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ELECTIVE PERCUTANEOUS CORONARY INTERVENTIONS WITHOUT ONSITE CARDIAC SURGERY

A REPORT TO THE STATE OF WASHINGTON DEPARTMENT OF HEALTH

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I. Scope of Work/Work Plan

The State of Washington Department of Health contracted with Health Management Associates to conduct an evidence-based review and to submit a report of findings and recommendations concerning the circumstances under which adult elective percutaneous coronary interventions should be allowed in State of Washington hospitals that do not provide on-site cardiac surgery. For the purpose of this report percutaneous coronary interventions are considered to be invasive but non-surgical mechanical procedures and devices that are utilized by cardiologists for the revascularization of obstructed coronary arteries. These procedures and devices include percutaneous transluminal coronary angioplasty (PTCA), bare and drug-eluting stent implantation, cutting balloon atherectomy, rotational atherectomy, directional atherectomy, excimer laser angioplasty and extractational thrombectomy.

II. Methodology

An extensive literature search, including the National Library of Medicine Public Health data base for peer reviewed journal publications that reviewed and studied the provision, safety, quality prerequisites, operator credentialing, and patient selection criteria for elective percutaneous coronary interventions (PCIs) in hospitals with and without on-site cardiac surgery was performed. There were direct communications with nationally respected interventional cardiologists and practicing cardiologists at private and public medical centers (Mayo Clinic, Johns Hopkins, Rush Medical Center, Cook County Hospital). State of Washington hospitals that are currently performing elective PCIs and other hospitals that are interested in starting elective PCI programs were interviewed by phone and e-mail. The national guidelines developed by the American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions were reviewed. A search for established regulations in other States that currently allow PCI in hospitals without on-site cardiac surgery was done. Accreditation Council for Graduate Medical Education (ACGME) guidelines for cardiovascular disease (cardiology) and for interventional cardiology training programs were reviewed. The Director of the Regional Heart Center and Professor of Medicine in the Cardiology Training Program at the University of Washington in Seattle was interviewed.

The weight of evidence for all publications reviewed and cited was graded as A, B, or C. The basis for the assigned grades is detailed as follows:

- Level of Evidence A: Data derived from multiple well powered prospective randomized clinical trials or meta-analyses.
- Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies including retrospective and registry reviews.
- Level of Evidence C; Only consensus opinion of experts, case studies, or standard of care.

III. Introduction

In 1977 the first percutaneous transluminal coronary angioplasty (PTCA) was performed in a human. The initial technology was innovative but primitive. During the initial decade, even though only clinically stable patients with relatively uncomplicated single vessel lesions were selected, major adverse coronary events were reported in over 13% of patients¹. With as many as 5-6% of all patients requiring immediate referral for coronary artery bypass grafts, PTCA was only performed in hospitals with active open heart surgery programs. Operating rooms were reserved with a cardiac surgeon in house ready to immediately perform coronary artery bypass grafts (CABG). Over the past 30 years, as operators have gained increasing experience combined with major technological and pharmacological advances including stents, digital radiology, anti-platelet therapies, intra-vascular ultrasonography, and glycoprotein IIb/IIIb inhibitors, the complication rate for percutaneous coronary interventions steadily decreased. Even though higher risk patients began to undergo PCI there was a sustained decrease in the indication for emergency CABG² (Level of Evidence B). The current rate of immediate CABG post-PCI is now less than 1%. As the need for emergency CABG dropped, PCIs continued to be performed only in hospitals with on-site cardiac surgery but it was no longer deemed necessary to reserve operating rooms.

A prospective randomized trial in the late 1990s determined that treatment of an acute myocardial infarction with primary PCI was superior to thrombolytic therapy and that this procedure could be safely performed at hospitals without on-site cardiac surgery³ (Level of Evidence A). In order to expand the access of patients to this therapy, primary PCI was allowed in hospitals without on-site surgery.

Evaluation of complications of primary PCIs performed in hospitals without on-site surgery revealed that only a small percentage of these patients actually required emergency transfer to a back-up hospital for a CABG. This data, combined with studies that reported only limited numbers of complications for non-emergent PCIs in hospitals with on-site surgery, led some hospitals without on-site cardiac surgery to initiate elective PCI programs

Initially only low risk patients and low risk morphological lesions were performed. With time higher risk patients and more complicated coronary lesions were being treated with elective PCI at hospitals without on-site cardiac surgery. A number of single site, comparative, retrospective and non-randomized prospective studies were published that suggested that elective PCI performed on low and even selected high risk patients could be safely performed in hospitals without on-site cardiac surgery.

PCI has almost replaced Coronary Artery Bypass (CABG) as the procedure of choice for emergent and non-emergent invasive treatment of coronary artery disease in the United States. However, before deciding the best place to perform elective PCI, one should consider the clinical indications for elective PCI or CABG. There are, strictly defined, limited indications to perform PCI or CABG in stable, non acute coronary artery disease. The indications are to treat patients with activity-limiting symptoms despite maximum medical therapy and with anatomy for which revascularization has a proven survival benefit.

Elective PCI use has also been extended to patients who feel more comfortable with the procedure. This "indication" may be susceptible to contemporary lay opinion of the superiority of the procedure to medical therapy or CABG. In any case, the growth and use of PCI has outstripped expectation for its utilization. As an effect, untoward effects of the procedure, discovered after the development and release of the technology associated with PCI, must now be considered in a large number of patients who received the procedure for expanded indications. The unexpected occurrence of coronary thrombosis in patients who have received drug eluting stents is one example⁴ (Level of Evidence A). It is therefore important to apply a rigorous scientific standard when considering the dissemination of an invasive procedure that is resource intensive and leaves a life long effect on patients. The standard we will use here is that further dissemination of PCI should meet rigorous scientific level of evidence.

The gold standard for effectiveness and safety of a procedure is a study of a large number of subjects, planned specifically to test the results of the procedure's use, where people are randomized to a group that gets the procedure and a group that obtains an alternate intervention, or no intervention at all. However there have not been well powered, multiple-site, randomized prospective published studies in the USA that have definitively compared and assessed the safety and efficacy of elective PCIs in hospitals with and without on-site cardiac surgery. However, the release of a recent study in 2007 demonstrated that PCI did not reduce the risk of death, myocardial infarction, or other major cardiovascular events when added to optimal medical therapy for stable angina patients⁵ (Level of Evidence A).

The current status of PCI is of an intervention that has been widely disseminated and utilized. It may be equal to alternatives but evidence has recently been introduced that may shift therapy away from its use. In addition, recognition of serious adverse effects of the procedure, although rare, has recently emerged.

In this context the lack of well powered "Level of Evidence A" randomized prospective studies concerning the comparative safety and efficacy of elective PCIs in hospitals with and without on-site cardiac surgery has contributed to the reluctance of expert panels, professional societies, and governmental regulatory agencies to fully endorse and permit the provision of elective PCI in hospitals without on-site cardiac surgery.

IV. Public Health Environment

Between 1980 and 2000 the USA age-adjusted death rate for coronary heart disease fell from 542.9 to 266.8 in men and 263.3 to 134.4 in women. This reduction in US deaths was attributed equally to reductions in major risk factors (44%) and to treatments (43%) including revascularization procedures (11%)⁶. It is estimated that 13 million Americans and nearly 250,000 Washington residents have coronary artery disease⁷. 1.2 million PCIs are performed annually in the USA and approximately 22,000 in the State of Washington⁸.

The increasing prevalence of obesity, diabetes, hypertension, metabolic syndrome, and hyperlipidemia and an aging population portend a rise in the incidence of coronary artery disease in the near future and an anticipated need for increased diagnostic and interventional coronary artery procedures. Whether an increased shift toward medical therapy for chronic angina⁵ (Level of Evidence A), increased utilization of statins, beta blockers, and anti-platelet medications, continued lifestyle improvements, and further advances in non-invasive coronary artery diagnostic imaging will offset the potential increased need for angiography and interventional coronary procedures is yet to be determined.

Nationwide 1/3 of cardio-thoracic fellowship positions are unfilled⁹ and it is projected that there will be an insufficient number of cardiologists to meet the increasing clinical needs of the USA population. A reduced number of cardio-thoracic surgeons may impact the number of hospitals with on-site cardiac surgery that would be available and capable to serve as backup sites for hospitals performing PCIs.

Non-invasive coronary artery digital imaging technology is rapidly advancing. It is not unreasonable to foresee a not so distant time when non-invasive imaging may diminish or eliminate the role of coronary angiography in the diagnosis of coronary artery disease. If proven to be effective, this advanced technology could have a major impact on the utilization and need for diagnostic cardiac catheterization laboratories, would free up a significant amount of cardiology space, staffing, and equipment resources, and would result in further discussion concerning the most suitable location for the performance of elective interventional procedures.

This is the public health environment in which the State of Washington has requested a review and report on the circumstances in which elective PCI should be available in hospitals without on-site cardiac surgery.

V. **Elective Percutaneous Coronary Interventions in Hospitals Without On-Site Cardiac Surgery**

The American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) in its "consensus of experts" 2005 Guideline Update for Percutaneous Coronary Intervention listed elective PCI without on-site cardiac surgery as Class III indication. (Class III is defined as "conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful"). The ACC/AHA/SCAI 2005 guidelines state "elective PCI should not be performed at institutions that do not provide on-site cardiac surgery". "A small but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with immediate on-site availability of cardiac support but cannot be managed effectively by urgent transfer"¹⁰ (Level of Evidence C).

In spite of this firmly worded recommendation by this consortium of national experts, as of late 2006 elective PCI without on-site surgery is being performed in the USA in nearly 180 hospitals in 27 different States.

A number of USA studies concerning the outcomes and safety of elective PCI without on-site cardiac surgery have been published^{2,11,12,13,14,15,16} (Level of Evidence B and C). Most have been retrospective reviews or registry reports. In other words, they do not meet the gold standard for evaluating a medical intervention's efficacy or safety. The shortcomings of these studies have been noted⁹ (Level of Evidence C). In addition, negative outcomes are not required to be published.

Paraschos et al reviewed elective PCIs done on 489 lower risk patients from 1998-2002 at a single regional medical center in **North Carolina**. 98% were successfully completed, 1% had in-house treatable complications, and 0.8% required transfer to the backup hospital. 5.3% were readmitted within 6 months for clinical restenosis within the same vessel. This study concluded that elective PCI with off-site surgical backup is feasible and safe for selected patients under specific conditions¹¹ (Level of Evidence B).

