Washington State Health Care Authority

Health Technology Assessment

Cardiac Stents – Re-Review

Draft Evidence Report: Comment & Response

December 11, 2015

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RESPONSES TO CLINICAL AND PEER REVIEWERS (SECTION 1, TABLE 1)

RESPONSES TO PUBLIC COMMENTS (SECTION 2, TABLE 2)

Spectrum Research is an independent vendor contracted to produce evidence assessment reports for the Washington HTA program. For transparency, all comments received during the public comment periods are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

The first section responds to clinical and peer reviews received from the following parties:

Draft Report

- Michael Ring, MD, FACC, FSCAI; Medical Director of Quality, Co-Director Transcatheter Aortic Valve Replacement Program; Providence Spokane Heart Institute
- Rita Redberg, MD, M.Sc., FACC; Professor of Clinical Medicine, Division of Cardiology, Director, Women's Cardiovascular Services, University of California, San Francisco

Specific responses pertaining to comments are included in Table 1.

Responses to public comment are found in Table 2.

Full text of peer review and public comments follows in the Appendix.

	Comment	Response
Peer Review: Michael E. Ring, MD, FACC, FSCAI		
Introduction Page 1 Line 2	Note that in Washington State, the leading cause of death has been cancer, not heart disease since 2004. (http://www.doh.wa.gov/DataandStatisticalReports/VitalStatisticsandPopulationData/Death/DeathTablesbyTopic (table C2)	Thank you for your comments. Edits have been made to the introduction
Introduction Page 1 Line 9	Note that in addition to plaque rupture, it is currently recognized that endothelial erosion is a major factor in myocardial infarction and ACS, especially in women.	Thank you for your comments. Edits have been made to the introduction.
1.4.1 Interventions Page 43 Line 11	Statement that most stents are used for stable CAD and asymptomatic patients is not correct. Currently about 2/3rds of PCI procedures performed in patients with ACS, at least for last 5 years (COAP can provide numbers for WA State). Also the discussion on ad hoc PCI does not seem balanced; most non-ACS patients typically have had some sort of stress testing pre-procedure and cath is usually done to correlate anatomy with physiologic stress studies. Also, no discussion on role of FFR on evaluating intermediate lesions and helping to identify patients who would benefit from PCI versus optimal medical therapy alone. Would strongly consider reviewing and incorporating FAME and other pivotal FFR studies, particularly in reviewing evidence of PCI versus medical therapy in patients with stable CAD.	Thank you for your comments. Edits have been made to this section. Publically available data from COAP and information from a recent publication suing NCDR CathPCI data have been described. The June 2014 COAP report indicates that, on average, less than 30% of PCI is elective or "non-acute" with a decrease seen between 2012 and 2013. From the COAP website for the last 2 quarters of 2014 and first 2 quarters of 2015, The percent of elective PCI ("non-acute") ranged from 0% to 72%, across sites with a minimum of 50 cases per quarter. It is acknowledge that individual site documentation of procedures may impact reported ranges. Additional context has been added regarding the FFR in this section and section 2 of the report Exclusion of FFR studies was based on consultation with a clinical expert during topic refinement given that FFR is not routinely done, with an anecdotal estimate of FFR frequency in less than 10%-15% of procedures. A 2014 survey of interventionalists reported that the majority used FFR less than 1/3 of the time in patients without ACS, 15% never used it and 47% reported that FFR was not available in their institution (Hannawi, B, *Tex Heart Inst J*

	Comment	Response
		2014;41(6):579-84) The 2014 update to the ACCF/AHA guideline on stable CAD (Fihn 2014) considered results newer date from the Fractional Flow Reserve versus Angiography for Multivessel Evaluation 2 Trial (FAME 2) but did not alter the recommendations in the full 2012 guideline text. The 2014 update states that: "FFR can assess the hemodynamic significance of angiographically "intermediate" or "indeterminant" lesions and allows one to decide when PCI may be beneficial or safely deferred" and that several studies suggest "a PCI strategy guided by FFR may be superior to a strategy guided by angiography alone." The initial FAME trial (and other studies of FFR) did not meet inclusion criteria as it (they) did not address comparators of interest which were determined *a priori*. Contextual information from the FAME 2 Trial is now described in this section (Key Considerations Highlighted by Experts) and abstraction of data relevant to our report's primary outcomes is presented in Appendix G, Table G10. There were no differences between FFR-guided PCI with medical therapy versus medical therapy alone for the following primary outcomes: All –cause mortality (24 month HR 0.74, 95% CI 0.26 to 2.14), cardiac death (24 month HR 0.99, 95% CI 0.20 to 4.90), MI (after the periprocedural period to 24 months 0.85, 95% CI 0.50 to 1.45) or stroke (24 month HR 1.74, 95% CI 0.51 to 5.94). With regard to the intermediate outcome of revascularization, FFR-guided PCI was associated with significantly lower risk of any revascularization (24 month HR 0.16, 95% CI 0.11 to 0.22) and urgent revascularization (24 month HR 0.23, 95% CI 0.14 to 0 .38). Frequency of MI within the first seven days was 2% for FFR-PCI patients and 0.9% for

