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

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Preamble

The Society for Cardiovascular Angiography and Interventions (SCAI) co-authored and co-sponsored 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]. About one year earlier, the SCAI leadership commissioned a working group to examine the current status of PCI without on-site surgical backup. This group, composed of Gregory J. Dehmer, MD (Chair), James Dwyer, MD, Kirk Garrett, MD, Mirle Kellett, MD, Lloyd Klein, MD, Barry F. Uretsky, MD, and Thomas Wharton MD, provided a final report which was approved by the SCAI Board of Trustees on October 10, 2005. The Board of Trustees then commissioned a writing group to develop an expert consensus document on the current status of PCI without on-site cardiac surgery. SCAI carefully considered and ultimately approved the 2005 PCI guidelines update which continued to designate elective PCI without on-site surgery a Class III indication and primary PCI for ST-segment elevation myocardial infarction (STEMI) a class IIb indication. Nevertheless, there was a clear opinion within the Society that a comprehensive review of the status of PCI without on-site surgery was warranted.

The performance of PCI without on-site surgical backup is currently the subject of debate [2-5]. Although providing the highest quality of care and best outcomes to patients should always be the primary goal, it must be acknowledged that this debate has the potential to supersede quality of patient care issues. On one side, opponents of PCI without on-site surgery believe that personal, financial and market-driven motives have eclipsed quality of care issues and fostered the increased and unregulated growth of this practice. On the opposite side, proponents of PCI without on-site surgery believe that personal, financial and

market-driven motives also exist at PCI centers with on-site surgery where fears of increased competition and loss of market share have promoted unnecessarily restrictive standards and state regulations against a practice which facilitates early and convenient access to PCI services in local communities. It is within this context that the SCAI engaged in this effort to determine the current status of PCI without on-site surgery not only in the US, but globally. The specific goals of this effort were to:

1. Gather facts and trends on the prevalence of PCI without on-site surgery.
2. Review existing guidelines and competency statements related to the performance of PCI without on-site surgery.
3. Review and summarize literature related to the performance of PCI without on-site surgery.
4. Define the best practice methods at facilities that are currently performing PCI without on-site surgery.
5. Make recommendations with universal applicability on the role of PCI without on-site surgery.

This document will not address every possible issue or circumstance related to PCI at facilities without on-site cardiac surgery. Rather, the desired endpoint is to focus on providing the highest quality care to patients.

Background

The use of PCI has grown tremendously over the past 20 years. Many factors have contributed to this growth including equipment improvements, new anticoagulant and antiplatelet therapies and, most recently, the development of the coronary artery stent. These improvements have not only expanded PCI indications, but have also improved dramatically

procedural safety. In the early days of balloon angioplasty, 1.0 - 2.5% of patients died and 1.9 - 5.8% required urgent coronary artery bypass graft (CABG) surgery [6-8]. In contrast, recent surveys performed at high volume centers show an in-lab mortality rate of 0.23% and a 0.3 – 0.6% incidence of urgent CABG surgery [9-11]. Although the frequency of emergency CABG has declined, perioperative mortality has remained high and may be increasingly due to an unfavorable shift in patient risk factors and morbidity when urgent surgery is necessary [12].

One of the current PCI indications is acute reperfusion in STEMI patients. Pooled analyses have demonstrated the superiority of primary PCI over thrombolytic therapy [13, 14]. However, the superior outcomes of primary PCI are adversely affected by time delays in initiating the PCI procedure [15, 16]. Such delays may occur at many levels within the continuum of care including patient delay from failure to recognize the importance of symptoms, delay in patient transfer to a PCI center and delay at the PCI hospital once the patient enters the door [17]. Trials combining various pharmacologic agents to improve reperfusion before transfer to a PCI center (so called "facilitated PCI") have not shown dramatic advantages compared with primary PCI alone [18], but ongoing trials are currently exploring different pharmacologic options [19-21]. Moreover, studies examining patient transport to PCI hospitals have shown suboptimal initial door-to-balloon times, especially in the US [22, 23]. As the advantages of primary PCI became more widely accepted, two separate initiatives developed to deliver this care to as many acute STEMI patients as possible. Efforts to diagnose acute STEMI "in the field" and rapidly transport patients to PCI centers are receiving increasing emphasis with some suggesting regional MI centers be developed and patterned after the successful trauma center concept [24-26]. Concurrently,

efforts to provide primary PCI services locally at community hospitals without on-site cardiac surgery have developed and demonstrated outcomes comparable to facilities that have on-site cardiac surgery [27-32]. The rationale for providing PCI at qualified hospitals without on-site cardiac surgery to support local health needs has been discussed [4, 33, 34]. 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 [30-32]. Other non-elective subgroups, such as those with high-risk acute coronary syndromes, but with no evidence of myocardial necrosis may benefit from PCI at local facilities, especially when the distance to a facility with on-site surgery is considerable.

Prevalence and Trends of PCI without On-site Surgery

United States data. Data on the prevalence of PCI performed without on-site surgical backup are not easily found and are changing rapidly. Data were gathered primarily from a web survey of the SCAI membership and then supplemented and confirmed by several independent sources. These data, which we believe are 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 (Fig 1). Facilities performing both primary and elective PCI without on-site surgery currently exist in 28 states. In some states, this situation is allowed only through a controlled demonstration project run by the state's Department of Health. A large (n = 13,200) randomized trial of elective PCI without on-site surgery (The Atlantic C-PORT Elective Angioplasty Study) is currently enrolling patients and includes facilities in several states where elective PCI without on-site backup has been prohibited.

International data. International data were derived from three sources: a web-based survey of non-US SCAI members; letters of inquiry to leadership of several international interventional cardiology societies; and the medical literature if a study reported PCI without on-site backup in a country. In total, data were available from 39 countries indicating PCI without on-site surgical backup is being performed in 35 (90%) (Table 1).

PCI trends in the US. The number of patients receiving PCI at facilities without on-site surgery is unknown. However, a recent assessment of trends in PCI without on-site surgical backup was performed using data from the CathPCI Registry™ of the ACC-National Cardiovascular Data Registry (ACC-NCDR®) [35]. From January 2001 to December 2004, 39 facilities without on-site surgical backup submitted PCI data to the ACC-NCDR®. These data showed that the number of both primary and elective PCIs with or without on-site surgical backup enrolled in the ACC-NCDR® per quarter increased significantly ($p<0.0001$) from 2001 to 2004. Moreover, the proportion of elective PCIs performed at facilities without on-site surgical backup increased over this time interval. ACC-NCDR® data from 2005 show a further increase to 75 facilities performing PCI without on-site surgical backup with a continued increase in the number of patients receiving PCI in this setting. (Fig 2) These data suggest growth in the performance of PCI without on-site surgery, but are subject to reporting bias since only 463 of approximately 2100 cardiac catheterization laboratories in the US report data to the ACC-NCDR®.

Existing Guidelines and Competency Documents

ACC/AHA/SCAI guidelines. A revision of the 2001 guideline was released in November 2005 [1]. Primary PCI for STEMI without on-site surgical backup remained a Class IIb indication and elective PCI without on-site surgery remained a Class III indication.

Several additional recommendations were made that primary PCI for STEMI be performed by higher volume operators experienced in both elective PCI and primary PCI for STEMI with ongoing activity levels of greater than 75 elective PCI procedures per year and, ideally, annual PCI for STEMI activity levels of at least 11 per year. Numerous other programmatic recommendations were made [1].

European Society of Cardiology (ESC) guidelines. In contrast to the ACC/AHA/SCAI guidelines, the 2005 ESC guidelines do not comment on PCI without on-site cardiac surgery or issues related to institutional or operator competency [36]. Data from our survey of international members indicate that PCI without on-site surgery is performed widely in several European countries and is growing rapidly in the Asia-Pacific rim.

British Cardiac Society and British Cardiovascular Intervention Society guidelines. Guidelines from these groups were published in 2000 [37]. These guidelines contain a comprehensive discussion of this issue and acknowledge that differences of opinion exist regarding the need for on-site cardiac surgical backup. These guidelines state:

> *"While acknowledging that differences of opinion do exist, we believe that there is still a general consensus that access to emergency surgery, whether on-site or off-site, should be available for all patients undergoing PTCA, other than for those individuals who have been prospectively agreed not to require cover . . . ."*
> *"We recommend that all centres, whether with on-site or off-site surgical cover, should be able to establish cardiopulmonary bypass within 90 minutes of the referral being made to the cardiac surgical service. For all patients requiring emergency cardiac surgery the time taken to establish cardiopulmonary bypass should be recorded and subsequently audited."*

These guidelines further emphasize those PCI facilities without on-site surgery should ensure:

- explicit, reliable arrangements are in place for the prompt transfer of a patient in an appropriate transport vehicle should the need for urgent surgery arise.