A single site study initiated in 2000 of the first 1000 elective non-selected PCIs including some high risk patients at a public hospital without on-site surgery in **Arizona** resulted in a 96.2% target vessel revascularization with 0.9% in-house treated perforations, 0.2% mortality within 48 hours, 0.9% transfers for elective coronary artery bypass graft (CABG), and no transfers for emergency CABG. The authors concluded that "advances in interventional cardiology allow for safe performance of PCI ... without on-site cardiac surgery facilities if proposed conditions were met"¹² (Level of Evidence B).

A prospective single site 2002-2004 study of 401 consecutive elective low to high risk elective PCIs at a VA hospital in **Virginia** revealed a 97% success rate with 0% peri-procedural or in-hospital deaths and no transfers for emergency cardiac surgery. It was concluded that “nonemergent PCI can be performed effectively and safely...without on-site backup surgery”¹³ (Level of Evidence B).

The Mayo Clinic in conjunction with a community hospital without onsite cardiac surgery in central **Minnesota** case matched 1:1 study of 722 patients requiring elective PCI. The success rate was 97% at the community hospital and 95% at Mayo. The community hospital did use more stents per patient (1.5 v 1.3) and had a significantly higher use of new anti-platelet agents. “Similar outcomes for elective PCI...were achieved at a community hospital without on-site cardiac surgery compared to a tertiary care center...using a rigorous protocol for case selection and PCI program requirements.”^{14, 15} (Level of Evidence B).

A 1999-2001 review of 8,168 PCIs performed on Medicare A patients, 78% of which were non –primary/rescue procedures, at hospitals without on-site surgery revealed a higher 30-day mortality (4.6% v 2.8%, adjusted odds ratio 1.38) in comparison to PCIs done with onsite surgery. This increased mortality was mostly confined to low volume (<50 annual PCIs) centers. This study concluded that “...PCI in hospitals without cardiac surgery may inadvertently lead to an overall increase in mortality related to PCI”¹⁶ (Level of Evidence B).

Internationally many countries including Canada, Israel, Britain, Belgium, Holland, Germany, and Spain permit elective PCI procedures without on-site surgical backup; most have guidelines that recommend well coordinated transfer protocols, use of highly experienced operators, and carefully selected patients. Most international publications have been from registries and single site studies and mixed primary and elective PCIs. The results of these publications consistently attest to the safety and efficacy of performing PCIs in hospitals without onsite surgery^{9, 17, 18, 19} (Level of Evidence B). The first hospital in the **Netherlands** permitted to perform PCI procedures without onsite surgery reported its 2002-2007 experience. This single site retrospective review mixed the outcomes for both primary and elective PCIs. The incidence of emergency cardiac surgery post PCI was 0.2%. The authors noted “With appropriate settings, off site PCI may not be associated with an increase in the risk of adverse events”¹⁹ (Level of Evidence B). A 1997-2001 prospective randomized study in **Norway** with @300 patients meeting low risk criteria in each group who were randomized to have elective PCI either in a community hospital without onsite cardiac surgery or in a regional surgical hospital 130 miles away found equal angiographic success rates (96%) and peri-procedural complication rates (0.3%) and 30-day outcomes in both patient groups. There were no deaths or urgent transfers for CABG from the community hospital. There were worse outcomes (repeat target vessel revascularizations 6.9% v 2.3%, P = 0.3) at 6-months in high risk patients treated at the community hospital¹⁷ (Level of Evidence B).

Lofti et al reviewed 6,682 patients who had undergone primary or elective PCI from 1996-2000 at a tertiary care hospital in **Canada**. 0.7% required urgent CABG after failed PCI. The study concluded that “approximately 25% of urgent CABG patients had potential for serious harm if additional delays to surgery were introduced, representing an absolute risk of one to two patients per 1,000 PCI.”²⁹ (Level of Evidence B).

Sites that offer on-site cardiovascular surgery also readily offer cardiovascular consultation and ongoing contact and interaction between Cardiologists and Cardiovascular Surgeons. The decision to choose CABG versus PCI is complex and multifactorial. The availability of surgery on-site offers more than a technical consideration; it offers. It may improve the decision making itself.

In 2007, The Society for Cardiovascular Angiography and Interventions (SCAI) issued a consensus document of USA and international experts on “the current status and future direction of PCI without on-site surgical backup”. The SCAI recognized that the number of hospitals in the USA and worldwide that perform elective PCI without on-site surgery is increasing. Among this document’s stated goals were the definition of best practices and quality standards and recommendations with universal application for PCI without on-site surgery. The report emphasized that decisions about performing PCI without on-site surgery must be primarily based on meeting the health needs of a local area and maximizing patient safety and quality outcomes of PCI. The authors noted that data were not easily found and that most existing elective PCI data consisted of retrospective reviews or prospective registries without standardized patient inclusion criteria. The SCAI directly stated that this document was “not an open endorsement of PCI without on-site surgery” and stated that further data and analysis is needed to understand the role of PCI without on-site cardiac surgery⁹ (Level of Evidence C).

Blue Cross/Blue Shield has determined that hospitals that perform PCI without on-site cardiac surgery may be considered for designation as a Blue Distinction Center for Cardiac Care if they are part of a cooperative system with a qualifying facility that provides emergency backup CABG for PCI²⁰ (Level of Evidence C).

As noted in this section, the lack of the highest level of data related to the outcomes of PCI performed with or without on-site surgery complicates the development of national and international evidence based standards. The Atlantic Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study (C-PORT E)²¹ lead by providers at Johns Hopkins was designed with the intent of addressing this vital deficiency of valid data. It is a large (n-18,000) multi-site, multi-State randomized comparison of outcomes after PCIs performed at hospitals with and without cardiac surgery on-site. It is currently enrolling centers and patients and is still open to additional sites. There are no hospitals in the State of Washington that are currently enrolled in C-PORT E.

The question that the above studies and reports seek to answer is whether PCI in hospitals without on-site surgery is of sufficient quality to justify a change in practice. A policy change should be as safe as current practice and should not encourage overuse of PCI in patients who would benefit more from medical therapy or CABG. The policy should also include consideration of issues of access for both geographic challenges and socioeconomic barriers to PCI.

Recommendation:

Elective PCI should not be performed in hospitals without on-site surgery. Although published studies (Level of evidence B) suggest that elective PCI can be safely performed under rigorous standards, the highest level (A) of investigation has not yet been performed to fully confirm the safety and quality of performing elective PCI without on-site cardiac surgery.

Approval should only be considered for a program that serves a community or patient population with a fully documented pattern of unmet need and where the establishment of a new elective program would not jeopardize the quality standards of an existing interventional program and if the new program was permitted to participate in a well powered, prospective randomized multiple site study assessing the outcomes of elective PCIs performed in hospitals with and without on-site cardiac surgery.

VI. Volume Related Standards for Programs and Interventional Cardiologists

Although it is well understood that the documentation over time of risk-adjusted patient outcomes is the true indicator of the quality of an interventional cardiologist or a PCI program, nationally and internationally professional cardiology associations and governmental regulatory agencies have attempted to identify volume standards for both individual operator/cardiologists and programs that perform PCI procedures. The current PCI volume recommendations for operators and programs were mostly developed before the implementation of many of the current technological advances (including stents and glycoprotein IIb/IIIa inhibitors).²²

A retrospective registry review of the New York PCI Reporting System for 1998-2000 determined that for a hospital volume threshold of 400, lower volume programs had higher in-hospital mortality (OR 1.98, 95% CI, 1.17, 3.35), same-day CABG (OR 2.07, 95% CI, 1.36, 3.15), same-stay CABG (OR 1.51, 95% CI, 1.03, 2.21). For operator volume threshold of 75, lower volume cardiologists had higher same-day CABG (OR 1.65, 95% CI, 1.05, 2.60) and same-stay CABG (OR 1.55, 95% CI, 1.10, 2.18) but did not have significantly different in-hospital mortality. Lower volume hospitals with lower volume operators had even worse outcomes (OR 5.92, 4.02, 3.92) for the three indicators when compared to high volume hospitals with high volume operators^{23, 36} (Level of Evidence B, C).

A retrospective analysis of the AHRQ 1998-2000 hospital data base compared in-hospital mortality post-PCI in hospitals with low volume (<200), medium (200-399), high (400-999), and very high PCI annual volumes (>1000). Patients treated in low volume programs had higher risk adjusted mortality (OR 1.21, 95% CI) than high volume hospitals but medium, high, and very high volume centers had comparable risk of in-hospital mortality²² (Level of Evidence B).

A study of Medicare National Claims History for 1997 of PCIs revealed that low annual volume cardiologists (<30 Medicare PCIs) had an increased risk of CABG compared to higher volume (>60 Medicare PCIs) hospitals (2.25% v 1.55% ; P<.001) but the same 30 day mortality. Lower volume programs (<80 Medicare PCIs) had a higher 30-day mortality (4.29% v 3.15%; P<.001) than higher volume hospitals (>160 Medicare PCIs). When the analysis compared PCIs placing stents, the same increased risks were found for lower volume versus higher volume cardiologists and programs. The authors concluded that Medicare patients receiving PCIs in the era of stents experience better outcomes at high volume centers and with treatment by high volume cardiologists²⁴ (Level of Evidence B).

A 1999-2001 retrospective registry of Medicare A patients that evaluated the outcomes of PCIs in centers with and without on-site surgery, found that there was a higher mortality for elective PCIs performed in hospitals without on-site surgery but this increase in mortality was primarily confined to hospitals performing <50 Medicare PCIs per year¹⁶ (Level of Evidence B).

A consortium of hospitals in Michigan divided 165 operators who performed over 18,000 PCIs in 2002 into 5 quintiles with PCI volumes of 1-33, 34-89, 90-139, 140-206, 207-582. In this prospective, quality-controlled 2002 study, operators in the lowest 2 volume groups had significantly higher adverse outcomes (CABG, CVA, MI, repeat PCI at same site during same hospital admission) but not mortality. "Overall, high volume operators had better outcomes...in low-risk and high-risk patients." The authors also stated that "procedure volume is a poor surrogate for quality and outcomes."²⁵ (Level of Evidence B).