	Comment	Response
		medical therapy patients. The frequency of serious cardiovascular events was 17% in the FFR-PCI group compared with 25.4% of the medical therapy group. Authors did not report definite stent thrombosis or health-related quality of life measures
Background 1.6 Epidemiology and Burden of Death Page 50 Line 7	Although most PCI currently performed by femoral approach, radial approach is increasing in popularity.	The text has been edited accordingly. Thank you for your comment.
Background Table 2. Indications and contraindications for DES	Table does not include the recently introduced Boston Scientific Synergy DES stent	Thank you for your comment. The recently FDA-approved (October 2015) Synergy DES stent has been added to the table. No studies of this device met inclusion criteria for this HTA.
The Evidence 1.14.3 Critical and primary outcomes Page 82 Line 8	Although it stated that the primary focus of revascularization is improvement in clinical health outcomes (Mortality and freedom of MI), the main purpose of PCI in carefully selected patients with stable CAD is to relieve angina symptoms not responsive to medical therapy. In almost all patients with stable CAD who do not have LM disease, there is little argument that PCI prevents death or MI. As identified in the ACC AUC, there may be some stable CAD patients with high risk stress studies who may benefit from revascularization (currently being studied in the ISCHEMIA Study).	This statement is based on the ACCF/AHA clinical guideline on the diagnosis and treatment of stable ischemic heart disease. As stated in the 2012 guideline "Revascularization recommendations have been formulated to address issues related to 1) improved survival and/or 2) improved symptoms" and "When one method of revascularization is preferred over the other for improved survival, this consideration, in general, takes precedence over improved symptoms." The AUC and Guidelines are summarized in the report.
Methods Page NR	As indicated earlier, would consider including studies on the use of FFR to identify appropriate stable CAD patients for treatment with PCI and OMT or OMT alone.	Thank you for your comments; please see previous response regarding FFR.
Results Page NR	When interpreting the results of any study, it is obviously important to recognize the limitations of the results as a function of the study inclusions and exclusions. For the most part it was not clear what were the important inclusion/exclusions for each of the studies reviewed, nor how representative was each study of the population studied. For instance, in the COURAGE study, less than 10% of the	Thank you for your comments. All studies, including RCTs, have limitations that may or may not influence generalizability. Inclusion/exclusion criteria and patient population characteristics for all included studies of PCI with medical therapy versus

	Comment	Response
	~36,000 patients screened were enrolled in the study. I would suggest the following article for a more detailed criticism of the COURAGE Study: http://www.sciencedirect.com/science/article/pii/S0735109707026629	medical therapy alone are in Appendix F Table 17 in the full report summarizes patient demographics and study characteristics across study for comparison of patient populations.
Results Page NR	An additional major limitation in assessing the studies of PCI/OMT vs OMT in stable CAD is how similar was the PCI performed in these studies to contemporary PCI practice. Since the primary purpose of PCI in these patients is to reduce angina, the high use of stand-alone PTCA and BMS in these studies is likely to result greater restenosis compared to NG DES which would limit long-term angina relief.	A report of this nature is a snapshot of the available evidence and may not fully represent current practice for either stenting *or* optimal medical therapy/guideline directed medical therapy. We specifically sought studies of newer generation stents that met *a priori* inclusion criteria. To decrease heterogeneity based on use of PCTA alone, studies that used PCTA alone without stenting were excluded; all included studies used ≥70% stenting, with most using stents in >80%.
Conclusions Are the conclusions reached valid?	I am not sure how to answer this. There really are not any conclusions in this report but rather a summary of the review of the studies expressed as RR as associated p value for each variable examined.	Thank you for your comments.
Overall Presentation	There was a great deal of repetition in the presentation of the studies and the Tables. Would consider a more succinct format, at least for the “average reader”	Thank you for your comments. It a challenge to present data in a variety of formats to serve a broad audience.
Clinical Relevancy	From a practical clinical viewpoint, almost all clinicians involved in the care of patients with CAD recognize the benefit of DES in reducing TLR/TVR in patients who do require PCI. The previous safety concerns about higher stent thrombosis with DES (compared to BMS) has been alleviated with the new generation DES. In fact as the review shows, there are strong signals that the NG DES may actually be safer long term than BMS. The current clinical practice in PCI for the over-whelming majority of patients is to use DES unless the patient is not felt to be an appropriate patient for long-term DAPT.	Thank you for your comments.