- that the covering surgeon know, in advance, that PCI is being undertaken.
- cases are selected on the basis of an overall lower anticipated risk and need for emergency surgery with additional consideration given to the hemodynamic consequences and the patient's likely clinical stability, were abrupt occlusion of the target coronary lesion to occur.

Data from 1996 showed that 7% of 20,511 PCI procedures performed in the United Kingdom were at facilities without on-site cardiac surgery. The 2004 update from the British Cardiovascular Intervention Society (www.bcis.org.uk) PCI registry shows that 20 (26%) of the 77 PCI centers in the United Kingdom do not have on-site cardiac surgery. Of the 62,780 PCI procedures performed in 2004, 15% (9,390) were performed at facilities without on-site surgery.

German guidelines. The only German guidelines found were published in 1987 [38] and thus may not be relevant today. However, there is substantial evidence that PCI without on-site surgical backup is widely performed in Germany. An abstract from Germany published in 1994 described 38 sites performing PCI without on-site cardiac surgery [39].

The Cardiac Society of Australia and New Zealand (CSANZ) guidelines. A policy statement on support facilities for coronary angiography and PCI was published (on-line) in 2003 [40]. These state:

> *"The Cardiac Society believes that coronary interventional procedures are preferably performed in hospitals with on-site surgical support. The Council of the Society believes that the requirements for on-site cardiac surgical facilities for laboratories performing coronary interventional procedures may be omitted in certain circumstances . . . . .* and *"that appropriately trained individuals can perform coronary interventional procedures safely in hospitals without on-site surgical backup".*

Additional recommendations included: a) operators with adequate experience and training be individually accredited by the hospital; b) that facilities should be performing diagnostic coronary angiography with acceptable morbidity and mortality before performing PCI and have a formal written transfer agreement with a cardiac surgical center; c) that facilities have adequate equipment and staff capable of maintaining a patient with intraaortic balloon pump and temporary pacemaker; d) careful selection of cases with the statement that stable patients with high risk anatomy may be better served by performing the procedure in a facility with on-site surgical backup; e) patient consent include an explanation of the potential additional patient risk as a result of delayed surgical intervention for a complication due to the time involved in transporting the patient to the surgical facility and f) mandatory careful and complete record keeping and peer-review auditing of individual and procedural results as an intrinsic part of quality assurance related to coronary angiography and coronary interventional procedures.

CSANZ posted a policy statement on the performance of coronary angiography and PCI at rural sites in 2005 [41]. This document acknowledges that rural patients have reduced access to diagnostic angiography and interventional procedures and further states that providing this service as close to the patient's place of residence as possible facilitates equity of access which should result in improved quality of care. CSANZ supports the view that it is safe to perform interventional procedures in rural locations remote from surgical units provided certain conditions are met. These conditions include a proper hospital infrastructure and facilities, critical mass of appropriately trained individuals and formalized links with major tertiary units. In addition, procedure safety requires: a) careful patient selection; b) comprehensive staff training; c) structured clinical protocols; and d) guaranteed

priority access to a surgical unit. All patients undergoing coronary angiographic and interventional procedures should be informed that the procedure is being performed without surgery on site, and that access to emergency surgical procedures would likely take additional time. Other management options, including PCI performance in a center with on-site surgery should be made clear. A minimum case load of 200 procedures annually was recommended.

Spanish Society of Cardiology guidelines. Published in 1999 [42], these guidelines are specific for the PCI performance at hospitals without on-site cardiac surgery. PCI performance without on-site cardiac surgery is not prohibited provided a program meets certain requirements including a) dedicated in-house services such as general or vascular surgery, ICU, anesthesia and blood bank, b) a formal transfer arrangement with a cardiac surgery center with a travel time less than 1 hour, c) experienced and proficient operators defined as 50-75 PCI/year and d) a laboratory volume of at least 500 diagnostic studies and 100 PCIs annually. It was emphasized that low to moderate risk cases with a reasonable likelihood of success and low likelihood of complications should be the focus of such a program. The consent must include information about the transport to another center should the need for cardiac surgery arise.

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" [43].

Operator competency documents. There are no publications specifically defining operator competency for PCI performance in facilities without on-site cardiac surgery.

However, operator and institutional criteria have been proposed by individual authors [34, 44]. Most guideline documents discuss operator competency, but there is no distinction regarding the presence or absence of on-site surgical backup. In general, a minimal annual case load of 50-75 procedures is recommended for operator competency. The 2005 ACC/AHA/SCAI PCI guidelines state that primary PCI for STEMI should be performed by higher volume operators experienced in both elective and primary PCI for STEMI with ongoing activity levels of greater than 75 elective PCI procedures per year and, ideally, an annual STEMI PCI activity level of at least 11 per year [1]. Other publications consistently emphasize that PCI without on-site cardiac surgery be performed by experienced high-volume interventionalists without providing specific volume or experience requirements.

Developing countries. PCI is now being used in several developing countries where cardiac surgery is not available and patients are sometimes unable to travel to surrounding nations for care. This document is intended for developed countries and not emerging nations where surgical back-up is not possible. Frequently, experienced physicians from developed countries volunteer to perform and teach PCI in this setting.

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 [27-32, 45-70]. Many studies focus on either primary or elective PCI, but several include all PCI patients without on-site surgical backup.

Primary PCI. Publications reporting only primary PCI or data related to primary PCI extracted from mixed studies (primary and elective PCI) are summarized in Table 2 [27,28,32, 45-61]. These studies report retrospective reviews or prospective registries with

considerable variation in patient entry criteria. Moreover, these studies span a time period from 1993 to 2006 and thus incorporate changing treatment paradigms including fibrinolytic therapy before PCI, glycoprotein IIb/IIIa inhibitors and coronary artery stents. Accordingly, simple aggregation of outcome data is not appropriate or meaningful. Even total patient number within these reports is not easily derived because some of the studies listed are expanding experiences within the same registry [28, 32, 53, 54], and thus may duplicate early patient experiences. The more recent reports show that primary PCI without on-site surgical backup is performed with a high success rate, low in-hospital mortality rate and a low rate of urgent cardiac surgery (Table 2). The highest mortality rate was reported in a study that included only Medicare patients and is a 30 day rather than in-hospital mortality rate [61]. In this study, the 30-day mortality rate for primary PCI in facilities without on-site backup was not different from that at facilities with on-site backup. Moreover in this study, the majority of hospitals without on-site cardiac surgery performed ≤ 25 Medicare PCIs per year, while only a small number of hospitals with on-site cardiac surgery were low volume hospitals.

Elective PCI. Publications of only elective PCI or data related to elective PCI extracted from mixed studies (primary and elective PCI) are summarized in Table 3 [29-32, 57, 58,61-70]. These studies consist of retrospective reviews or prospective registries with considerable variation in the patient entry criteria. They span a time period from 1990 to 2006 and thus reflect therapeutic advances such as glycoprotein IIb/IIIa inhibitors and coronary artery stents. Some studies apply strict screening criteria to identify only low-risk PCI patients while others describe PCI in a broad patient range including several high-risk subgroups. Therefore, simple aggregation of the outcomes data is difficult to interpret. Recent reports show that elective PCI without on-site surgical backup is performed with a

high success rate, low in-hospital mortality rate and a low rate of urgent cardiac surgery (Table 3). The highest mortality rate was observed in a Medicare population, but with 75% of the hospitals performing ≤ 25 PCI procedures annually on Medicare patients [61].

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. The generally favorable reports may also reflect publication bias as there is no requirement for public reporting of programs that have not succeeded at PCI without on-site surgical backup. A well-controlled, properly powered and randomized study has not been performed, but one large study is now underway. Simply showing that the need for urgent CABG following PCI at facilities without on-site surgical backup is low and not different than facilities with on-site surgical backup is insufficient to completely determine the safety of performing PCI without on-site surgery. Since facilities without on-site surgical backup should be performing lower risk cases in the elective setting, it is anticipated the risk of emergency CABG will be lower than at centers with on-site surgery. It must be shown that the mortality of patients requiring transfer for urgent CABG surgery is no different than the mortality of patients requiring urgent surgery at facilities with on-site 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 US indicate that the use of PCI without on-site surgery is growing [35]. The purpose of this document is neither to challenge the ACC/AHA/SCAI

guideline recommendations nor 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. Several prior publications have set forth recommendations for PCI without on-site surgery and have been used in developing the standards recommended by the SCAI in this document [27-32, 34, 44].