Great Britain, Australia, and New Zealand recommend that PCI programs have an annual minimal PCI volume of 200 and that operators have a minimum annual volume of 75. Britain advises an optimal annual PCI volume of 400 for programs and an optimal annual volume of 150 for operators. Spain recommends an annual PCI volume of 100 for programs and 50-75 annual volume for operators⁹ (Level of Evidence C).

Blue Cross/Blue Shield requires a minimum of 200 PCIs per year for a hospital to qualify for designation as a Blue Distinction Center for Cardiac Care²⁰ (Level of Evidence C).

ACC/AHA/SCAI Guideline Update for PCI recommends that elective PCIs should be performed by operators with annual volumes of 75 including 11

primary PCIs at high volume centers with more than 400 annual procedures including 36 primary PCIs (Class I recommendation) and between 200-400 (Class IIa recommendation). It also advises that low volume interventionalists (<75 annual PCIs) perform at centers with >400 and preferably >600 annual PCIs and these low volume operators develop a mentorship relationship with highly experienced operators who perform >150 PCIs per year. (Class IIa recommendation) Low volume operators should not perform PCIs at low volume centers (<200 annual PCIs) and these low volume centers should consider closure unless they are located in a geographical area that would otherwise be underserved^{10, 26} (Level of Evidence C).

The Society for Cardiovascular Angiography and Interventions (SCAI) recommends that “initial operators at a facility without on-site backup should not begin performing PCIs in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship”. Operators who have <500 lifetime PCI experience should be mentored and monitored by experienced physicians. Operators performing PCIs without on-site surgery should perform >100 annual PCIs including >18 primary PCIs per year. Interventionalists who cannot achieve optimal PCI volumes at their primary practice site should perform PCIs at a second high volume service site in order to comply with these annual volume requirements⁹ (Level of Evidence C).

Recommendation:

PCI programs in hospitals with and without on-site cardiac surgery should have minimum annual PCI volumes of >300 and an optimal annual volumes of >400 including 36 primary PCIs. A minimum annual volume of >300 was selected based on a balanced review of the literature. Publications suggest or recommend minimum volumes ranging from >200, 400, 500, to even 600. Most experts recommend that PCI programs with <200 be evaluated for closure. It is logical to recommend a minimum that exceeds the closure set point.

Operators should have minimum annual PCI volumes of >75 and an optimal annual volume of 100 including a minimum of 11 annual primary PCIs and an optimal volume of 18 primary PCIs. Operators in newly established programs should have a lifetime experience of 500 PCIs as primary providers. New operators with <75 annual PCIs and <500 lifetime experience should be mentored by an experienced operator until it is determined that their skills and outcomes meet national standards.

New programs and operators should achieve the minimum annual volumes within 2 years. There are no restrictions on operators meeting their annual volume requirements at more than one hospital. There was no literature identified that allowed modified PCI volume standards for rural programs.

VII. Communities with Diminished Access to Interventional Cardiology

The expansion of existing or the start-up of new elective PCI programs must be primarily driven by documentation that there is a quantifiable unmet need for PCI in a patient population. The barriers to access to PCI include geography, socio-economic status, lack of adequate insurance, or lack of sufficient providers and catheterization laboratories^{18, 27, 28} (Level of Evidence B,C). Barriers can exist in rural and urban areas and in areas where there is adequate PCI capacity. Low income patients, especially women, ethnic minorities, and the uninsured in low income communities are less likely to receive cardiac procedures. Patients who lack insurance or are underinsured, if they are to receive PCI, are cross-subsidized by the insurance of others, in order to support hospitals and cardiologists. Capital demands for invasive heart procedures are high. It is no wonder that hospitals in low income areas are less likely to offer PCI or have staff capable of performing it. There is also concern that patients treated at facilities without PCI capability are less likely to receive a recommendation for necessary revascularization procedures^{27, 28}, (Level of Evidence B, C).

Recommendation:

Although hospitals must be financially viable in order to continue to exist, it is not acceptable for a new elective PCI program to be developed when there is documented adequate access to elective PCI in the community. Programs that focus on the care of the underserved and uninsured offer the potential to bring this procedure to a population with a high level of heart disease but poor access to PCI. Although the overall facility and staffing requirements for all hospitals that would participate in expansion of new interventional cardiology programs should be the same, those hospitals with a mission and history of serving the underserved should receive priority consideration to expand.

VIII. Patient, Lesion and Device Selection for Elective PCI in Hospitals without On-site Surgery

The complications of PCIs that can result in emergency CABG are flow limiting dissections, abrupt artery closure, uncorrectable occlusion of a larger side branch, and coronary perforations¹² (Level of Evidence B). These complications can result in acute myocardial infarction and death.

As PCI techniques have been improved, particularly with the development of stents and advanced anti-platelet agents, the rates of PCI complications requiring emergency CABG have decreased. The rate of PCI caused emergency CABG is now stated as 0.4%¹⁸ (Level of Evidence B).

The ACC/AHA/SCAI 2005 Guidelines state “a small but valid fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate availability of cardiac surgical support but cannot be managed by urgent transfer”¹⁰ (Level of Evidence C). It is important to attempt to prospectively identify those patients who are at risk for complications during

elective PCI and have these patients treated in a center with on-site cardiac surgery.

It was reported in a study of 6,582 procedures at single hospital in which 0.7% had complications requiring CABG that only ¼ of these post-PCI CABGs actually had to be performed as emergency (<2 hours) procedures. The other ¾ were safely delayed for 12 or more hours²⁹ (Level of Evidence B, C).

Ting reported in a prospective matched study that elective PCIs could be safely performed in a hospital without on-site surgery if rigorous patient and lesion criteria were observed. None of the 722 elective patients in this study had to be transferred for emergency surgery¹⁴ (Level of Evidence B). The rigorous criteria excluded the elderly, patients with low ejection fractions, congestive heart failure, and high risk angiographic findings including left main disease, extensive calcifications, and tortuosity. Initially only A and B1 lesions were eligible for elective PCI but in the 2nd year of the study low to moderate risk B2 and C lesions were included. (See definition of A, B1, B2, C coronary lesions³⁰). Atheroablative devices were deemed too complication-prone and were not utilized at the hospital without on-site surgery (Level of Evidence C). These criteria have continued without change from 1999 through 2007³¹.

Melberg's randomized prospective study in Norway excluded patients from having PCI at the hospital without on-site surgery if they had unprotected left main stenosis, internal mammary artery graft, or saphenous vein graft supplying critical part of the myocardium, proximal left anterior descending stenosis, LAD size <2.5mm, LVEF <35%, and a previous MI in which target vessel supplies most of remaining viable myocardium. There were no deaths or emergency CABGs in this study¹⁷ (Level of Evidence B).

Mayo Clinic reported an incidence of 0.58% (95/16,298 over 11 years) for coronary artery perforation during primary and elective PCIs. Both the use of an atheroablative device (OR 2.68, 95% CI, 1.54-4.64, p<0.001) and female sex (OR 2.38, 95% CI, 1.48-3.83, p<0.001) were correlated with perforations. 11% of the 95 perforations were serious enough to require a CABG³² (Level of Evidence B).

The ACC/AHA/SCAI 2005 Guideline Update for PCI cited the combined results of two 1994 studies identifying perforation rates caused by various PCI devices. The rates of perforation were: directional atherectomy 0.25%-0.7%, rotational atherectomy 0.0% -1.3%, extraction atherectomy 1.3%-2.1%, and excimer laser angioplasty 1.9%-2.0%¹⁰ (Level of Evidence B, C). Perforations, especially type III, caused by atheroablative devices commonly require surgical repair¹⁰ (Level of Evidence C).

A registry review of 5,463 PCIs performed between 1996-1999 at a single referral center hospital was used to develop a bedside "integer risk score" for PCIs.

Although the study included both primary and elective PCIs, age (primarily >70 years), CHF, renal failure, and three angiographic variables (thrombus, multi-vessel disease, and left main disease) were determined to be helpful in risk stratification of elective patients undergoing PCI. The author stated “no model can predict which individual patients will experience complications; however, the model can estimate the likelihood... any model is limited for ... elective patients because of the overall low probability of an event”³³ (Level of Evidence C).

The ACC/AHA has used a lesion classification system based on an A, B, C grading system. High risk (C) lesions had at least one of the these characteristics: diffuse (>2cm), excessive tortuosity of proximal segment, extremely angulated segments (>90 degrees), total occlusions more than 2 months old and/or bridging collaterals, inability to protect major side branches, and degenerated vein grafts with friable lesions. Some of these C characteristics are more associated with technical failure and not for acute complications¹⁰ (Level of Evidence C).

The SCAI, using data from the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR) database, developed a simplified lesion classification grouping lesions into four classes that utilized vessel patency or occlusion in addition to C and non-C lesion grades. The patent, non-C lesions had the lowest risk for complications and the highest success rates¹⁰ (Level of Evidence C).

In its 2007 expert consensus report on elective PCI without on-site surgical backup, the SCAI developed recommendations for patient and lesion selection and backup cardiac surgery strategy. The report designated the following conditions as **high patient risk**: decompensated congestive heart failure (Killip class 3), LEVF <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. Vessel morphology with **increased lesion risk** were: diffuse disease (>2cm in length) with tortuosity of proximal segments, > than moderate calcification of a stenosis or proximal segment, location in an extremely angulated segment (>90 degrees), 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 was judged to impede stent implantation, and lesions requiring aggressive measures to open chronic total occlusion. This consensus report recommended that elective PCIs on high risk patients with high risk lesions only be performed in a hospital with on-site surgery and high risk patients with low risk lesions could be performed in a facility without on-site surgery only if a surgeon and an OR were immediately available (backup hospital pre-notified with OR reserved). Not-high risk patients with high risk lesion could be performed in a hospital without on-site surgery without additional precautions. The report noted that not-high risk patients with not-high

risk lesions presented the “best scenario” for elective PCI without on-site cardiac surgery^{9,18} (Level of Evidence C).

Recommendation:

In order to minimize complications and maximize the procedural success, rigorous patient and lesion criteria must be applied to all patients undergoing elective PCI at a hospital without on-site cardiac surgery.

Patients with increased risk for procedural failure and increased potential for clinical demise if peri-procedural complications occur are to have elective PCI performed in a hospital with on-site cardiac surgery.

High risk patient and lesion criteria including decompensated congestive heart failure, left ventricular ejection fraction <25%, left main coronary artery stenosis (>50%) or three vessel disease unprotected by previous CABG, single target lesion that supplies over 50% of viable myocardium, renal failure, recent CVA, coagulation disorders, and other serious, complicated, or uncontrolled medical conditions are to be referred to a hospital with on-site cardiac surgery for the performance of elective PCIs.