	Comment	Response
Clinical Relevancy	From a financial viewpoint the difference in unit cost for DES and BMS is currently only a few hundred dollars. In addition the majority of coronary stent patients receive aspirin and clopidogrel for their DAPT. Since 2009, clopidogrel is now available generically which has resulted in a significant reduction in the cost of DAPT.	Thank you for your comments. Section 1.4.2 on costs has been edited.
Clinical Relevancy	Regarding the use PCI for treatment of patients with stable CAD, I have concerns that this document does not capture the clinical decision making for these patients. The term "stable CAD" is an extremely broad term that incorporates a myriad of clinical situations and variables (age, severity of symptoms, response to medical therapy, lifestyle, occupation, comorbidities, coronary and lesion anatomy as well as personal preferences of the patient). There is currently a great deal of attention to proper selection and documentation when performing PCI in these patients as reflected to the development of the AUC for PCI, which is captured on our regional and national registries. Note that institutional AUC data for WA State hospitals is currently publically reported (http://www.coap.org/). In fact there are currently few medical procedures that are as closely scrutinized and publicly reported as PCI.	Thank you for your comments. Yes, definitions of CAD as well as others (e.g. unstable angina, ACS) are broad and variable across studies; in addition definitions have changed and been refined over time. As previously noted, publically available information from COAP has been included.
Clinical Relevancy	Unlike the 2009 HTA Review on DES/BMS which could draw on multiple RCT to provide relatively straight forward recommendations for most clinical scenarios to guide appropriate use of DES versus BMS, it will be much more difficult (perhaps impossible) to achieve a binary recommendation regarding PCI for stable CAD.	Thank you for your comments.
Quality of the Report	Good The report covers an extremely large amount of material and studies and does a good job of organizing a large number of studies. Please see limitations above.	Thank you for your comments.

	Comment	Response
Peer Review: Rita F. Redberg, MD, MSc, FACC		
Introduction	I would suggest adding some big picture statements. For example, as the trials do not show any advantage (no reduction in MI or death) for BMS versus medical therapy (GDMT) , it does not seem that showing no differences between DES and BMS is relevant, should be compared to GDMT. Same for cost –effectiveness, how can you do CEA when there is no clinical effectiveness. Should be infinity, unless you fudge the QALYs attributed to PCI.	Thank you for your comments. The role of the evidence vendor is to systematically review, appraise and synthesize the evidence; statements related to possible policy implications are the purview of the Health Technology Clinical Committee.
Introduction	Would note limitations of the RCT are that none were blinded. As we know there is a significant placebo effect for procedures (up to 60%), it is not established that the short term symptom benefit seen in some of the unblinded RCTs with PCI is due to the actual stent, or due to just having a procedure. To answer that question, one would need a study where all of the patient got angiography and were told the same thing. Currently, one group was told they were going to be fixed by a procedure, and one was not. Lack of blinding is a major limitation for subjective symptoms endpoint. Additionally, the endpoint of target vessel revascularizations, especially in trials with mandated 6 month post angiography, is a very soft outcome. It is not driven by symptoms, it is driven by the interventional cardiologists.	Thank you for your comments. A sentence has been added to the results: Trials were not blinded, thus the extent to which a placebo effect may influence results for patient reported outcomes is unclear. Across included trials, the extent to which revascularization was “clinically driven” was not uniformly described, nor did studies generally describe any threshold/criteria for revascularization overall. Trials did not uniformly specify whether or not there was angiographic follow-up that may have impacted additional stent placement. Below is a summary trials of PCI plus medical therapy vs. medical therapy alone with regard to revascularization: · COURAGE: revascularization performed at discretion of physician (no other info) · MASS-II: indications NR · Hambrecht: indications NR · BARI 2D (type 2 diabetes): Reasons for the first subsequent revascularization (PCI vs MT) included acute coronary syndrome (26% versus 22%), severe angina symptoms (33% versus 45%), worsening ischemia (18% versus 20%), unsatisfactory results of recent