Qualifications of the physician. All prior publications emphasize that PCI without on-site surgery should be performed by "experienced interventionists" but this term is not defined precisely. 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. Although no PCI data registry should be considered comprehensive at this time, for the US we recommend benchmarks of the most current ACC-NCDR® CathPCI Registry™ be used including median rates of risk-adjusted mortality, door-to-balloon time ≤ 90 minutes, overall vascular complications, angiographic luminal success, urgent revascularization and peri-procedural MI stratified for primary, urgent and elective PCI. The adverse events tabulated should include events at the original PCI facility and at centers to which the patient may be subsequently transferred. The operator also must actively

participate in a facility's quality improvement program. Participation in a continuous quality improvement program has been suggested to improve selected PCI outcomes [71]. 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, but operator outcomes cannot be accurately determined until a substantial number of cases have been completed. Accordingly, 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 certified 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. Operators who cannot maintain these case volume recommendations at their primary practice site should maintain privileges and continue to perform PCI

procedures at a high-volume institution with on-site surgical backup to meet these annual volume requirements.

d. In the US, board certification in interventional cardiology by the American Board Internal Medicine is strongly recommended for all physicians performing PCI. Since 2003, board eligibility can only be obtained by completion of an additional training program in interventional cardiology. It is recognized that there are a substantial number of experienced interventional cardiologists who developed their skills before formal training programs or board certification existed, but this number is gradually diminishing. Individuals who do not possess board certification, but with substantial lifetime experience and monitored outcomes that are within benchmark standards should continue to perform PCI. Although board certification provides confirmation of a satisfactory knowledge base, it is not a guarantee that an individual can apply that knowledge to obtain satisfactory clinical outcomes in practice. Formal physician certification programs do not exist in many other countries where high quality PCI is performed. Ultimately, developing benchmark performance metrics is a necessary step to improving the quality of PCI care worldwide.

Facilities and support personnel. Requirements for personnel and facilities are listed in Table 4. 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.

Much has been written about the association between facility/operator procedure volumes and patient outcomes. Many of the initial studies examining these relationships occurred in an era when balloon angioplasty was the only treatment modality and thus are less meaningful today [72-74]. In the "stent era", a relationship between procedure volume and patient outcome is apparent in some [75-78], but not all studies [79]. It is important to note that data examining the volume-outcome relationship are derived predominantly from facilities with on-site cardiac surgery and thus are difficult to apply to facilities without on-site surgery because the risk profile of patients treated at such facilities may be different. Moreover, the validity of judging program quality, based on volume data alone has been challenged not only for PCI, but also for CABG surgery [80-83].

Although the minimal acceptable annual procedure volume for a facility is ill-defined and subject to debate, there must be some minimal threshold below which the experience and proficiency of personnel at a facility would be difficult to maintain. The 2005 ACC/AHA/SCAI guideline update recommends 200 PCIs annually as the absolute minimum number for operation of a facility unless located in an underserved area and defines facilities performing 200-400 PCIs annually to be "low volume" centers [1]. Based on the available data and in concordance with the 2005 ACC/AHA/SCAI guideline update and other guidelines, it is recommended that facilities performing both primary and elective procedures without on-site surgery 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 US, there is no justification for a PCI program without on-site surgery to perform only elective procedures, 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 two consecutive years should not remain open under any circumstance.

Patient and lesion selection. Rigorous clinical and angiographic selection criteria are essential for the success of any program, especially programs performing PCI without on-site surgery. These criteria must be developed and documented in each laboratory. Since the clinical situation and risk-to-benefit ratio is different for primary versus elective PCI, different criteria and standards should apply. In the setting of primary PCI for STEMI, the goal is to quickly establish flow in the infarct-related artery yet avoid provoking a situation which could lead to clinical deterioration and possibly urgent CABG surgery (Table 5). In elective PCI without on-site surgery, it is 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. Several risk models have been developed to predict the likelihood of an adverse outcome based on clinical and angiographic variables [84-88] (Table 6). 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. Some patients deemed too great a risk for PCI at a facility without on-site surgery, may still be candidates for PCI at a facility with on-site surgery. Established

treatment guidelines and indications should be followed as adherence to these guidelines is also associated with improved outcomes [89].

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 7). 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. Should urgent surgery be required, patients are stabilized while awaiting transfer to an open operating room. Because the need for urgent 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. In one study [11], transport to the operating room within 2 hours was provided to all patients felt to be at increased risk of harm by further delays in transport to the operating room. 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. One of the possible reasons for urgent surgery is acute vessel occlusion. Although acute vessel closure occurs less frequently now during PCI than in the past, it is a situation similar to primary PCI for STEMI where the goal for door-to-balloon time is $\leq$ 90 minutes. 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 minutes. 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. Coronary vessel perforation is another potential reason for urgent surgery [90, 91]. Although the incidence of coronary perforation is low, operators must be familiar with and have access to equipment for the percutaneous management of this complication including prolonged balloon inflations, covered stent placement, embolization of the affected vessel, and pericardiocentesis.

In addition to hemodynamic support with an intra-aortic balloon pump, several percutaneous support devices exist or are in development which may be useful in patients with failed PCI awaiting urgent surgery [92].

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. Several states now mandate the collection and reporting of PCI outcome data and make these data available to the public. Other independent organizations collect PCI data, sometimes limited to Medicare patients, and issue public reports. Public reporting of outcome data has the potential to drive quality improvement and eliminate programs with poor performance, but may also have unintended negative effects [93, 94]. 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.

With emphasis in the US shifting to enhancing PCI program quality, and "pay-for-performance" initiatives on the horizon, it will be necessary to have an effective and impartial evaluation of the quality of PCI performance. One of the challenging issues is deciding who should provide oversight of PCI programs. Ideally, each facility should establish an internal, objective and impartial oversight mechanism, but this approach is infrequently accomplished because of conflicting local issues and financial constraints. External oversight already exists in the US for hospitals and oversight of PCI programs will be necessary either through an independent organization, state government agencies, or professional societies. It is critical that such a program be fair, impartial, not burdensome and focused on providing the best possible PCI care for the locale under consideration. Any program with specified performance metrics below (more than one standard deviation or in the lower quartile) compared with the accepted standard should be on probation pending improvement in the next monitoring period. Programs failing to improve should be closed by the monitoring authority.

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. For example, door-to-balloon times for primary PCI in patients with STEMI are not

optimal. Transfer delays to PCI centers exist [22, 95, 96] and, in non-STEMI acute coronary artery syndromes, may exceed the optimal interval recommended for treatment [97]. The need to develop a national strategy for the timely treatment of STEMI has recently been highlighted along with the potential barriers to this goal [25, 26]. The AHA's Acute Myocardial Infarction Working Group recommended strategies to increase the number of STEMI patients with timely access to primary PCI [26]. Their strategies included:

1. Patient-centered care as the first priority
2. High-quality care that is safe, effective, and timely
3. Stakeholder consensus on systems infrastructure
4. Increased operational efficiencies
5. Appropriate incentives for quality, such as "pay for performance," "pay for value," or "pay for quality"
6. Measurable patient outcomes
7. An evaluation mechanism ensuring that quality-of-care measures reflect changes in evidence-based research, including consensus-based treatment guidelines
8. A role for local community hospitals so as to avoid a negative impact that could eliminate critical access to local health care
9. A reduction in disparities of healthcare delivery, such as those across economic, education, racial/ethnic, or geographic lines

These principles provide an excellent roadmap for the future and are applicable to all PCI programs world-wide. Unresolved is what role facilities without on-site cardiac surgery will play in such a national strategy. Data from facilities participating in NRMI 3 and 4

indicate that hospitals performing primary PCI without on-site cardiac surgery have quality-of-care indicators and adherence to ACC/AHA management guidelines that are comparable to hospitals with on-site cardiac surgery [59].