Applying the 2007 SCAI criteria and definitions of patient and lesion case selection, high risk patients with low and high risk lesions and low risk patients with high risk lesions are to be excluded from having elective PCIs performed at a hospital with off-site backup surgery. Only low-risk patients with low-risk lesions will be eligible to have elective PCI performed at hospitals without on-site cardiac surgery.

After two years of operation, institutions and operators whose risk-adjusted outcome statistics are comparable to national data registries may expand their patient selection criteria to include low risk patients with high risk lesions.

Patients whose angiographic findings indicate that atherectomy devices (directional, rotational, laser) and/or extractional thrombectomy are likely to be utilized will be excluded from having an elective PCI performed at a hospital without on-site surgery. Cutting balloon atherectomy will be allowed.

The hospital’s quality improvement committee should include the monitoring of compliance with the established patient and lesion selection guidelines and the utilization of excluded devices and procedures.

IX. Impact on Cardiovascular Disease (Cardiology) and Interventional Cardiology Training Programs in the State of Washington

The University of Washington School of Medicine is the sponsoring institution and the University of Washington Medical Center the major participating

institution for the only Cardiovascular Disease (Cardiology) and Interventional Cardiology (IC) fellowship programs in the WAMI (Washington, Alaska, Montana, Idaho) and Oregon region of northwestern USA. Harborview Medical Center and the Veterans Administration Hospital are satellite affiliates of these training programs. Both programs are accredited by the Accreditation Council for Graduate Medical Education (ACGME). The ACGME mandates that the primary cardiac catheterization laboratory at hospitals with Interventional Cardiology programs perform a minimum of 400 interventional procedures per year and that secondary catheterization labs perform a minimum of 200 interventional procedures per year.³⁴

The University of Washington Medical Center performs somewhat >400 interventional procedures per year and its satellite affiliate at the VA @200 elective percutaneous coronary interventions. Harborview Medical Center does only emergency primary PCIs. The primary cath lab at the University of Washington and the secondary cath lab at the VA meet the ACGME mandated minimum volume standards by slim margins.

ACGME requires that each Cardiovascular Disease (Cardiology) fellow performs 100 diagnostic angiograms during their 3 years of training and each Interventional Cardiology fellow must perform a minimum of 250 coronary interventions during his/her year of fellowship³⁴. All 18 Cardiovascular Disease positions are filled. The Interventional Cardiology program at the University of Washington is approved by the ACGME for 2 fellows but due to its current annual interventional procedure volume only one Interventional Cardiology (IC) fellow position is filled.

Recommendation

The University of Washington Medical Center and its affiliates house the only Cardiovascular Disease and Interventional Cardiology fellowship programs in northwestern USA. The University system currently meets the ACGME interventional procedure minimum annual volume requirements for its primary and secondary cardiac catheterization laboratories but by only a slim margin.

The expansion of elective PCIs in Seattle area hospitals without on-site cardiac surgery has the potential for negatively impacting on the current ACGME accreditation of the existing Interventional Cardiology fellowship training program and its future ability to fill both approved positions at the University of Washington. This potential negative impact could be offset by demographic and socio-economic changes in the greater Seattle metropolitan area and its surrounding counties.

- X. **Impact on Existing Elective PCI Programs in the State of Washington**
Samples of historical primary and elective PCI volume data for 2004 - 2006 for hospitals in the State of Washington were reviewed.(see Table 3) Estimated current PCI volumes and services were obtained by direct telephone communication with eight (see Table 4) individual hospitals (4 with existing elective PCI programs and 3 with interest in initiating elective PCI services). The preliminary elective PCI annual statistics for these four institutions with existing programs range between 350 and 600 elective PCIs and 50-250 primary PCIs. Two of the three hospitals interested in establishing elective PCI programs are currently performing primary PCIs. These two annually perform between 100-150 primary emergency PCIs.

The largest primary and elective PCI programs in the State located in populated urban areas have sufficient volumes that they would continue to be able to meet minimal and optimal volume standards even if additional elective programs in hospitals without on-site surgery were to open in the same service area. They would however experience a not insignificant decrease in revenue from the loss of elective cases to the new programs. However the ability of 7-10 current programs, mostly in rural and micro-urban areas, to meet minimum and optimal volume standards would be clearly jeopardized if new programs were established in the same patient catchment region. It is also quite likely that the new programs would struggle to meet minimum and optimal volume standards.

Hospitals in rural and micro-urban counties with established elective PCI programs or interested in initiating elective programs tend to be staffed by the same cardiologist and cardiology group practices. In one situation two hospitals located approximately 1 mile apart currently have the same cardiology practice covering their two emergency rooms 24 hours per day, 7 days per week for the performance of primary PCIs.

All programs with and without existing primary and elective PCI programs that were interviewed stated that the current angiography and percutaneous coronary interventional needs of their communities were being met. Patient preference, additional patient costs, need to transfer patients with abnormal angiograms who could have been immediately treated, incomplete utilization of existing cardiac catheterization lab capacity, and hospital fiscal concerns were mentioned as reasons for interest in initiating elective PCI services at their hospital.

Recommendation/Assessment:

Although there may be fiscal and even clinical reasons for the expansion of elective PCI programs into hospitals without on-site cardiac surgery, the current need for elective PCI procedures appears to be reasonably met. This is not to infer that there are not some communities (rural) or populations (underinsured, immigrant) in the State of Washington where the PCI needs are not fully being addressed.

Based on current PCI volumes, the initiation of elective (and primary) PCI programs without on-site cardiac surgery in the catchment/referral communities of some existing programs has a strong potential risk of decreasing the PCI volume at existing programs to levels below the minimum and optimal recommended annual volumes and preventing new startup PCI programs from attaining the recommended minimum and optimal volumes. This could jeopardize the existence and certification of both the existing and new PCI programs. This could potentially be offset by future growth in the population or the prevalence of coronary artery disease in the involved areas.

There exists a legitimate concern that the expansion of elective PCIs into hospitals without on-site cardiac surgery, especially in rural and micro-urban areas, could stretch the capability of available cardiologist and cardiac catheterization lab staff to provide 24/7 primary PCI coverage and to perform elective PCIs at multiple hospitals in the same or adjacent communities or counties.

XI. Cost and Financial Feasibility and Sustainability

Diagnostic and interventional cardiac catheterization laboratories are generally quite profitable to the sponsoring hospital. Based on Medicare Ambulatory Payment Classification (APC) diagnostic angiography alone can conservatively generate in excess of \$1.5 - \$3 million in annual gross revenue per cath lab. (Estimated 500-1000 angiograms per lab per year x @\$3000 payment received /angiogram). Percutaneous coronary interventions can generate more than twice the revenue of a diagnostic angiogram. A program that performs 200 PCIs can gross over \$1 million dollars annually for in-cath lab activities. (200 PCIs x \$6,400 payment received per PCI = @\$1.3 million.) Based on APC projections, the establishment of a new diagnostic catheterization laboratory would have to perform 87 PCIs per year to cover the startup costs. Only 35 PCIs per year would generate adequate revenue to pay the costs of staffing and supplying an existing cardiac cath lab (see attached Tables 1 and 2). The actual revenues for hospitals with full service PCI programs are much higher given that private third party reimbursement may exceed APCs by 30-40%. Of interest is one publication that noted that cost of elective PCI was 28% higher in one community hospital without on-site cardiac surgery compared to matched cohort in the backup hospital with on-site surgery¹⁵ (Level of Evidence C).

New interventional cardiology programs serving the same patient population as adjacent hospital(s) will precipitate a cascade of fiscal implications. Assuming that the PCI needs of the community are currently being met, as the new program expands the number of PCIs at the existing hospital will decrease. The revenue at the new program will increase while that of the existing program will decrease.

The actual costs and payments by third parties and patients will generally remain the same for the PCI but will be divided between two facilities. In certain

situations community hospitals with lower cost differentials may have lower Medicaid payment rates. Community hospitals are also likely to receive lower Medicare payments than tertiary care hospitals with indirect medical education costs and hospitals designated as Medicare DSH facilities.

There will some savings for those patients who previously received diagnostic catheterizations and had to be transferred (ambulance \$500-\$1000) and admitted/scheduled to hospital with on-site cardiac surgery for a PCI with a repeat angiogram performed (additional \$5-6000 in costs). On the other hand there will be increased costs generated by the initiation of new elective (and primary PCI) programs for those patients being transferred for emergency CABG (<1%) who previously would not have left the hospital with on-site cardiac surgery.

The total fiscal impact is difficult to determine and quantify – presently some hospitals with only diagnostic cardiac catheterization labs refer patients with higher probability of lesions requiring intervention to hospitals with on-site surgery for the initial diagnostic catheterization and intervention, thus avoiding a second costly procedure. A number of these diagnostic angiograms would subsequently be performed at the hospitals with new elective PCI programs and not have been referred to the existing programs.

XII. Minimum Criteria for the Performance of PCI in Hospitals Without Onsite Cardiac Surgery

Expanding PCI availability may in certain settings provide needed access, but it may have the untoward effect of splitting the need between competing institutions. This may cause a situation where critical mass to maintain quality and financial viability is lost to all programs.

Recommendation: The State of Washington should permit hospitals without onsite cardiac surgery to perform adult elective percutaneous coronary interventions only if the following minimum criteria are met:

- 1) The applicant hospital must provide a detailed demographic and patient need analysis/assessment of its service area that documents an unmet need for the provision of adult elective percutaneous coronary interventions and its plans to address this unmet need, including providing access to those with lack of insurance or in areas with insufficient numbers of cardiologists. The assessment must demonstrate how the implementation of a new elective PCI program in their community would result in improved clinical access and outcomes for the patient population served.**
- 2) The hospital must submit a detailed analysis of the impact that their new elective PCI program will have on the utilization and volume of PCI performance at other hospitals with established elective PCI programs that are currently providing this service to the same patient population with an**

opportunity for the other hospitals in the community to respond. It is the responsibility of the State to assure that all communities have access to vital services but it is also its duty to assure that valuable health care resources are effectively and efficiently utilized. It would not be in the best interest of the communities served if the initiation of new PCI programs resulted in the development of new low volume programs or converted a formerly high-volume program into a low-volume program.