<table>
<tr><th></th><th>Comment</th><th>Response</th></tr>
<tr><td></td><td></td><td>intervention (3% versus 0%), objective evidence of CAD progression (13% versus 8%), or other reasons (8% versus 6%).
Below is a summary of trials of newer DES vs. BMS with regard to revascularization protocol
<table>
<tr><th>Trial</th><th>Revascularization protocol</th></tr>
<tr><td>BASKET-PROVE</td><td>Follow-up angiography and revascularization were performed only if clinically indicated.</td></tr>
<tr><td>ENDEAVOR II</td><td>Angiographic follow-up at eight months was specified for the first 600 consecutive patients enrolled and for all patients implanted with two or more stents.</td></tr>
<tr><td>EXAMINATION</td><td>No angiographic follow-up is mandated per protocol. Thus, any follow-up angiography will be clinically indicated.</td></tr>
<tr><td>PRODIGY</td><td>UNCLEAR</td></tr>
<tr><td>XIMA</td><td>UNCLEAR</td></tr>
<tr><td>X-MAN</td><td>“clinically indicated target vessel revascularization (TVR)”</td></tr>
<tr><td>ZEUS</td><td>UNCLEAR: “All TLRs were classified prospectively as either clinically or not clinically indicated by the investigator prior to the reintervention.”</td></tr>
</table></td></tr>
<tr><td>Introduction
Page 1 Line 22-23</td><td>I would delete "greater discomfort" this is unclear. could say - increasing frequency or intensity of usual pattern of angina – instead</td><td>Thank you for your comments. Edits have been made to this sentence.</td></tr>
<tr><td>Introduction
Page 1 Line 22</td><td>I would say decreasing levels of, instead of less</td><td>Thank you for your comments. Edits have been made to this sentence.</td></tr>
<tr><td>Introduction
Page 2 Line 1</td><td>Patients with stable CAD should be treated with medical therapy. there is no mortality risk reduction with revascularization.</td><td>Thank you for your comments. The statement is consistent with the wording in the ACCF/AHA guidelines.</td></tr>
<tr><td>Introduction
Page 2 Line 2</td><td>This is nonspecific. should be defined, for example - acute coronary syndrome with troponin increases - would be high risk and considered for ICA.</td><td>Thank you for your comments. Edits have been made to this sentence.</td></tr>
</table>

	Comment	Response
Introduction Page 2 Line 26	Should remove the d from “updated”	Thank you for your comment. This edit has been made to this sentence.
Introduction Table 4. KQ1 Strength of Evidence Page 16 Line 15-18	Table 4, conclusion column I am wondering how you could compute a cost per life year gained for PCI when there were no life years gained. and no symptom benefit over the lifetime horizon either.	Thank you for your comments. The information in the table reflects what was reported in the study.
Introduction Table 9 KQ2c: Summary of findings for.. Page 31 Line 9-11 Row 1 Column 2	How many were older than 75? (“STEMI (n=1498) reported post-hoc analysis on the effect of age…”)	Among the 1498 enrolled, 16.3% (n = 245) were ≥ 75 years old; n=132 were allocated to BMS and 113 allocated to EES. This information has been added to the results and table.
Background/Introduction Page 1 Line 16-17	I thought 70 -80% of CAD presents with chest pain	Thank you for your comment. The sentence has been edited and the reference for the 50% statement has been added.
Background 1.11 Clinical Guidelines Table 6. CAD Revascularization Guidelines Page 59 Row “I-A, I-B, II-CC”	What is data for this, which refs, i am not aware of these RCTs	Thank you for your comment All RCTs are in support of the second portion of this recommendation (1 or more significant stenosis): Statement: In survivors of sudden cardiac death with presumed ischemia-mediated ventricular tachycardia caused by significant stenosis in a major coronary artery Statement: To improve symptoms in patients with 1 or more significant coronary artery stenosis amenable to revascularization and unacceptable angina despite GDMT (I-A) (5 RCTs, 6 citations); It is noted that some of the trials (RITA-2, ARTS) listed did not meet inclusion criteria for this HTA. • Boden WE, O’Rourke RA, Teo KK, et al. Optimal medical therapy with or without PCI for stable coronary disease. N Engl J Med.2007;356:1503–16. (366) • Weintraub WS, Spertus JA, Kolm P, et al. Effect of PCI on quality of life in patients with stable coronary disease. N Engl J Med. 2008;359:677– 87. (407) • Hueb W, Lopes N, Gersh BJ, et al. Ten-year follow-up survival of the Medicine,