Data indicate that the number of coronary artery bypass operations is declining. This trend is likely to continue. Percutaneous treatments for valvular heart disease may further reduce the number of cardiac surgeries resulting in the closing of smaller surgical programs and the coalescence of cardiac surgical services to more centralized locations. Data from the National Residency Matching Program indicate 33% of the thoracic surgery training slots went unfilled for the appointment year beginning 2007 [98]. If cardiac surgery programs begin to shrink, it will become more difficult for all PCI facilities to have on-site cardiac surgery. This situation already exists internationally, where there are fewer cardiac surgery centers per capita, yet substantial portions of the population require revascularization.

Just as it would be inappropriate to open more low volume cardiac surgery centers if not needed, it likewise 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 US 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. It was estimated that nearly 80% of the adult population in

the US lived within 60 minutes of a PCI hospital in 2000 [99]. Moreover, among those living closer to non-PCI hospitals, almost three fourths would experience < 30 minutes of additional delay with direct referral to a PCI hospital. In some areas the appropriate solution may be the development of a "hub-and-spoke" system for the efficient transfer of patients to a PCI facility. However, in other areas developing a PCI program at a hospital without on-site surgery may be preferable. It is clear that there are multiple different opportunities to improve the care of patients requiring PCI and the best solution for one area may not be the best solution for another area.

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 which 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 U.S. and many other countries. The practice guidelines outlined in this document are recommended to assure 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 US, 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 the 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. 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.
5. 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: http://www.acc.org/clinical/guidelines/percutaneous/update/index.pdf.
2. Kansagra SM, Curtis LH, Schulman KA. Regionalization of percutaneous transluminal coronary angioplasty and implications for patient travel distance. JAMA 2004;292:1717–1723.
3. Weaver WD. Is onsite surgery backup necessary for percutaneous coronary interventions? JAMA 2004;292:2014–2016.
4. Wharton TP Jr. Should patients with acute myocardial infarction be transferred to a tertiary center for primary angioplasty or receive it at qualified hospitals in the community: the case for community hospital angioplasty. Circulation 2005;112:3509–3534.
5. Keeley EC, Grines CL. Should patients with acute myocardial infarction be transferred to a tertiary center for primary angioplasty or receive it at qualified hospitals in the community: the case for emergency transfer for primary percutaneous coronary intervention. Circulation 2005;112:3509–3534.
6. Kent KM, Bentivoglio LG, Block PC, Cowley MJ, Dorros G, Gosselin AJ, Gruntzig A, Myler RK, Simpson J, Stertzer SH, Williams DO, Fisher L, Gillespie MJ, Detre K,

Kelsey S, Mullin SM, Mock MB. Percutaneous transluminal coronary angioplasty: report form the Registry of the National Heart, Lung, and Blood Institute. Am J Cardiol 1982;49:2011–2020.

7. Detre KM, Holubkov R, Kelsey S, Cowley M, Kent K, Williams D, Myler R, Faxon D, Holmes D Jr, Bourassa M, Block P, Gosselin A, Bentivoglio L, Leatherman L, Dorros G, King SB 3rd, Galichia J, Al-gassan M, Leon M, Robertson T, Passamini E, for the Coinvestigators of the NHLBI PTCA Registry. Percutaneous transluminal coronary angioplasty in 1985–86 and 1977–81: the National Heart, Lung, and Blood Institute Registry. N Engl J Med 1988;318:265–270.
8. Williams DO, Holubkov R, Yeh W, Bourassa MG, Al-Bassam M, Block PC, Coady P, Cohen H, Cowley M, Dorros G, Faxon D, Holmes DR, Jacobs A, Kelsey SF, King SB 3rd, Myler R, Slater J, Stanek V, Vlachos HA, Detre KM. Percutaneous coronary intervention in the current era compared with 1985–1986: the National Heart, Lung, and Blood Institute Registries. Circulation 2000;102:2945–2951.
9. 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.
10. Seshadri N, Whitlow PL, Acharya N, Houghtaling P, Blackstone EH, Ellis SG. Emergency coronary artery bypass surgery in the contemporary percutaneous coronary intervention era. Circulation 2002;106:2346 –2350.
11. Lofti M, Mackie K, Seidelin PH. Impact of delays to cardiac surgery after failed angioplasty and stenting. J Am Coll Cardiol 2004;43:337-342.

12. Reinecke H, Fetsch T, Roeder N, Schmid C, Winter A, Ribbing M, Berendes E, Block M, Scheld HH, Breithardt G, Kerber S. Emergency coronary artery bypass grafting after failed coronary angioplasty: what has changed in decade? Ann Thorac Surg 2000;70:1997-2003.

13. 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.

14. Boersma E and The Primary Coronary Angioplasty vs. Thrombolysis (PCAT)-2 Trialists' Collaborative Group. Does time matter? A pooled analysis of randomized clinical trials comparing primary percutaneous coronary intervention and in-hospital fibrinolysis in acute myocardial infarction patients. Eur Heart J 2006;27:779-788.

15. Cannon CP, Gibson CM, Lambrew CT, Shoultz DA, Levy D, French WJ, Gore JM, Weaver WD, Rogers WJ, Tiefenbrunn AJ. Relationship of symptom-onset-to-balloon time and door-to-balloon time with mortality in patients undergoing angioplasty for acute myocardial infarction. JAMA 2000;283:2941–2947.

16. 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.

17. Hutter AM Jr, Weaver WD. 31st Bethesda Conference: emergency cardiac care: Task Force 2: acute coronary syndromes: section 2A: prehospital issues. J Am Coll Cardiol 2000;35:846–853.

18. Keeley EC, Boura JA, Grines CL. Comparison of primary and facilitated percutaneous coronary interventions for ST-elevation myocardial infarction: quantitative review of randomised trials. Lancet 2006; 367:543-546.

19. Ellis SG, Armstrong P, Betriu A, Brodie B, Herrmann H, Montalescot G, Neumann FJ, Smith JJ, Topol E; Facilitated Intervention with Enhanced Reperfusion Speed to Stop Events Investigators. Facilitated percutaneous coronary intervention versus primary percutaneous coronary intervention: design and rationale of the Facilitated Intervention with Enhanced Reperfusion Speed to Stop Events (FINESSE) trial. Facilitated Intervention with Enhanced Reperfusion Speed to Stop Events Investigators Am Heart J. 2004;147:1-8.

20. Di Mario C, Bolognese L, Maillard L, Dudek D, Gambarati G, Manari A, Guiducci V, Patrizi G, Rusconi LC, Piovaccari G, Hibon AR, Belpomme V, Indolfi C, Olivari Z, Steffenino G, Zmudka K, Airoldi F, Panzarasa R, Flather M, Steg PG. Combined Abciximab REteplase Stent Study in acute myocardial infarction (CARESS in AMI). Am Heart J. 2004;148:378-385.

21. Armstrong PW, WEST Steering Committee. A comparison of pharmacologic therapy with/without timely coronary intervention vs. primary percutaneous intervention early after ST-elevation myocardial infarction: the WEST (Which Early ST-elevation myocardial infarction Therapy) Study. Eur Heart J 2006; 27:1530-1538.

22. Nallamothu BK, Bates ER, Herrin J, Wang Y, Bradley EH, Krumholz HR and the NRMI Investigators. Time to treatment in transfer patient undergoing primary percutaneous coronary intervention in the United States. National Registry of Myocardial Infarction (NRMI-3/4) analysis. Circulation 2005;111:761-767.

23. Nallamothu BK, Bates ER. Percutaneous coronary intervention versus fibrinolytic therapy in acute myocardial infarction: is timing (almost) everything? Am J Cardiol 2003;92:824-826.

24. Califf RM, Faxon DP. Need for centers to care for patients with acute coronary syndromes. Circulation 2003;107:1467–1470.

25. Henry TD, Atkins JM, Cunningham MS, Francis GS, Groh WJ, Hong RA, Kern KB, Larson DM, Ohman EM, Ornato JP, Peberdy MA, Rosenberg MJ, Weaver WD. ST-segment elevation myocardial infarction: Recommendations on triage of patients to heart attack centers. Is it time for a national policy for the treatment of ST-segment elevation myocardial infarction? J Am Coll Cardiol 2006; 47:1339-1345.

26. Jacobs AK, Antman EM, Ellrodt G, Faxon DP, Gregory T, Mensah GA, Moyer P, Ornato J, Peterson ED, Sadwin L, Smith SC. Recommendation to develop strategies to increase the number of ST-segment–elevation myocardial infarction patients with timely access to primary percutaneous coronary intervention. The American Heart Association's Acute Myocardial Infarction (AMI) Advisory Working Group. Circulation 2006; 113:2152-63.