- 3) The hospital must submit a plan on how they will be able to effectively recruit and staff the new cardiac catheterization laboratory program with qualified technicians, nurses, and cardiologists without negatively effecting existing programs' ability to continue their existing programs. The recruitment of qualified providers and ancillary support may be more problematic in rural and micro-urban communities and in public and governmental hospitals. Providing coverage of two 24/7 primary PCI programs in the same or proximate rural or micro-urban communities could be problematic.
- 4) The hospital must submit a detailed analysis of the impact that their new adult elective PCI program will have on the Cardiology and Interventional Cardiology Training program at the University of Washington with an opportunity for the University to respond. It clearly is in the best of the State of Washington and other surrounding States to protect the training programs at the only Cardiovascular Disease and Interventional Cardiology fellowship programs in northwestern USA.
- 5) Hospitals initiating new elective PCI programs without on-site cardiac surgery must apply and qualify for participation in a well powered, prospective randomized multiple site study, such as the currently in progress C-PORT E project, assessing the outcomes of elective PCIs performed in hospitals with and without on-site cardiac surgery as a prerequisite for approval.
- 6) The hospital must submit a detailed analysis of the projected volume of elective percutaneous coronary interventions that it anticipates will be performed in years 1-2-3. All new elective PCI programs are to be in compliance with national guidelines and State of Washington standards for annual institutional volumes for the performance of elective PCIs by the end of year 2. The institution must be performing a minimum of 300 annual PCIs by the end of year two and an optimal annual volume of >400 by year 3. The projected volumes must be sufficient to assure that all interventional cardiologists working only at this hospital will be able to meet volume standards (minimum >75, optimal >100) for annual *elective* PCIs by year 2.
- 7) The hospital must have two fully equipped cardiac catheterization laboratories with all the necessary and appropriate procedural devices,

optimal imaging systems, IAPB compatible with the transporting vehicle, resuscitative equipment and supplies required for adult elective and primary percutaneous coronary interventions. Two cath labs are needed to reasonably assure the availability of a cath lab for an emergency PCI when elective PCIs are being performed.

- 8) The hospital must have experienced interventional cardiologists who meet the established minimum lifetime and annual PCI volumes. All operators must be credentialed and privileged to perform elective and primary PCIs**

All operators performing PCIs must meet the following requirements:

- Board certification in Internal Medicine and Cardiovascular Disease Board certification in interventional cardiology by the American Board of Internal Medicine (In lieu of board certification in IC, lifetime PCI volumes >500 and >75 annually for previous two years may be accepted)**
 - Lifetime experience of 500 PCIs as primary providers and >75 PCIs annually for the previous 2 years, or a requirement for mentoring by an experienced operator who performs > 150 PCIs per year until proficiency is verified and it is determined that skills and outcomes meet national standards.**
 - Verification of PCI outcomes during the previous 2 years equivalent or superior to national benchmarks**
 - New operators should achieve minimum volumes within two years.**
 - Volume requirements may be met at more than one hospital.**
- 9) In order to minimize complications and maximize the procedural success, rigorous patient and lesion criteria must be applied to all patients undergoing elective PCI at a hospital without on-site cardiac surgery.**
- Patients with increased risk for procedural failure and increased potential for clinical demise if peri-procedural complications occur are to have elective PCI performed in a hospital with on-site cardiac surgery.**
 - High risk patient criteria including decompensated congestive heart failure, left ventricular ejection fraction <25%, left main coronary artery stenosis (>50%) or three vessel disease unprotected by previous CABG, single target lesion that supplies over 50% of viable myocardium, renal failure, recent CVA, coagulation disorders, and other serious, complicated, or uncontrolled medical conditions are to**

be referred to a hospital with on-site cardiac surgery for the performance of elective PCIs.

- Applying the 2007 SCAI criteria and definitions of patient and lesion case selection, high risk patients with low and high risk lesions and low risk patients with high risk lesions are to be excluded from having elective PCIs performed at a hospital with off-site backup surgery. Only low-risk patients with low-risk lesions will be eligible to have elective PCI performed at hospitals without on-site cardiac surgery.
- Low risk patients with low risk lesions are most appropriate for the performance of elective PCI at a hospital without on-site cardiac surgery⁹ (Level of Evidence C)
- After two years of operation, institutions and operators whose risk-adjusted outcome statistics are equivalent or superior to risk adjusted national data registries may apply for expansion of their patient selection criteria to include low risk patients with high risk lesions.
- Patients whose angiographic findings indicate that atherectomy devices (directional, rotational, laser) and/or extractational thrombectomy are likely to be utilized will be excluded from having an elective PCI performed at a hospital without on-site surgery.
- Percutaneous Transluminal Angioplasty (PTCA), PTCA with stent implantation, and cutting balloon atherectomy will be allowed in hospitals without on-site surgery.

10) Informed consents for elective (and primary) percutaneous coronary interventions must explicitly communicate to the patients that the intervention is being performed without on-site surgery backup and addresses risks related to transfer, the risk of urgent surgery, and the established emergency transfer agreements.

11) The hospital must provide both primary (emergency) and elective percutaneous coronary interventions. The ACC/AHA/SCAI recommends that wherever elective PCIs are performed that primary PCIs also be provided^{9,10}. The professional associations recommend the provision of both primary and elective PCIs at all programs for purpose of maintaining the skills and experience of the operator and the cardiac catheterization team.

The hospital must have a sufficient number of interventional cardiologists on staff so that both primary and elective PCIs can be performed in a timely manner.

The authors of this report were unable to identify any hospitals in the USA performing elective PCI that do not also perform primary PCI. It is nonetheless conceivable that the USA may someday develop primary PCI “centers of excellence” (similar to centralized Trauma Centers) to which patients with Acute Myocardial Infarction and Acute Coronary Syndromes are directly transported bypassing other hospitals. This would help to avoid the costly duplication of services and redundancy of interventional cardiologist and cardiac laboratory team coverage of emergency rooms in adjacent hospitals for primary PCIs.

- 12) The catheterization laboratory and post-procedure recovery must be staffed with a qualified, trained team of technicians and nurses. The cardiac catheterization laboratory staff should be experienced in interventional laboratories and in the treatment of acutely ill patients with hemodynamic and electrical instability. Nursing staff should have coronary care unit experience and have demonstrated competency in invasive hemodynamic monitoring, temporary pacemaker operation, and intraaortic balloon pump management. Staff should also be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.⁹
- 13) The hospital must have a signed written agreement with a hospital(s) with onsite cardiac surgery and with the cardiac surgeons stating that the referred patient will be accepted based on the medical condition.
 - The availability of the back-up hospital’s surgical team and OR must be confirmed before the start of elective PCIs.
 - The backup hospital/surgeons must agree to provide cardiac surgical backup for emergency CABG 24 hours/day, 7 days/week and during all hours that elective PCIs are being performed at the hospital without on-site surgery.
 - All clinical data including images and videos must be transferred with the patient; ideally this transfer of vital information will be performed electronically in real time.
 - The Interventional cardiologist must directly communicate and review with the cardiac surgeon the clinical reasons for urgent transfer and the clinical condition of the patient.
- 14) The hospital must provide a mode of emergency transport and/or have a signed transportation agreement with a vendor who will expeditiously transport by air or land all patients who experience complications during elective PCIs that require transfer to a backup hospital with on-site cardiac surgery. Transportation shall begin in <20 minutes.

- 15) **The emergency transport staff must be qualified, trained, and ACLS certified and have the skills, experience, and equipment to monitor and treat the patient en route and to manage an Intra-Aortic Balloon Pump (IABP).**
- 16) **The hospital must be able to document that the transportation time from the decision to transfer the patient with an elective PCI complication to arrival in the OR of the backup hospital is < 90 minutes and ideally, <60 minutes. No less than two annual timed transportation drills will be performed and reported to the quality program.**
- 17) **The hospital will conduct regular, ongoing quality assurance/improvement evaluation and analysis of the outcomes (success and complication rates) of elective PCIs, benchmarking, compliance with hospital and program guidelines for patient and lesion selection and exclusion and device utilization, reviews of patients transferred for emergency cardiac surgery, and formalized case reviews. The surgeons at the backup hospital are to formally participate in the review of all elective PCIs transferred to backup hospital.**
- 18) **The hospital's cardiac catheterization laboratory and PCI program will fully participate in a national percutaneous coronary intervention data base such as the American College – National Cardiovascular Data Registry (ACC-NCDR) in the United States.**

XIII. Executive Summary

The current State of Washington Certificate of Need standard for nonemergent interventional cardiology states "all nonemergent percutaneous coronary angioplasty (PTCA) and all nonemergent interventional cardiology procedures are tertiary services and shall be performed in institutions which have an established on-site open heart surgery program performing emergency open heart surgery." The State of Washington Department of Health contracted with Health Management Associates to conduct an evidence-based review of the medical literature and to provide recommendations based on this review concerning whether there has developed significant experience and data in the USA that would allow adult elective PCIs to be safely performed in hospitals without on-site cardiac surgery. Expanding elective PCI availability may in certain settings provide needed access, but it may have the untoward effect of splitting the need between competing institutions. This may cause a situation where critical mass to maintain quality and financial viability is lost to all programs. With the fullest understanding that any modifications in the current CON standards must only be enacted if they address the health needs of local communities and advance the quality of care for the patients served by the hospitals of Washington, Health Management Associates have submitted the following recommendations.

Recommendations

1) Elective PCI should not be performed in hospitals without on-site surgery. The highest level (A) of investigation, well powered prospective randomized studies, has not yet been performed to fully confirm the safety and quality of performing elective PCI without on-site cardiac surgery. This lack of gold standard evidence has contributed to the reluctance of expert panels, professional societies, and governmental regulatory agencies to endorse and permit the provision of elective PCI in hospitals without on-site cardiac surgery. Until Level A studies have been completed and evaluated, it is not in the best interests of the health of the residents of Washington to allow elective PCI to be performed without on-site surgery.

Circumstances under which elective PCI without on-site surgery could be allowed:

2) The applicant hospital must objectively quantify and document that there exists a significant unmet need and diminished access to medically justified elective PCI services and how their program will address this need in order for the State of Washington to consider the initiation of an elective PCI program in a hospital without on-site cardiac surgery. Programs that focus on the care of the underserved and uninsured may need to be provided with special consideration for developing new interventional cardiology programs.