	Comment	Response
		Angioplasty, or Surgery Study (MASS II): a randomized controlled clinical trial of 3 therapeutic strategies for multivessel coronary artery disease. Circulation. 2010;122:949 –57. • Pocock SJ, Henderson RA, Seed P, et al. Quality of life, employment status, and anginal symptoms after coronary angioplasty or bypass surgery. 3-year follow-up in the Randomized Intervention Treatment of Angina (RITA) Trial. Circulation. 1996;94:135– 42. • Pocock SJ, Henderson RA, Clayton T, et al. Quality of life after coronary angioplasty or continued medical treatment for angina: three-year follow-up in the RITA-2 trial. Randomized Intervention Treatment of Angina. J Am Coll Cardiol. 2000;35:907–14. • Abizaid A, Costa MA, Centemero M, et al. Clinical and economic impact of diabetes mellitus on percutaneous and surgical treatment of multivessel coronary disease patients: insights from the Arterial Revascularization Therapy Study (ARTS) trial. Circulation. 2001;104:533– 8.
Background 1.11 Clinical Guidelines Table 6. CAD Revascularization Guidelines Page 60 Row 4	Row 4 , “PCI may be reasonable as an alternative to CABG in selected stable patients” This recommendation is unclear. i know of no RCT to support this statement, please explain. for what kind of patients.	Thank you for your comment. The following RCTs were referenced in support of this recommendation. It is for a population of patients with significant unprotected left main CAD (clarification has been added to the report): • Buszman PE, Kiesz SR, Bochenek A, et al. Acute and late outcomes of unprotected left main stenting in comparison with surgical revascularization. J Am Coll Cardiol. 2008;51:538–45. • Boudriot E, Thiele H, Walther T, et al. Randomized comparison of percutaneous coronary intervention with sirolimus-eluting stents versus coronary artery bypass grafting in unprotected left main stem stenosis. J Am Coll Cardiol. 2011;57:538–45.

	Comment	Response
		The following observational study was also cited: • Morice MC, Serruys PW, Kappetein AP, et al. Outcomes in patients with de novo left main disease treated with either percutaneous coronary intervention using paclitaxel-eluting stents or coronary artery bypass graft treatment in the Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery (SYNTAX) trial. Circulation. 2010;121:2645–53.
Background 1.11 Clinical Guidelines Table 7. Chronic Stable Angina Guidelines Page 61 Row 3	Again this is confusing. Class C means expert opinion, no RCT. so what are these 3 RCTs. there is no benefit in asx ischemia.	This table summarizes the 2002 ACC Chronic Stable Angina Guideline and included for completeness. References to PCI in this guideline relate primarily to angioplasty with one trial comparing stenting with angioplasty. Edits have been made to clarify the evidence base and point to newer guidelines.
Background 1.11 Clinical Guidelines NSTEMI Definition Page 64	Not the definition used in ACC/AHA guidelines, which are much broader, any new murmur, older than 75, LBBB, etc.	Thank you for your comment. The updated definition of ACS has been added to the report.
Report Objectives & KQs Page 43	The data is strongest for STEMI. There is a lot of heterogeneity in the definition of ACS and would not include ACS in the high risk group where benefit is clearly shown. ACS is very loosely and variably defined, and many patient groups labeled as ACS get no benefit for PCI compared to GDMT.	Thank you for your comments. This section has been revised.
Report Objectives & KQs 1.9 PCI with stenting Page 50	This description of PCI jumps around, would reorganize to start with a description of ICA, then what a PCI procedure entails, which would follow the diagnostic angiography.	Thank you for your comments. Edits have been made to this section.
Report Objectives & KQs 1.9.1 BMS Page 51	This line is confusing - a 10% decrease in restenosis rates, 22% to 32% Would clarify that the stent is a foreign body and causes an inflammatory reaction, buildup of cells and fibrosis, which is what leads to the high restenosis rates Would clarify that there are no RCT showing	Thank you for your comments. Edits regarding BMS have been made. We have cited a recent meta-analysis of short (<12 month) vs. extended (<12 months) DAPT (Navarese, EP, BMJ 2015;350:h1618) Detailed review of DAPT is not within the scope of this HTA, however.