27. 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.

28. Aversano T, Aversano LT, Passamani E, Knatterud GL, Terrin ML, Williams DO, Forman SA; Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT). Thrombolytic therapy vs. primary percutaneous coronary intervention for myocardial infarction in patients presenting to hospitals without on-site cardiac surgery: a randomized controlled trial. JAMA 2002;287:1943-1951.

29. Ting HH, Garratt KM, Singh M, Kjelsberg MA, Timimi FK, Cragun KT, Houlihan RJ, Boutchee KL, Crocker CH, Cusma JT, Wood DL, Holmes DR. Low-risk percutaneous coronary interventions without on-site cardiac surgery: two years' observational experience and follow-up. Am Heart J 2003;145:278-284.

30. Zavala-Alarcon E, Cecena F, Ashar R, Patel R, Van Poppel S, Carlson R. Safety of elective – including "high-risk" –percutaneous coronary interventions without on-site cardiac surgery. Am Heart J 2004;148:676-683.

31. Paraschos A, Callwood D, Wightman MB, Tcheng JE, Phillips HR, Stiles GL, Daniel JM, Sketch MH Jr. Outcomes following elective percutaneous coronary intervention without on-site surgical backup in a community hospital. Am J Cardiol 2005;95:1091-1093.

32. Ting HH, Raveendran G, Lennon RJ, Hall Long KH, Singh M, Wood DL, Gersh BL, Rihal CS, Holmes Jr DR. 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.

33. Weaver DW. All hospitals are not equal for the treatment of patients with acute myocardial infarction. Circulation 2003;108:1768-1771.

34. Wharton TP. Nonemergent percutaneous coronary intervention with off-site surgical back-up. Crit Pathways in Cardiol 2005;4:98-106.

35. 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 February 2007]

36. 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.
37. Joint Working Group on Coronary Angioplasty of the British Cardiac Society and British Cardiovascular Intervention Society. Coronary angioplasty: guidelines for good practice and training. Heart 2000;83:224–235.
38. Deutsche Gessellschaft fur Herz- und Kreislaufforschung. Kommission fur Klinische Kardiologie (unter Mitwirking der Arbeitsgruppe Transluminale Angioplastie): Empfehlungen fur die Durchfuhrung der Perkutanen Transluminalen Koronarangioplastie (PTCA). Z Kardiol 1987;76:382–385.
39. Bonzel T, Neuhaus K-L, Vogt A, von Leitner E-R, Harmjanz D for the Multicenter Quality Control Project of the ALKK Study Group. PTCA with and without in hospital surgical standby in 12,965 patients. J Am Coll Cardiol 1994;23(Suppl):223A.
40. Cumpston N and 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 http://www.csanz.edu.au/guidelines/practice/index.htm.
41. Brieger D and 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 http://www.csanz.edu.au/guidelines/practice/index.htm

42. 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.
43. 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.
44. Singh M, Ting HH, Berger PB, Garratt KN, Holmes DR, Gersh BJ. Rationale for on-site cardiac surgery for primary angioplasty: A time for reappraisal. J Am Coll Cardiol 2002; 39:1881-1889.
45. Iannone LA, Anderson SM, Phillips SJ. Coronary angioplasty for acute myocardial infarction in a hospital without cardiac surgery. Tex Heart Inst J 1993;20:99-104.
46. Weaver WD, Parsons L, Every N, for the MITI project investigators. Primary coronary angioplasty in hospitals with and without surgery backup. J Invas Cardiol 1995;7:34F-39F.
47. Weaver WE, for the MITI project investigators. PTCA in centers without surgical backup - outcome, logistics and technical aspects. J Invas Cardiol 1997;9:20B-23B.
48. Brush JE, Thompson S, Ciuffo AA, Parker J, Stine RA, Mansfield CL, Hagerman P. Retrospective comparison of a strategy of primary coronary angioplasty versus

intravenous thrombolytic therapy for acute myocardial infarction in a community hospital without cardiac surgical backup. J Invas Cardiol 1996;8:91-98.

49. Moquet B, Huguet RG, Cami G, Linassier P, Decomis MP, Guille des Buttes P, Goralski M, Lepifre P, Pigale C, Placente M. Primary angioplasty in acute myocardial infarction: a one-year experience in a small urban community. Arch Mal Coeur Vaiss 1997;90:11-15.
50. Smyth DW, Richards AM, Elliott JM. Direct angioplasty for myocardial infarction: one-year experience in a center with surgical back-up 220 miles away. J Invas Cardiol 1997;9:324-332.
51. Ribichini F. Experiences with primary angioplasty without on site-cardiac surgery. Semin Interv Cardiol 1999;4:47-53.
52. Ribichini F, Steffenino G, Dellavalle A. Primary angioplasty without surgical back-up at all. Results of a five years experience in a community hospital in Europe (abstract). J Am Coll Cardiol 2000;35:364A.
53. Aversano T. Primary angioplasty at hospitals without cardiac surgery: C-PORT Registry outcomes (abstract). Circulation 2003;108: IV-613.
54. Aversano T, C-PORT Investigators. Outcomes of primary PCI performed at hospitals without on-site cardiac surgery: The C-PORT Registry. Circulation 2005;112 (Suppl II):II-481.
55. Politi A, Zerboni S, Galli M, Mameli S, Botto GL, Lombardi R, Bonatti R, Ferrari G. Primary angioplasty in acute myocardial infarction: experience and results in the first 1,000 consecutive patients. Ital Heart J Suppl 2003;4:755-763.

56. Singh M, Ting HH, Gersh BJ, Berger PB, Lennon RJ, Holmes DR, Garratt KN. Percutaneous coronary intervention for ST-segment and Non-ST-segment elevation myocardial infarction at hospitals with and without on-site cardiac surgical capability. Mayo Clin Proc 2004;79:738-744.

57. Kutcher MA, Klein LW, Wharton TP, Applegate RJ, Brindis RG, Shaw RE, Weintraub WS. Clinical outcomes in coronary angioplasty centers with off-site versus on-site cardiac surgery capabilities: a preliminary report from the American College of Cardiology-National Cardiovascular Data Registry (abstract). J Am Coll Cardiol 2004;43:96a.

58. Foster JK, Klein LW, Veledar E, Kolm P, Zhang Z, Anderson GT, Brindis RG, Mitchel KR, Hewitt, KM, Krone R, Wharton TP, Kutcher M. On-site surgical backup as a predictor of mortality among PCI patients with STEMI, NSTEMI, or no AMI. Circulation 2005;112 (Suppl II):II-737.

59. Sanborn TA, Jacobs AK, Frederick PD, Every NR, French WJ; National Registry of Myocardial Infarction 3 and 4 Investigators. Comparability of quality-of-care indicators for emergency coronary angioplasty in patients with acute myocardial infarction regardless of on-site cardiac surgery (Report from the National Registry of Myocardial Infarction). Am J Cardiol 2004;93:1335-1339.

60. Wharton TP Jr, Grines LL, Turco MA, Johnston JD, Souther J, Lew DC, Shaikh AZ, Bilnoski W, Singhi SK, Atay AE, Sinclair N, Shaddinger DE, Barsamian M, Graham M, Boura J, Grines CL. Primary angioplasty in acute myocardial infarction at hospitals with no surgery on-site (the PAMI-No SOS study) versus transfer to surgical centers for primary angioplasty. J Am Coll Cardiol 2004;43:1943-1950.

61. Wennberg DE, Lucas FL, Siewers AE, Kellett MA, Malenka DJ. Outcomes of percutaneous coronary interventions performed at centers without and with onsite coronary artery bypass graft surgery. JAMA 2004;292:1961-1968.

62. Richardson SG, Morton P, Murtagh JG, O'Keeffe DB, Murphy P, Scott ME. Management of acute coronary occlusion during percutaneous transluminal coronary angioplasty: experience of complications in a hospital without on site facilities for cardiac surgery. Br Med J 1990;300:355–358.

63. Meier B, Urban P, Dorsaz PA, Favre J. Surgical standby for coronary balloon angioplasty. JAMA 1992;268:741–745.

64. Klinke WP, Hui W. Percutaneous transluminal coronary angioplasty without on-site surgical facilities. Am J Cardiol 1992;770:1520 –1525.