3) The applicant hospital must submit a detailed analysis of the impact that their new elective PCI program will have on the utilization and volume of PCI performance at other hospitals with established elective PCI programs that are currently providing this service to the same patient population. The existing programs will have an opportunity to respond. New programs should not be allowed if they would reduce the volume of existing hospitals below minimum national and State volume standards.

4) New elective PCI programs must submit a detailed recruitment and staffing plan for qualified nurses, catheterization lab techs, and interventional cardiologists that does not jeopardize the continued functioning of existing elective PCI programs in the same service area. Recruiting qualified staff and providing 24/7 emergency PCI coverage in proximate rural or micro-urban hospitals could be problematic and could jeopardize the sustainability of both existing and new programs.

5) Hospitals initiating new elective PCI programs without on-site cardiac surgery must apply and qualify for participation in a well powered, prospective randomized multiple site study, such as the currently in progress C-PORT E project, assessing

the outcomes of elective PCIs performed in hospitals with and without on-site cardiac surgery as a prerequisite for approval. Failure to qualify for participation in such study will result in the denial of the elective PCI application.

- 6) **The applicant hospital must submit a detailed analysis of the impact the new elective PCI services will have on the Cardiovascular Disease (Cardiology) and Interventional Cardiology Fellowship Training programs at the University of Washington.** The University will have an opportunity to respond. It is in the best interests of Washington and other surrounding States to protect the only Cardiology and Interventional Cardiology training programs in northwest USA.
- 7) **The applicant hospital must submit an objective plan to achieve minimum PCI volume standards >300 by the end of year two and optimal volumes >400 by year 3.** Inability to meet volume standards should result in a review of their CON approval.
- 8) **The applicant hospital must have two functional and fully equipped cardiac catheterization laboratories with all appropriate devices, optimal digital imaging systems, life sustaining apparatus including IABP staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients .** Two labs are needed to assure the availability of catheterization lab for an emergency PCI when an elective PCI is in process.
- 9) **The applicant hospital's catheterization laboratory must be staffed by a qualified, trained team of technicians and nurses experienced in interventional labs and in the treatment of acutely patients with hemodynamic and electrical instability.** The nursing staff must have CCU experience and documented competencies in invasive monitoring, temporary pacemaker placement, and IABP management.
- 10) **The applicant hospital must have on staff experienced Interventional Cardiologists who meet the certification, lifetime and annual PCI volume experience, and national benchmark outcome standards.**
- 11) **Hospitals without on-site cardiac surgery must implement and monitor rigorous patient and lesion selection guidelines.** High risk patients and patients with high risk lesions must be referred to a hospital for elective PCI. Low risk patients with low risk lesions are most appropriate for elective PCI in a hospital without on-site surgery. After two years of operation, institutions and operators whose risk-adjusted outcome statistics are equivalent or superior to risk adjusted national data registries may apply for expansion of their patient selection criteria to include low risk patients with high risk lesions.
- 12) **PCI devices (rotational atherectomy, directional atherectomy, laser atherectomy, extractional thrombectomy) with higher risks for acute complications should not be used at hospitals without on-site surgery.** Patients in whom the use of these devices is anticipated are to be referred to a hospital with on-site surgery.

13) Applicant hospitals must be prepared and staffed to perform primary emergency PCI 24 hours per day, 7 days per week in addition to the scheduled elective PCIs. Professional associations recommend the provision of primary and elective PCIs for a facility and cardiologist to maintain adequate skills and competency.

14) The applicant hospital must a signed written agreement with a hospital with on-site cardiac surgery and with cardiac surgeons stating that referred patients will be accepted based on their medical condition and that cardiac surgery will be available for emergency CABG 24 hours per day, 7 days per week and during the hours of elective PCI performance. The cardiologist will communicate directly with the surgeon concerning all transfers and will assure that vital patient information including images and videos be transferred if not already sent electronically.

15) The applicant hospital must provide emergency transport or have a signed agreement with a vendor who will initiate transportation to the backup hospital within 20 minutes and can achieve a transfer from decision to transfer to arrival in OR of backup hospital in <90 and ideally in <60 minutes. The emergency transport staff is qualified, trained, ACLS certified and competent in use of monitoring equipment, the management of an IABP, and provision of life sustaining support in route. A minimum of two annual timed transportation drills will be performed and reported to the quality program.

16) The applicant hospital will conduct ongoing quality improvement evaluation and analysis of the outcomes (success and complication rates) of elective PCIs, benchmarking, compliance with hospital and State guidelines for patients and lesion selection/exclusion and device utilization, reviews of patients transferred for emergency cardiac surgery, and formalized case reviews. The surgeons at the backup hospital are to formally participate in the review of all elective PCIs transferred for cardiac surgery.

17) The applicant hospital's cardiac catheterization laboratory and PCI program will fully participate in a national percutaneous intervention data base such as the American College of Cardiology – National Cardiovascular Data Registry (ACC-NCDR). Failure to meet or exceed national benchmarks for two consecutive years will result in a review of the program's certification.

Recommendation for Designation of Primary PCI Centers of Excellence

18) The State of Washington should formally consider the designating selected regional hospitals with on-site cardiac surgery (and in certain regions possibly without on-site cardiac surgery) as primary PCI "centers of excellence" (similar to centralized Level I Trauma Centers) to which patients with Acute Myocardial Infarction and Acute Coronary Syndromes would be directly transported bypassing other hospitals. This designation could result in improved outcomes and would help to avoid the costly round-the-clock duplication of services and redundancy of interventional

cardiologist and cardiac catheterization laboratory team coverage of emergency rooms in nearby hospitals for primary PCIs.

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Table One
Cost and Financial Feasibility

1) To finance the start up cost for the Cath lab fixed equipment	
Total Cost	\$1,500,000.00
Interest rate	6%
Loan duration (mos)	180
Monthly cost	\$12,657.85
Annual cost	\$151,894.23

2) Fixed additional costs	
Annual staffing	\$175,000.00
Benefits % sal	25%
Non call Staff cost	\$218,750.00
Call cost	\$52,000.00
Total Staff cost	\$270,750.00
Equipment	\$150,000.00
Number of cath	100
Equip Cost / Cath	\$1,500.00

3) Average reimbursement	
	\$ 6,375.58

4) Number of APC needed to cover the finance of start up	
Annual cost	\$151,894.23
Total Staff cost	\$270,750.00
Equipment/APC	\$1,500.00
Number APC	87

5) Number of APC needed existing Cath lab	
Total Staff cost	\$270,750.00
Equipment/APC	\$1,500.00
Number APC	35

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**Table Two
Weighted Reimbursement**

APC	Group Title	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment	Total Collection	Weight	Weighted reimbursement
0082	Coronary Atherectomy	4,690.22	1,008.90	938.04	5,626.26	1.5%	\$ 84.42
0083	Coronary Angioplasty and Percutaneous Valvuloplasty	3,538.79		707.76	4,246.55	2.0%	\$ 84.93
0104	Transcatheter Placement of Intracoronary Stents	5,415.31		1,083.06	6,498.37	92.5%	\$ 6,010.99
0229	Transcatheter Placement of Intravascular Shunts	4,067.31		813.46	4,880.77	4.0%	\$ 195.23
						100.0%	\$ 6,375.58
0268	Level I Ultrasound Guidance Procedures	73.66		14.73	88.39		
0309	Level II Ultrasound Guidance Procedures	131.01		26.20	157.21		

Note the second group of procedures of unsure significance, unsure of weighted values.

Definition key

- 1) Payment Rate: The amount received by the third party payor for the procedure
- 2) Minimum Unadjusted Copayment : The amount we can
- 3) Weight: The average percentage that we bill the given APC per total billed APC's

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Table Three
2004 – 2006 PCI DRG Data

Solvent Discharge Data										
Washington State hospitals with discharges from ID, OR, MT and WA										
2004										
Hospital Name	Zip	DRGs								
		110	111	516	517	518	526	527	total	
Discharges										
AUBURN REGIONAL MEDICAL CENTER	98001	25	8	44	6	1	32	4	120	
SAINT FRANCIS HOSPITAL	98003	8	3	31	3	1	41	3	90	
OVERLAKE HOSPITAL MEDICAL CENTER	98004	76	19	23	53	106	160	733	1170	
STEVENS HEALTHCARE	98026	33	2	22			3	52	8	120
EVERGREEN HOSPITAL MEDICAL CENTER	98034	22	8	52	4	2	93	9	190	
GROUP HEALTH EASTSIDE HOSPITAL	98052	12	4						16	
VALLEY MEDICAL CENTER - RENTON	98055	34	7	55	2	2	60	4	164	
VIRGINIA MASON MEDICAL CENTER	98101	93	31	30	19	44	110	128	455	
HARBORVIEW MEDICAL CENTER	98104	65	4	27	10	1	19	3	129	
CHILDRENS HOSPITAL AND REGIONAL MEDICAL CENTER	98105	37	9			24			70	
SEATTLE CANCER CARE ALLIANCE	98109	1							1	
SWEDISH MEDICAL CENTER	98122	56	12	7	7	26	150	267	525	
SWEDISH PROVIDENCE MEDICAL CENTER	98122	56	9	7	5	41	53	121	292	
NORTHWEST HOSPITAL	98133	33	2	6	3	9	73	210	336	
HIGHLINE MEDICAL CENTER	98166	15	8	22	4	4	31	7	91	
UNIVERSITY OF WASHINGTON MEDICAL CENTER	98195	68	11	7	12	76	44	119	337	
PROVIDENCE EVERETT MEDICAL CENTER	98201	90	15	129	83	89	209	356	971	
ISLAND HOSPITAL	98221	2							2	
CASCADE VALLEY HOSPITAL	98223	2							2	
SAINT JOSEPH HOSPITAL - BELLINGHAM	98225	52	9	58	64	46	173	409	811	
SKAGIT VALLEY HOSPITAL	98274	7	2	34	14		31	5	93	
HARRISON MEMORIAL HOSPITAL	98310	49	13	26	19	3	103	150	363	
GOOD SAMARITAN HOSPITAL	98372	45	10	51	3	1	58	3	171	
MARY BRIDGE CHILDRENS HEALTH CENTER	98405	25	7			3			35	
SAINT JOSEPH MEDICAL CENTER	98405	53	12	43	42	59	172	499	880	
TACOMA GENERAL HOSPITAL	98405	51	8	48	71	37	136	543	894	
SAINT CLARE HOSPITAL	98499	9	2						11	
CAPITAL MEDICAL CENTER	98502	20	5	11	11	1	17	8	73	
PROVIDENCE SAINT PETER HOSPITAL	98506	65	8	57	58	27	259	571	1045	
GRAYS HARBOR COMMUNITY HOSPITAL	98520	2							2	
PROVIDENCE CENTRALIA HOSPITAL	98531	1							1	
PEACEHEALTH SAINT JOHN MEDICAL CENTER	98632	15	4						19	
SOUTHWEST WASHINGTON MEDICAL CENTER	98664	37	8	44	10	13	210	228	550	
CENTRAL WASHINGTON HOSPITAL	98801	45	9	19	17	6	91	111	298	
YAKIMA REGIONAL MEDICAL AND HEART CENTER	98902	44	12	34	16	12	152	306	576	
YAKIMA VALLEY MEMORIAL HOSPITAL	98902	10		18			25	4	57	
DEACONESS MEDICAL CENTER	99204	93	17	89	59	55	99	192	604	
SACRED HEART MEDICAL CENTER	99204	192	51	135	268	243	245	966	2100	
HOLY FAMILY HOSPITAL	99208	30	8	50	4		1		93	
VALLEY HOSPITAL AND MEDICAL CENTER - SPOKANE	99216	8	1						9	
KENNEWICK GENERAL HOSPITAL	99336	3	3						6	
KADLEC MEDICAL CENTER	99352	44	8	48	24	8	93	76	301	
SAINT MARY MEDICAL CENTER	99362	2	1						3	
WALLA WALLA GENERAL HOSPITAL	99362	10	2						12	
TRI-STATE MEMORIAL HOSPITAL	99403	1							1	

