropriate to open PCI centers if they are not based on the health needs of the community. Opening a low-volume PCI program within the same geographic area and thereby converting a high-volume program at another facility to a low-volume program is not necessarily in the best interests of patients in the community. There is clearly a potential for unnecessary or inappropriate PCI program development in the same geographic area and this is strongly discouraged. However, the factors that define a geographic area are not consistent throughout the United States or other countries. The level and availability of emergency transport services, response times of emergency medical transport, immediate availability of qualified cath lab personnel, and coverage by interventional cardiologists must be considered.

Desires for personal or institutional financial gain, prestige, market share, or other similar motives should not be part of the decision process in determining the need for a PCI program. These considerations apply equally to those wishing to start a new PCI program without on-site backup and those wishing to protect existing programs with on-site backup. In the final analysis, every PCI procedure, regardless of where it is performed, should be of the highest possible quality. This means the PCI is done for appropriate clinical indications, by a skilled operator with documented satisfactory outcomes in a laboratory with appropriate equipment and personnel that has careful tracking of patient outcomes and corrective mechanisms in place to manage individual operator or laboratory outcome data that fall below national standards. Ensuring that all PCI programs meet appropriate performance metrics is likely to save more lives than requiring all PCI programs have on-site surgery.

RECOMMENDATIONS

1. PCI without on-site surgical backup is being performed with acceptable outcomes and risks in the United States and many other countries. The recommendations outlined in this document are made to ensure patient safety and quality outcomes in such a work environment. This is not an open endorsement of PCI without on-site surgery and we do not support the wide-spread use of PCI without on-site surgery especially in the United States, but acknowledge that this practice may be appropriate in some circumstances.
2. The decision to begin or operate a PCI program without on-site surgical backup should be based on the health needs of a local area, not on desires for personal or institutional financial gain, prestige, market share, or other similar motives. Rural communities may have different health care delivery needs than urban centers and this should be considered.

3. It is the goal of SCAI to promote the highest possible program quality. Accordingly, PCI programs both with and without on-site surgical backup must evaluate their outcomes against their countries' benchmark for program performance or other acceptable standard.
4. Operators performing PCI without on-site surgery should perform ≥ 100 total PCIs per year, including ≥ 18 primary PCIs per year. The initial operators at a facility without on-site backup should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Only operators with complication rates and outcomes equivalent or superior to national benchmarks should perform PCI procedures.
5. Independent program oversight should occur either within the context of a local facility's quality assurance program or through an independent government or external agency. Any program failing to perform adequately should close.
6. Further data collection and analysis should be done to more completely understand the role of PCI without on-site surgical backup as a strategy for the delivery of care.