65. Iniguez A, Macaya C, Hernandez R, Alfonzo F, Goicolea J, Casado J, Zarco P. Comparison of results of percutaneous transluminal coronary angioplasty with and without selective requirement of surgical standby. Am J Cardiol 1992;69:1161-1165.

66. Baduini G, Belli R, de Benedictis M, Bronzetti C, Corongiu MR, Alberti A, di Summa M. Coronary angioplasty in an Italian hospital without on-site cardiac surgery: the results and outlook. G Ital Cardiol 1994;24:1537-1539.

67. Dellavalle A, Steffenino G, Ribichini F, Russo P, Uslenghi E. Elective coronary angioplasty with and without surgical standby: clinical and angiographic criteria for the selection of patients. Cor Art Dis 1995;6:513-520.

68. Loubeyre C, Morice M, Berzin B, Virot P, Commeau P, Drobinski G, Ethevenot G, Moquet B, Marco J, Labrunie P, Cattan S, Coste P, Aubry P, Ferrier A. Emergency

coronary artery bypass surgery following coronary angioplasty and stenting: Results of a French Multicenter registry. Cathet Cardiovasc Intervent 1999;47:441-448.

69. Dudek D, Rakowski T, Legutko J, Mielecki W, Dziewierz A, Bartus S, Rzeszutko L, Sadowski J, Zmudka K, Dubiel JS. Efficacy and safety of percutaneous interventions in patients with non ST segment elevation acute coronary syndrome in catheterization laboratory without on-site surgical back-up. Kardiol Pol 2003;58:356-365.
70. Turgeman Y, Atar S, Suleiman K, Feldman A, Bloch L, Freedberg NA, Antonelli D, Jabaren M, Rosenfeld T. Diagnostic and therapeutic percutaneous cardiac interventions without on-site surgical backup – Review of 11 years experience. Isr Med Assoc J 2003;5:89-93.
71. Moscucci M, Rogers EK, Montoye C, Smith DE, Share D, O'Donnell M, Maxwell-Eward A, Meengs WL, De Franco AC, Patel K, McNamara R, McGinnity JG, Jani SM, Khanal S, Eagle KA, for the Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2). Association of a continuous quality improvement initiative with practice and outcome variations of contemporary percutaneous coronary interventions. Circulation 2006; 113:814-822.
72. Jollis JG, Peterson ED, DeLong ER, Mark DB, Collins SR, Muhlbaier LH, Pryor DB. The relation between the volume of coronary angioplasty procedures at hospitals treating Medicare beneficiaries and short term mortality. N Engl J Med 1994;331:1625-1629.
73. Kimmel SE, Berlin JA, Laskey WK. The relationship between coronary angioplasty procedure volume and major complications. JAMA 1995;274:1137-1142.
74. Hannan E, Racz M, Ryan TJ, McCallister BD, Johnson LW, Arani DT, Guerci AD, Sosa J, Topol EJ. Coronary angioplasty volume-outcome relationships for hospitals and

operators in New York State: 1991-1994. JAMA 1997;277:892-898.

75. Epstein AJ, Rathore SS, Volpp KGM, Krumholz HM. Hospital percutaneous coronary intervention volume and patient mortality, 1998 to 2000. Does the data support the current procedure volume minimums? J Am Coll Cardiol 2004;43:1755-1762.
76. McGrath PD, Wennberg DE, Dickens JD, Siewers AE, Lucas FL, Malenka DJ, Kellett MA, Ryan TJ. Relation between operator and hospital volume and outcomes following percutaneous coronary interventions in the era of the coronary stent. JAMA 2000;284:3139-3144.
77. Hannan EL, Wu C, Walford G, King III SB, Holmes DR, Ambrose JA, Sharma S, Katz S, Clark LT, Jones RH. Volume-outcome relationships for percutaneous coronary interventions in the stent era. Circulation 2005;112:1171-1179.
78. Moscucci M, Share D, Smith D, O'Donnel MJ, Riba A, McNamara R, Lalonde T, Defrance AC, Patel K, Rogers ER, D'Haem C, Karve M, Eagle KA. Relationship between operator volume and adverse outcome in contemporary percutaneous coronary intervention practice. An analysis of a quality-controlled multicenter percutaneous coronary intervention clinical database. J Am Coll Cardiol 2005;46:625-632.
79. Cantor WJ, Hall R, Tu JV. Do operator volumes relate to clinical outcome after percutaneous coronary intervention in the Canadian health care system? Am Heart J 2006;151:902-908.
80. Klein LW, Schaer GL, Calvin JE, Palvas B, Allen J, Loew J, Uretz E, Parrillo JE. Does low individual operator coronary interventional procedural volume correlate with worse institutional procedural volume? J Am Coll Cardiol 1997;30:870-877.
81. Kuntz RE, Normand ST. Measuring percutaneous coronary intervention quality by

simple case volume. Circulation 2005;112: 1088-1091.

82. Brindis RG, Weintraub WS, Dudley RA. Volume as a surrogate for percutaneous coronary intervention quality: is this the right measuring stick? Am Heart J 2003;146:932-934.
83. Peterson ED, Coombs LP, DeLong ER, Haan CK, Ferguson TB. Procedure volume as a marker of quality for CABG surgery JAMA 2004;291:195-201.
84. Meier B. 2002 Percutaneous coronary intervention. In: Topol EJ, editor. Textbook of Cardiovascular Medicine, 2nd ed. Philadelphia: Lippincott Williams and Wilkins. pg 1665-1676.
85. O'Connor GT, Malenka DJ, Quinton H, Robb JF, Kellett MA Jr, Shubrooks S, Bradley WA, Hearne MJ, Watkins MW, Wennberg DE, Hettleman B, O'Rourke DJ, McGrath PD, Ryan T Jr, VerLee P. Multivariate prediction of in-hospital mortality after percutaneous coronary interventions in 1994–1996. Northern New England Cardiovascular Disease Study Group. J Am Coll Cardiol 1999;34:681–691.
86. Ellis SG, Guetta V, Miller D, Whitlow PL, Topol EJ. Relation between lesion characteristics and risk with percutaneous intervention in the stent and glycoprotein IIb/IIIa era: an analysis of results from 10,907 lesions and proposal for new classification scheme. Circulation 1999;100:1971–1976.
87. Rihal CS, Grill DE, Bell MR, Berger PB, Garratt KN, Holmes DR Jr. Prediction of death after percutaneous coronary interventional procedures. Am Heart J 2000;139:1032–1038.
88. Singh M, Lennon RJ, Holmes DR Jr, MD, Bell MR, Rihal CS. Correlates of procedural complications and a simple integer risk score for percutaneous coronary intervention. J

Am Coll Cardiol 2002;40:387–393.

89. Anderson HV, Shaw RE, Brindis RG, Klein LW, McKay CR, Kutcher MA, Krone RJ, Wolk MJ, Smith SS, Weintraub WS. Relationship between procedure indications and outcome of percutaneous coronary interventions by American College of Cardiology/American Heart Association task force guidelines. Circulation 2005;112:2786-2791.
90. Fasseas P, Orford JL, Panetta CJ, Bell MR, Denktas AE, Lennon RJ, Holmes DR, Berger PB. Incidence, correlates, management, and clinical outcome of coronary perforation: analysis of 16,298 procedures. Am Heart J 2004;147:140-145.
91. Ramana RK, Arab D, Joyal D, Steen L, Cho L, Lewis B, Liu J, Loeb H, Leya F. Coronary artery perforation during percutaneous coronary intervention: incidence and outcomes in the new interventional era. J Invasive Cardiol 2005;17:603-605.
92. Burkhoff D, O'Neill W, Bunckhorst C, Letts D, Lasorda D, Cohen HA. Feasibility study of the use of the TandemHeart® percutaneous ventricular assist device for treatment of cardiogenic shock. Cathet Cardiovasc Intervent 2006;68:211-217.
93. Werner RM, Asch DA. The unintended consequences of publicly reporting quality information. JAMA 2005;293:1239-1244.
94. Turi ZG. The big chill. The deleterious effects of public reporting on access to health care for the sickest patients. J Am Coll Cardiol 2005;45:1766-1768.
95. Zijlstra F. Angioplasty vs. thrombolysis for acute myocardial infarction: a quantitative overview of the effects of interhospital transportation. Eur Heart J 2003;24:21–23.
96. Magid DJ, Wang Y, Herrin J, McNamara RL, Bradley EH, Curtis JP, Pollack CV Jr, French WJ, Blaney ME, Krumholz HM. Relationship between time of day, day of week,

timeliness of reperfusion, and in-hospital mortality for patients with acute ST-segment elevation myocardial infarction. JAMA 2005; 294:803–812.