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Solient Discharge Data														
Washington State hospitals with discharges from ID, OR, MT and WA 2005														
Hospital Name	Zip	Service Line DRG												
		110	111	516	517	518	526	527	555	556	557	558	Total	
AUBURN REGIONAL MEDICAL CENTER	98001	23	14	13			38	6	2		16	112		
SAINT FRANCIS HOSPITAL	98003	4	1	4			1	48	10	4	14	86		
OVERLAKE HOSPITAL MEDICAL CENTER	98004	66	24	17	20	98	123	630	14	5	79	220	1296	
STEVENS HEALTHCARE	98026	17	5	7			51	9	7		14	110		
EVERGREEN HOSPITAL MEDICAL CENTER	98034	24	3	9	1	3	82	5	1		48	176		
GROUP HEALTH EASTSIDE HOSPITAL	98052	8	8									16		
VALLEY MEDICAL CENTER - RENTON	98055	32	10	5			79	4	4		22	156		
VIRGINIA MASON MEDICAL CENTER	98101	93	30	16	9	46	73	98	18	3	33	24	443	
HARBORVIEW MEDICAL CENTER	98104	66	12	9	3		23	10	4	1	8	3	139	
CHILDRENS HOSPITAL AND REGIONAL MEDICAL CENTER	98105	34	16				35						86	
SWEDISH MEDICAL CENTER	98122	68	20	9	3	24	113	177	12	1	59	35	521	
SWEDISH PROVIDENCE MEDICAL CENTER	98122	75	15	3			53	44	111	6		17	28	352
NORTHWEST HOSPITAL	98133	21	2	3	1	6	62	175	2		32	34	338	
HIGHLINE MEDICAL CENTER	98166	9	1	7	3	2	29	12	4		11	4	82	
UNIVERSITY OF WASHINGTON MEDICAL CENTER	98195	105	20	6	10	136	24	100	8	5	13	23	450	
PROVIDENCE EVERETT MEDICAL CENTER	98201	112	23	64	33	112	177	258	40	10	83	74	986	
ISLAND HOSPITAL	98221	6	1										7	
CASCADE VALLEY HOSPITAL	98223	8											8	
SAINT JOSEPH HOSPITAL - BELLINGHAM	98225	59	12	19	20	40	148	334	20	7	59	70	788	
SKAGIT VALLEY HOSPITAL	98274	15		17	2	1	51	7	1	1	16	7	118	
HARRISON MEMORIAL HOSPITAL	98310	67	17	16	12	8	88	128	7	3	40	46	432	
GOOD SAMARITAN HOSPITAL	98372	44	10	8			59	3	5		28	1	158	
MARY BRIDGE CHILDRENS HEALTH CENTER	98405	11	10			3			1				25	
SAINT JOSEPH MEDICAL CENTER	98405	58	8	10	6	30	147	219	10	3	52	25	566	
TACOMA GENERAL HOSPITAL	98405	53	7	5	13	34	127	476	6	3	77	99	900	
SAINT CLARE HOSPITAL	98499	9	4										13	
CAPITAL MEDICAL CENTER	98502	10	2	3	1		17	14	2		10	5	64	
PROVIDENCE SAINT PETER HOSPITAL	98506	66	8	28	32	28	223	448	22	4	93	101	1053	
GRAYS HARBOR COMMUNITY HOSPITAL	98520	6											6	
PROVIDENCE CENTRALIA HOSPITAL	98531	8	1										9	
PEACEHEALTH SAINT JOHN MEDICAL CENTER	98632	26	4										30	
SOUTHWEST WASHINGTON MEDICAL CENTER	98664	38	5	21	10	8	221	180	2	2	73	39	599	
LEGACY SALMON CREEK HOSPITAL	98686	1	1										2	
CENTRAL WASHINGTON HOSPITAL	98801	36	8	12	9	2	73	81	5	4	17	33	280	
YAKIMA REGIONAL MEDICAL AND HEART CENTER	98902	40	9	14	10	16	108	253	4	4	40	50	548	
YAKIMA VALLEY MEMORIAL HOSPITAL	98902	27	12	9			46	5	5		11	1	116	
KITTITAS VALLEY HOSPITAL	98926	1											1	
PULLMAN REGIONAL HOSPITAL	99163	1											1	
DEACONESS MEDICAL CENTER	99204	111	15	38	25	57	97	197	21	11	42	52	666	
SACRED HEART MEDICAL CENTER	99204	183	54	34	78	307	181	706	49	17	124	216	1949	
HOLY FAMILY HOSPITAL	99208	30	15	10	4		23	3	2		8		95	
VALLEY HOSPITAL AND MEDICAL CENTER - SPOKANE	99216	5											5	
KENNEWICK GENERAL HOSPITAL	99336	14	4										18	
KADLEC MEDICAL CENTER	99352	52	9	12	5	4	139	102	6	3	55	22	409	
SAINT MARY MEDICAL CENTER	99362	8	1										9	
WALLA WALLA GENERAL HOSPITAL	99362	6	1										7	

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Solvent Discharge Data										
Washington State hospitals with discharges from ID, OR, MT and WA 2006										
Hospital Name	Zip	Service Line DRG								Total
		110	111	518	555	556	557	558	Discharges	
AUBURN REGIONAL MEDICAL CENTER	98001	27	13	2	17		67	3	129	
SAINT FRANCIS HOSPITAL	98003	13	1		9		53	3	79	
OVERLAKE HOSPITAL MEDICAL CENTER	98004	81	30	59	36	26	258	825	1315	
STEVENS HEALTHCARE	98026	18	6	2	14	1	73	22	136	
EVERGREEN HOSPITAL MEDICAL CENTER	98034	19	5	2	19		135	6	188	
VALLEY MEDICAL CENTER - RENTON	98055	36	11	1	24		99	7	178	
VIRGINIA MASON MEDICAL CENTER	98101	90	16	44	68	19	135	108	480	
HARBORVIEW MEDICAL CENTER	98104	58	11	4	22	2	38	5	140	
CHILDRENS HOSPITAL AND REGIONAL MEDICAL CENTER	98105	49	17	69	7				142	
SWEDISH MEDICAL CENTER	98122	42	16	10	18	1	108	71	268	
SWEDISH PROVIDENCE MEDICAL CENTER	98122	102	15	36	46	12	217	204	632	
NORTHWEST HOSPITAL	98133	35	1	9	19	8	130	169	371	
HIGHLINE MEDICAL CENTER	98166	4	5	2	19		51	21	102	
UNIVERSITY OF WASHINGTON MEDICAL CENTER	98195	79	12	126	51	6	74	80	428	
PROVIDENCE EVERETT MEDICAL CENTER	98201	105	14	100	98	59	337	342	1055	
ISLAND HOSPITAL	98221	1							1	
CASCADE VALLEY HOSPITAL	98223	2	1						3	
SAINT JOSEPH HOSPITAL - BELLINGHAM	98225	68	6	55	94	45	302	346	916	
WHIDBEY GENERAL HOSPITAL	98239	1							1	
SKAGIT VALLEY HOSPITAL	98274	15		1	11		82	16	125	
HARRISON MEMORIAL HOSPITAL	98310	65	24	15	58	23	188	168	541	
GOOD SAMARITAN HOSPITAL	98372	35	6		13	1	101	6	162	
MARY BRIDGE CHILDRENS HEALTH CENTER	98405	11	3	3	1				18	
SAINT JOSEPH MEDICAL CENTER	98405	61	9	22	35	13	302	194	636	
TACOMA GENERAL HOSPITAL	98405	54	8	28	29	14	261	476	870	
SAINT CLARE HOSPITAL	98499	9	2						11	
CAPITAL MEDICAL CENTER	98502	20	1		2	1	34	16	74	
PROVIDENCE SAINT PETER HOSPITAL	98506	62	14	35	76	34	412	495	1128	
GRAYS HARBOR COMMUNITY HOSPITAL	98520	3							3	
PROVIDENCE CENTRALIA HOSPITAL	98531	2	1						3	
PEACEHEALTH SAINT JOHN MEDICAL CENTER	98632	26	3						29	
SOUTHWEST WASHINGTON MEDICAL CENTER	98664	58	9	12	35	9	303	228	654	
LEGACY SALMON CREEK HOSPITAL	98686	18	6						24	
CENTRAL WASHINGTON HOSPITAL	98801	42	18	4	23	4	113	79	283	
YAKIMA REGIONAL MEDICAL AND HEART CENTER	98902	42	3	5	28	13	186	235	512	
YAKIMA VALLEY MEMORIAL HOSPITAL	98902	21	4		19	1	64	8	117	
PULLMAN REGIONAL HOSPITAL	99163	1	1						2	
DEACONESS MEDICAL CENTER	99204	93	32	69	99	51	194	236	774	
SACRED HEART MEDICAL CENTER	99204	155	41	344	211	82	421	809	2063	
HOLY FAMILY HOSPITAL	99208	34	5	1	17		38	2	97	
VALLEY HOSPITAL AND MEDICAL CENTER - SPOKANE	99216	4							4	
KENNEWICK GENERAL HOSPITAL	99336	5	2						7	
KADLEC MEDICAL CENTER	99352	31	11	2	30	8	257	105	444	
SAINT MARY MEDICAL CENTER	99362	5	3						8	
WALLA WALLA GENERAL HOSPITAL	99362	7	2						9	
TRI-STATE MEMORIAL HOSPITAL	99403	1							1	