REFERENCES

1. Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention). Available at: www.acc.org/clinical/guidelines/percutaneous/update/index.pdf.
2. Yang EH, Gumina RJ, Lennon RJ, Holmes DR Jr, Rihal CS, Singh M. Emergency coronary artery bypass surgery for percutaneous coronary interventions. *J Am Coll Cardiol* 2005;46:2004–2009.
3. Keeley EC, Boura JA, Grines CL. Primary angioplasty vs. intravenous thrombolytic therapy for acute myocardial infarction: A quantitative review of 23 randomised trials. *Lancet* 2003;361:13–20.
4. De Luca G, Suryapranata H, Ottervanger JP, Antman EM. Time delay to treatment and mortality in primary angioplasty for acute myocardial infarction: Every minute of delay counts. *Circulation* 2004;109:1223–1225.
5. Nallamothu BK, Bates ER, Herrin J, Wang Y, Bradley EH, Krumholz HR, the NRMIs Investigators. Time to treatment in transfer patient undergoing primary percutaneous coronary intervention in the United States. National Registry of Myocardial Infarction (NRMIs-3/4) analysis. *Circulation* 2005;111:761–767.
6. Wharton TP, McNamara NS, Fedele FA, Jacobs MI, Gladstone AR, Funk EJ. Primary angioplasty for the treatment of acute myocardial infarction: Experience at two community hospitals without cardiac surgery. *J Am Coll Cardiol* 1999;33:1257–1265.
7. Ting HH, Raveendran G, Lennon RJ, Hall Long KH, Singh M, Wood DL, Gersh BL, Rihal CS, Holmes DR Jr. A total of 1,007 percutaneous coronary interventions without onsite cardiac surgery. Acute and long-term outcomes. *J Am Coll Cardiol* 2006;47:1713–1721.
8. Dehmer GJ, Kutcher MA, Dey S, Shaw RE, Weintraub WS, Mitchell KR, Hermann AJ, Lattoz DM, Brindis RG, on behalf of the ACC-NCDR. Performing percutaneous coronary intervention at facilities without onsite cardiac surgical backup is increasing: A report from the American College of Cardiology – National Cardiovascular Data Registry (ACC-NCDR). *Circulation* 2005;112(Suppl II):II-481. [In press, *Am J Cardiol*].
9. Silber S, Albertsson P, Aviles FF, Camici PG, Colombo A, Hamm C, Jorgensen E, Marco J, Nordrehaug JE, Ruzyllo W, Urban P, Stone GW, Wijns W. Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology. Guidelines for percutaneous coronary interventions: The task force for percutaneous coronary interventions of the European Society of Cardiology. *Eur Heart J* 2005;26:804–847.
10. Dawkins KD, Gershlick T, de Belder M, Chauhan A, Venn G, Schofield P, Smith D, Watkins J, Gray HH, Joint Working Group on Percutaneous Coronary Intervention of the British Cardiovascular Intervention Society and the British Cardiac Society. Coronary angioplasty: guidelines for good practice and training. *Heart* 2005;91(Suppl VI):vi1–vi27.
11. Deutsche Gesellschaft für Herz- und Kreislaufforschung. Kommission für Klinische Kardiologie (unter Mitwirkung der Arbeitsgruppe Transluminale Angioplastie): Empfehlungen für die Durchführung der Perkutanen Transluminalen Koronarangioplastie (PTCA). *Z Kardiol* 1987;76:382–385.
12. Cumpston N, the Interventional Working Group. Policy on support facilities for coronary angiography and percutaneous coronary intervention. The Council of the Cardiac Society of Australia and New Zealand, August 8, 2003. Available at www.csanz.edu.au/guidelines/practice/index.htm.
13. Brieger D, the Interventional Working Group. Policy on performance of coronary angiography and percutaneous coronary intervention in rural sites. The Council of the Cardiac Society of Australia and New Zealand, November 25, 2005. Available at www.csanz.edu.au/guidelines/practice/index.htm.
14. Oliveras EE, Hernández Antolín RA, Bescós LL, Burgos JM, Moya-Prats JLP. Requirements to perform coronary interventions at hospitals without coronary surgery. Guidelines of the Spanish Society of Cardiology. *Rev Esp Cardiol* 1999;52:5–12.
15. Moura AV, Gottschall CA, Costa EA, Falcão FC, Prudente ML, Furtado RJC. Sociedade Brasileira de Cardiologia. Guidelines for the indications and use of percutaneous interventions and intracoronary stent in clinical practice. *Arq Bras Cardiol* 2003;80(Suppl 1):1–14.
16. Legrand V, Wijns W, Vandenbranden F, Benit E, Boland J, Claeys M, De Scheerder I, Eemans T, Hanet C, Heyndrickx G, Lafontaine P, Materne P, Taeymans Y, Vrints C, Vrolix M. Belgian Working Group on Invasive Cardiology. Guidelines for percutaneous coronary intervention by the Belgian Working Group on Invasive Cardiology. *Acta Cardiol* 2003;58:341–348.

8 Executive Summary

APPENDIX

TABLE SCAI Writing Committee for Expert Consensus Document Disclosures

Name	Do you perform elective PCIs in a hospital that has on-site surgical backup?	Do you have an ownership or other financial relationship with a hospital that performs elective PCIs and has on-site surgical backup?	Do you perform elective PCIs in a hospital that does not have on-site surgical backup?	Do you have an ownership or other financial relationship with a hospital that performs elective PCIs and does not have on-site surgical backup?	Comments
Dr. Gregory J. Dehmer	Yes	No	No	No	None
Dr. James Blankenship	Yes	No	No	No	None
Dr. Thomas P. Wharton, Jr.	Yes	No	Yes	No	None
Dr. Ashok Seth	Yes	No	No	No	None
Dr. Douglass A. Morrison	Yes	No	No	No	I perform PCI at one hospital with on-site surgery and primary PCI only at a different hospital without on-site surgery.
Dr. Carlo DiMario	Yes	No	No	No	
Dr. David Muller	Yes	No	No	No	I perform primary PCI at a hospital without on site surgery
Dr. Mirle Kellett	Yes	No	No	No	None
Dr. Barry F. Uretsky	Yes	No	No	No	None

PCI, percutaneous coronary intervention.