97. Bhatt DL, Roe MT, Peterson ED, Li Y, Chen AY, Harrington RA, Greenbaum AB, Berger PB, Cannon CP, Cohen DJ, Gibson CM, Saucedo JF, Kleiman NS, Hochman JS, Boden WE, Brindis RG, Peacock WF, Smith SC Jr, Pollack CV Jr, Gibler WB, Ohman EM; CRUSADE Investigators. Utilization of early invasive management strategies for high-risk patients with non-ST-segment elevation acute coronary syndromes: results from the CRUSADE Quality Improvement Initiative. JAMA 2004;292:2096-2104.
98. http://www.nrmp.org/fellow/match_name/thoracic/stats.html. Accessed on June 19, 2006.
99. Nallamothu BK, Bates ER, Wang Y, Bradley EH, Krumholz HM. Driving times and distances to hospitals with percutaneous coronary intervention in the United States: Implications for prehospital triage of patients with ST-elevation myocardial infarction. Circulation 2006;113:1189-1195.

Table 1. Status of PCI without On-Site Surgical Backup by Country

Being Performed			Not Being Performed
Argentina	Israel	Russia	Bahrain
Australia	Italy	Saudia Arabia	Belgium
Brazil	Japan	Singapore	Greece
Canada	Lebanon	South Korea	Malaysia
Czech Republic	Mexico	Spain	
Egypt	Netherlands *	Sweden	
England	Norway	Syria	
France	Oman	Taiwan	
Germany	Pakistan	Thailand	
Guatemala	Panama	Turkey	
India	Phillipines	Vietnam	
Indonesia	Poland		

* Demonstration project only

Table 2: Studies of Primary PCI without On-site Cardiac Surgery

Study	Year	Country	n	Study type	Door-to-balloon time (min)	PCI success	In-hospital Mortality			Urgent CABG	Comments
							Total	Shock	No shock		
Iannone (45) *1 site*	1993	US	100	Retrospective review		82%	5%			7%	Rescue PCI after SK in 46%; 5 cath lab deaths who had average age of 81 yrs and LVEF = 0.23
Weaver (46,47) *4 sites*	1995	US	470	Registry	80† (55-126)	88%	7%			3.8%	MITI Registry. 6 sites with on-site surgery treated 592 pts. No difference in mortality with or without on-site surgery.
Brush (48) *1 site*	1996	US	62	Retrospective review		96%		30%	3%	0	40 pts having primary PCI with cardiogenic shock or rescue PCI were excluded
Moquet (49) *1 site*	1997	France	50	Retrospective review		90%	10%			0	All deaths in pts > 80 years
Smyth (50) *1 site*	1997	New Zealand	71	Retrospective review	72‡ (60, 90) †	86%	9.9%	60%	1.7%	0	Surgical backup 220 miles away. Included only pts with shock, anterior MI, post CABG, lytic ineligible or failure. Two pts transferred for non-urgent CABG
Wharton (27) *2 sites*	1999	US	335	Registry	109† (87, 148)	94%	6.6%	25%	3.8%	0	70% of pts had high risk clinical and/or angiographic predictors (Killip class 3-4, age ≥ 75 yrs, anterior MI, out-of-hospital VF, LM or 3 vessel CAD, LVEF < 0.45.
Ribichini (51,52) *1 site*	2000	Italy	284	Retrospective review	56±17§	96%	8.5%	32%	4.9%	0	55 pts had rescue PCI with a mortality of 16%
Aversano (28) *11 sites*	2002	US	171	Randomized PCI vs lytics	102† (82, 121)	96%	4.1%	#			C-PORT Study. Randomized PCI vs. lytics. 225 pts assigned to PCI, 212 received angiography, PCI performed in 171. Improved outcome and shorter LOS with PCI
Aversano (53) *14 sites*	2003	US	1103	Randomized vs lytics	107† (87,132)	97%	3.0%	#			C-PORT registry. (abstract)
Aversano (54) *29 sites*	2005	US	3733	Registry	103† (83, 128)	98%	3.2%				C-PORT Registry including only those treated by PCI. Stents in 93%, GP2b/3a inhibitors in 83%
Politi (55) *1 site*	2003	Italy	825	Retrospective review	58† (49, 71)		4.9%			0.9%	Includes rescue PCI in 35 pts (3.2%)
Singh (56) *1 site*	2004	US	160	Registry		96%	2%			0	No difference in outcome compared with 160 patients treated at site with on-site surgery
Kutcher (57) *17 sites*	2004	US	491	Registry		90%	4.9%			1.2%††	ACC-NCDR data. No difference in PCI success, U-CABG or death compared with centers having on-site surgery.
Foster (58) *28 sites*	2005	US	Not stated	Registry			4.6%				ACC-NCDR data. 6530 pts (primary and elective PCI) without on-site surgery. No mortality difference compared with on-site surgery after adjusting for demographic and clinical characteristics.
Sanborn (59) *97 sites*	2004	US	1874	Registry	110 || (107,113)		3.7%				NRMI data. Mortality in hospitals with on-site surgery = 4.8%
Wharton (60) *19 sites*	2004	US	440	Registry	105† (80,139)	96%	2.7%	#			PAMI No SOS Registry. Included only high risk pts (anterior MI, age >70, HR >100, or CHF)
Wennberg (61) *178 sites*	2004	US	1795	Retrospective review			11.3%			4.6%††	Medicare data from 1999-2001. Only data for primary/rescue PCI shown. No difference in mortality or U-CABG compared with hospitals having on-site surgery
Ting (32) *1 site*	2006	US	285	Registry		93%	4%			0%	Cases matched 1:1 for age, gender, clinical characteristics with data from hospital with on-site backup.

*Time from presentation in the emergency department to first balloon inflation. † Median value (25th percentile, 75th percentile). ‡ Time from decision to offer primary PCI to first balloon inflation. § Mean value ± SD. || Mean value, 95% CI. # Patients with cardiogenic shock excluded. †† Reason for emergency CABG not discriminated between PCI failure and discovery of high-risk anatomy.

ACC-NCDR = American College of Cardiology—National Cardiovascular Data Registry; AMI = acute myocardial infarction; CABG = coronary artery bypass graft surgery; CAD = Coronary artery disease; CHF = congestive heart failure.; C-PORT = Cardiovascular Patient Outcomes Research Team; GP2b/3a = Glycoprotein 2b/3a; HR = heart rate; LM = left main; LVEF = Left ventricular ejection fraction; LOS = Length of stay; Lytic = fibrinolytic therapy; MITI = Myocardial Infarction Triage and Intervention; NRMI = National Registries of Myocardial Infarction; PAMI-No SOS = Primary Angioplasty in Myocardial Infarction—No Surgery On Site; PCI = percutaneous coronary intervention; pts = patients; SBP = systolic blood pressure; SK = Streptokinase; U-CABG = Urgent CABG; VF = Ventricular fibrillation.