Table Four
State of Washington Hospital Interviews

<u>Hospitals Interviewed by HMA Consultants</u>	
Benton County	Kadlec Medical Center Kennewick General Hospital
Clark County	Southwest Washington Medical Center
King County	University of Washington (Interventional Cardiology Fellowship Program)
Spokane County	Valley Hospital and Medical Center
Thurston County	Capital Medical Center
Yakima County	Yakima Regional Medical Center Yakima Valley Medical Center
<u>Hospital System</u>	Providence Health and Services Hospitals in Washington

**Table Five
Recommendations Summary Table**

Recommendation Summary table		
Recommendation	Evidence	Consultants' Comments
1 Elective PCI should not be performed without on-site cardiac surgery	<p>Publications Not Supportive of EPCI without on-site surgery Reference 10. Smith p.93 (C) Reference 16 Wennberg p.1961-1968 (B) Reference 29 Lofii p.337-342 (B)</p> <p>Publications Supportive of EPCI without on-site surgery Reference 11 Paraschos p.1091-1093 (B), Reference 12 Zavala-Alarcon p.676-683 (B). Reference 13 Rossanov p.909-913 (B) Reference 14 Ting p.1713-1721 ((B) Reference 15 Long p.406-413 (B) Reference 17 Melberg p.888-895 (B) Reference 18 Wharton p.98-106 (B,C) Reference 19 Lemkes p.173-177 (B)</p> <p>Publication Not Fully Endorsing but establishing guidelines for EPCI without on-site surgery Reference 9 Dehmer p.1-21 (C)</p>	There are no Level of Evidence A, well powered, multiple site, randomized studies comparing elective PCIs with and without on-site cardiac surgery.
2 Programs applying for elective PCI without on-site surgery must prove unmet need in community served	Reference 9. Dehmer p16-17 (C) Reference 14 Ting p.1719 (B) Reference 18 Wharton p100-101 (C) Reference 27 Leape p183-192 (B,C) Reference 28 Phibin p III 107-115 (B,C)	Based on phone communication with existing PCI programs and interested hospitals, there were no reports of lack of access to EPCI in the communities served.(C)
3 Programs applying for EPCI without on-site surgery must report on impact of new programs volume of procedures at existing programs	Reference 9. Dehmer p16 (C)	Based on phone communication with WA hospitals with and without PCI programs and review of DRG data, potential exists that new and existing programs may not be able to meet minimum volume standards-especially in rural and micro-urban areas. (C)
4 Programs applying for EPCI without on-site surgery must report on impact of new programs on recruitment of cath teams/ICs at both the new and existing programs		Based on phone communication with WA hospitals with and without PCI programs, potential exists for difficulty recruiting qualified cath lab staff and ICs - especially in rural and micro-urban areas. (C)
5 Participation in well powered, national, multi-site randomized Level of Evidence A study comparing EPCI with and without on-site surgery is required.	Reference 14 Ting p.1720 (C) Reference 13 Roussanov p.909 (C)	Consultants' did not identify any Level of Evidence A published studies comparing EPCI with and without on-site surgery (C)
6 Applicant programs must report on the impact of new EPCI programs on the Cardiology and IC training programs at the University of Washington		Based on phone communication with UW IC training program, there is a potential that new EPCI programs could negatively impact on minimum volume standards required by the ACGME at UW IC training sites.(C)

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<p>7</p> <p>>300 minnum annual PCI program volume by year 2 and >400 optimal volume by year 3</p>	<p>Reference 9 Dehmer p.6 (C) >100 Spanish SCG Reference 9 Dehmer p.13 (C) <150 (after 2 years should not remain open) Reference 22 Epstein p.1755-61 (B) <200 (associated with increased mortality) Reference 10 Smith p.31 (C) <200 (should consider whether to continue) Reference 10 Smith p.31 (C) >200 (minimum volume) Reference 9 Dehmer p.5 (C) >200 British CIS (robustly move to >400) .</p> <p>Reference 10 Smith p.31 (C) 200-400 (considered low volume centers) Reference 22 Epstein p.1755-61 (B) 200-399, 400-899, >1000 (no difference in mortality) Reference 23 Hannan p.1171-79 (B) >400 (deceased same day and stay and in-house mortality) Reference 19 Lemkes p.177 (B) >400 French study (minimum volume) Reference 10 Smith p.35 (C) >400 (optimal minimum volume)</p>	<p>Experts recommend that <150 programs be closed and <200 be reviewed for closure, >300 minimum volume was recommended by consultants to allow a logical distance from closure and reviewable minimum PCI volumes ©</p>
<p>8</p> <p>Applicant programs must have 2 fully equiped cath labs with all appropriate devices, digital radiology, IABP, etc</p>	<p>Reference 9 Dehmer p.13 (C) Reference 10 Smith p.29 (C) Reference 14 Ting p.1720 (C) Reference 18 Wharton p. 99 (C)</p>	<p>Minimum of 2 labs recommended by HMA consultants so that programs with elective and primary PCI programs could more quickly access a cath lab in case of emergency even if an EPCI is in progress (C)</p>
<p>9</p> <p>Cath lab must be staffed with trained, qualified, experienced cath lab staff</p>	<p>Reference 9 Dehmer p.13 (C) Reference 10 Smith p.29 (C) Reference 14 Ting p.1720 (C) Reference 18 Wharton p.99 (C)</p>	
<p>10</p> <p>Programs must have experienced IC's with certification, (and/or)lifetime >500, and annual volume >75 requirements</p>	<p>Lifetime Volumes Reference 9 Dehmer p.12 (C) >500 Reference 10 Smith p.31 (C) >500 (for IC program director) Reference 9 Dehmer p.12 (C) <500 (must be mentored and monitored by an experienced IC) Operator Annual Volumes Reference 25 Moscucci (B) <33, 34-89 (higher MACE compared to >90, 140-206, 207-512) Reference 9 Dehmer p.6 (C) 50-75 Spanish SCI, Belgium WG on IC guidelines Reference 9 Dehmer p.6 (C) 50-75 Spanish SCL, Belgium WG on IC guidelines Reference 24 McGrath p.3139 (B) <75 (30 Medicare) (higher CABG rates compared to higher volumes but same mortality) Reference 23 Hannan p.1171 (B) <75 (increased same day and stay CABG, no difference in mortality) Reference 10 Smith p.31 (C) >75 (minimum volume) Reference 9 Dehmer p. 5-6 (C) >75 British CIS (minimum volume) Reference 25 Moscucci p.625 (B) 1-33, 34-89 (higher adverse outcomes compared to >90 annual PCI volume) Reference 9 Dehmer p.12 >100 (recommended for sites without on-site surgery) Reference 24 McGrath p.3139-3144 (B) >150 (60 Medicare)(decreased risk of CABG compared to <75) Reference 9 Dehmer p.5 >150 British CSI (optimal volume)</p>	

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11	<p>Elective PCI without on-site surgery must have rigorous patient and lesion selection criteria</p>	<p>Reference 9 Dehmer p.13-14 (C) Reference 10 Smith p 12-24 (C) Reference 11 Paraschos p.1093 (B) Reference 14 Ting p.1715,1718 (B) Reference 17 Melberg p.889, 891, 894 (B) Reference 18 Wharton p 100, 105 (B,C).</p>	<p>HMA consultants recommended that new programs without on-site surgery initially do EPCI on low risk patients with low risk lesions and progress to higher risk patients and lesions after documenting proven outcomes meeting or exceeding national benchmarks (C)</p>
12	<p>PCI devices (rotational, directional, laser atherectomy and extractional thrombectomy) with higher rates of complications are not to be used without on-site surgery.</p>	<p>Reference 9 Dehmer p.13 (B,C) Reference 10 Smith p.21-22 (B,C) Reference 31 Ting (C) Reference 32 Fasseas p.140-145 (B)</p>	
13	<p>Programs performing EPCI must also provide primary PCI 24/7</p>	<p>Reference 9 Dehmer p.13 (C) Reference 18 Wharton p.104-105 (C)</p>	
14	<p>Programs without on-site surgery must have signed written agreement with backup hospital with cardiac surgery and with cardiac surgeons for 24/7 emergency transfers. Patients being transferred with be accepted based on medical need</p>	<p>Reference 9 Smith p. 14-15 (C) Reference 10 Smith p.35-37 (B,C) Reference 18 Wharton p.104 (C)</p>	
15	<p>Emergency transport in fully equipped vehicle by trained, ACLS certified, qualified, experienced staff with ability to monitor patient, use IABP and arrive in OR of backup hospital in <60-90 minutes and</p>	<p>Reference 9 Dehmer p.12-13 (C) Reference 10 Smith p.35-37 (C) Reference 17 Melberg p. 890 (B) Reference 18 Wharton p.101 (C)</p>	
16	<p>Program will conduct ongoing QI evaluation of outcomes including comparison with national benchmarks, compliance with State and institutional guidelines for patient and lesion selection, review of transfers for emergency CABG, and case reviews.</p>	<p>Reference 9 Dehmer p.13,15-16 (C) Reference 10 Smith p.29-30 (C) Reference 17 Melberg, p.894 (C) Reference 18 Wharton p.101 (C)</p>	

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17	<p>Participation in a national PCI data base such as the ACC-NCDR</p>	<p>Reference 9 Dehmer p.13,17 (B,C) Reference 10 Smith p.29 (C) Reference 18 Wharton p.105 (C)</p>	
18	<p>State should consider whether selected regional hospitals should be designated as primary PCI referral centers (similar to centralized Level I Trauma Centers)</p>	<p>Reference 9 Dehmer p.17 (C)</p>	<p>Regionalized primary PCI centers could minimize costly duplication of services and maximize quality</p>