Table 3: Studies of Elective PCI without On-site Cardiac Surgery

Study	Year	Country	n	Study type	Patient criteria	PCI Success	In-hospital Mortality (Total)	Urgent CABG	Comments
Richardson (62) *1 site*	1990	Ireland	540	Retrospective review	Stable, unstable angina, post AMI	82%	0.9%	2.2%	Primary cause for delay was wait for OR availability, not time to transfer. No primary PCI included.
Meier (63) *1 site*	1992	Switzerland	811	Prospective nonrandomized	Excluded pts expected to have large MI if acute occlusion occurred	92%	0.1%	0.1%	Pts scheduled for PCI with or without backup, but at a hospital with on-site surgery. 189 pts done with standby. Primary PCIs excluded. Acute occlusion occurred in 6.9% of no standby group with 1.2% developing q wave MI.
Klinke (64) *1 site*	1992	Canada	847	Retrospective review	All pts, but excluding high-risk clinical or anatomic situations.	87%	0.9%	1.6%	Unspecified number of pts with AMI. 42% of U-CABG pts. suffered AMI. 2.1% of patients not sent for U-CABG also had AMI managed conservatively.
Iniguez (65) *1 site*	1992	Spain	1014	Retrospective review	Excluded pts expected to have life threatening MI if acute occlusion occurred	88%	0.7%	0.1%	Pts scheduled for PCI with or without backup, but at a hospital with on-site surgery. 269 PCIs done with standby. AMI (type unknown) in 2.7% of no standby group, not different from standby group 2.9%
Baduini (66) *1 site*	1994	Italy	742	Retrospective review	Not clearly defined, but some pts had AMI	91%	0.13%	0.8%	Mortality rate excludes pts presenting with cardiogenic shock. AMI (type unknown) occurred in 1.2%
Dellavalle (67) *1 site*	1995	Italy	232	Retrospective review	Strict criteria used to select low risk cases including no PCIs of LAD	93%	0	0	AMI (type unknown) occurred in 1%
Loubeyre (68) *Multiple sites*	1999	France	Not stated	Retrospective review and prospective registry	Included all patients undergoing PCI at registry sites		0.41%	0.25%	Total experience of French registry, 62% of sites without on-site surgery. Number of pts undergoing PCI at sites without surgery not reported. Report only details need for U-CABG and outcomes
Dudek (69) *1 site*	2003	Poland	479	Retrospective review	ACS and stable pts included	94%	0.6%	0.4%	Excludes STEMI
Turegman (70) *1 site*	2003	Israel	1016	Retrospective review	All patients including about 5% primary PCI	Not stated	0.3%	0.6%	Stents used in 70% of recent pts.
Kutcher (57) *17 sites*	2004	US	1668	Registry	Not defined	92%	0.5%	0.2%	ACC-NCDR data. No difference in PCI success, U-CABG or death compared with elective pts at sites having on-site surgery. (Abstract)
Zavala-Alarcon (30) *1 site*	2004	US	1000	Retrospective review	All pts included	96%	0.2%	0	Coronary perforation in 0.9%, all managed without surgery. Peri-procedure MI in 2.1%
Wennberg (61) *178 sites*	2004	US	6373	Retrospective review	Not defined	Not stated	4.6%	1.2%	Medicare data from 1999-2001. Only data for non primary/rescue PCI shown. Mortality higher ($p<0.001$) compared with hospitals having on-site surgery (2.8%). Rate of U-CABG not different
Foster (58) *28 sites*	2005	US	Not stated	Registry	Not defined	Not stated	0.4%	Not stated	ACC-NCDR data. 6530 total pts. (primary and elective PCI) without on-site surgery. No mortality difference compared with on-site surgery after adjusting for demographic and clinical characteristics.
Paraschos (31) *1 site*	2005	US	489	Retrospective review	Only low risk pts included	98%	0.2%	0.7%	The 1 death was due to renal failure. Mean time from departure to OR was 83 min.
Ting (29,32) *1 site*	2006	US	722	Registry	Low-to-moderate risk cases; no atherectomy, Mayo Clinic risk score ≤ 10	97%	0.3%	0%	Cases matched 1:1 for age, gender, clinical characteristics with data from hospital with on-site backup.

ACC-NCDR = American College of Cardiology—National Cardiovascular Data Registry; AMI = acute myocardial infarction; CABG = coronary artery bypass graft surgery; NSTEMI = Non-ST segment elevation myocardial infarction; PCI = percutaneous coronary intervention; pts = patients; STEMI = ST-segment elevation myocardial infarction; U-CABG = Urgent CABG.

Table 4. Personnel and Facility Requirements for PCI Programs without On-site Surgical Backup.

1. Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.
2. On-call schedule with operation of laboratory 24 hours per day, 365 days per year †.
3. 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 is necessary
4. Full support from hospital administration in fulfilling the necessary institutional requirements including appropriate support services (e.g. respiratory care, blood bank, etc . .).
5. 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.
6. 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.
7. 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.
8. Meticulous clinical and angiographic selection criteria for PCI (Tables 5 and 6).
9. 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 minutes. Outlier cases should be carefully reviewed for process improvement opportunities.
10. On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement and formalized periodic case review.
11. 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.

† Required for US facilities, but this may not be possible for all facilities world-wide.

Adapted from reference 27

Table 5. 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 who 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.

PCI = percutaneous coronary intervention; TIMI = Thrombolysis in Myocardial Infarction.

Adapted from reference 27

TABLE 6. Recommendations for Patient and Lesion Selection and Backup Strategy for Non-Emergent 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 ≤ 25%;
- left main stenosis (≥ 50%) or 3-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 (>2cm 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^{o});
- 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 non-emergent PCI at a facility without on-site surgery.

High Risk Patient with Not High Risk Lesion Non-emergent 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.

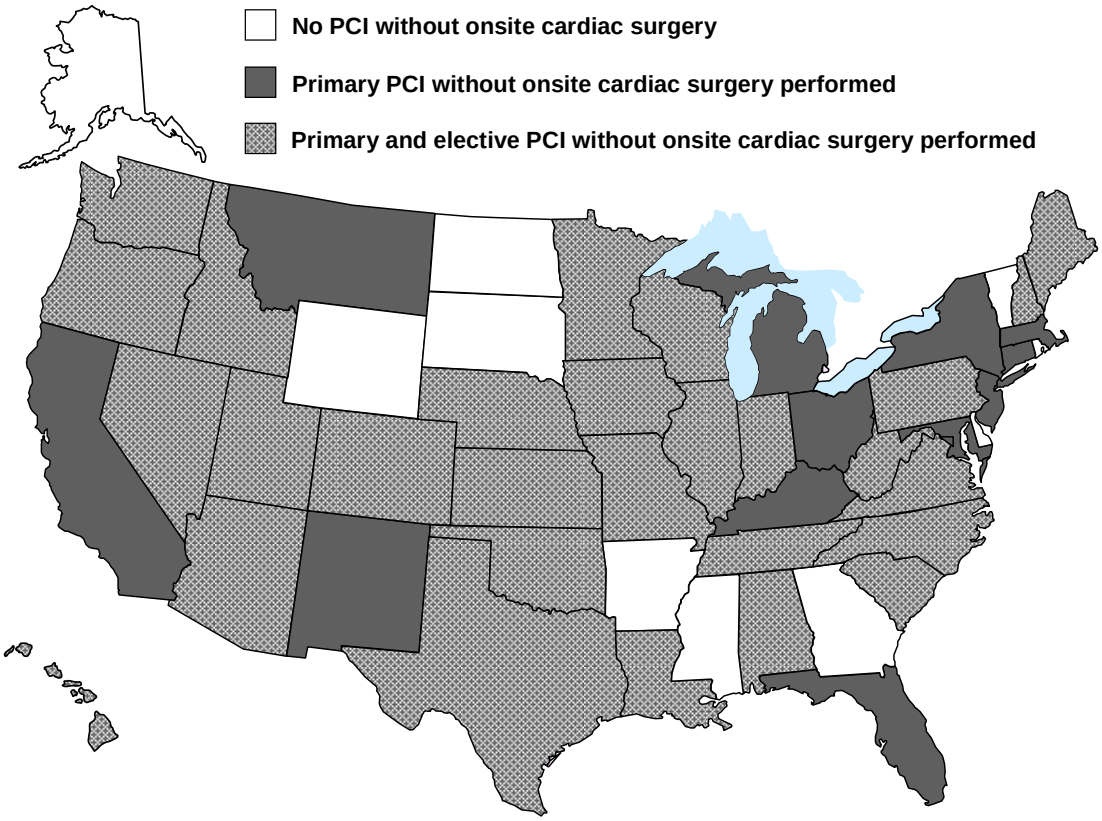
Adapted from references 27 and 84.

Table 7. 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 minutes 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 (approximately 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.

Adapted from reference 34.

Figure 1: States in which primary only or primary and elective percutaneous coronary intervention (PCI) are being performed.



PCI without onsite cardiac surgery is now being performed in Georgia, but only as part of the CPORT Elective Trial

Figure 2. Changes in PCI reporting to the ACC-NCDR® from 2001 through 2005.

Left panel: The bar indicates the number of centers reporting PCI cases without on-site surgical backup. The number above the bar is the percent of facilities reporting PCI without on-site surgical backup compared with the total number of ACC-NCDR® sites reporting data.

Right panel: The bar indicates the number of PCI procedures reported at centers without on-site surgical backup. The number above the bar is the percent of PCI procedures reported from centers without on-site surgical backup compared with the total number of PCIs reported in the ACC-NCDR®.