	Comment	Response
	any reduction of instent thrombosis with use of DAPT Similarly, it is not clear what the right duration of DAPT is. A recent study found that there was no benefit in extending past one year.	
Results Appropriate Use Criteria Page 65	Would note that AUC are not evidence based. They are the "expert opinion" of physicians, chosen by the various professional societies, who generally make their living from the procedures they are rating. For example, although there is no data of benefit for PCI on any objective outcomes, there are many situations where the AUC rate PCI in asymptomatic persons as appropriate. The evidence basis for this rating is lacking.	Thank you for your comments. A brief process description for the AUC criteria development has been added, based on what is reported in the AUC document.
Results 1.10.3 Indications and contraindications Page 55	While it is true that reducing symptoms and mortality is always the goal of therapy, as there is no data that PCI accomplishes this goal, would delete this line. GDMT should generally be continued unless patients have angina that cannot be controlled on maximal medical therapy.	Thank you for your comments. Edits have been made to this section.
Results Table 11. Additional PCI Guidelines in Special Populations Page 65	Usually "special populations"refers to groups like women, or the elderly. Can you report any analysis by sex or age?	This was mislabeled. The title has now been corrected. The guidelines referenced describe treatment in those with specific cardiac conditions.
Conclusions Are the conclusions reached valid?	Yes, they are clearly based on the evidence which is carefully collated and tabulated.	Thank you for your comments
Overall presentation and relevancy	The review is very high quality and well done. The information is clear. There is an overwhelming amount of information, due to the detailed presentation of results and multiple comparisons and key questions addressed. While the information is important, this full report takes many hours to read and absorb. The executive summary does summarize the key findings well and the main points are clear. It is relevant to clinical medicine. It may be helpful to have a few	Thank you for your comments. The comment regarding DES use being off label is noted.

	Comment	Response
	lines to try to help understand why actual clinical practice seems to differ so widely from the evidence for PCI. Also, it is worth noting that most DES use is off-label, in the section where you list the FDA indications.	
Overall presentation and relevancy	The findings are important for public policy and public health as there is clearly room for improvement in patterns of care for stable CAD. As the risks (and costs) of PCI are much greater than for medical therapy, treating more patients with medical tx would improve safety and effectiveness with equivalent or better outcomes and lower cost. This could be accomplished by a bundled payment policy for care of CAD, for example.	Thank you for your comments.

RESPONSES TO PUBLIC COMMENTS

Spectrum Research is an independent vendor contracted to produce evidence assessment reports for the Washington HTA program. For transparency, all comments received during the public comment periods are included in this response document. Comments related to program decisions, process, or other matters not pertaining to the evidence report are acknowledged through inclusion only.

This section responds to public comments from the following parties:

Draft Report

- Tim Dewhurst, MD, FACC on behalf of the Washington Chapter of the American College of Cardiology
- James Blankenship, MD, MHCM, FSCAI, on behalf of The Society for Cardiovascular Angiography and Interventions Foundation

Specific responses pertaining to comments are included in Table 2.

Table 2: Response to Public Comments Received

Comments		Response
Tim Dewhurst, MD, FACC on behalf of the Washington Chapter of the American College of Cardiology		
Summary	While we appreciate that the state wants to get the most for its dollars (as do all purchasers of health care), we feel that this HTA approach is (to use our AUC terminology) rarely appropriate for CAD and PCI when clinical experts have already done the work. Furthermore, there is abundant evidence that utilization of high cost procedures has already declined with no clinical loss of benefit. Looking at only at health care spending, WA State is much better than nationally and efforts to curtail costs in Washington State by the mechanism of the HTAC threaten to inappropriately ration care. We would respectfully suggest that the HTAC spend its time, and our tax dollars, on areas of clinical concern where there does not exist such science and consensus as there does for PCI and CAD. Promulgation of decisions to limit the particular type of stent for treatment are unlikely to have any meaningful financial impact, and be potentially costly to the state if sued over these deliberations. We are happy to provide clinicians to attend committee meetings or other deliberations and explain further the clinical context and answer questions.	Thank you for your comments. This topic was selected for an updated review based on the new literature identified since the original 2009 report. The new literature was judged to potentially change the outcome of the previous report and could therefore impact the HTCC's coverage determination upon review. HCA's goal is a current and accurate assessment of the evidence for this important policy topic.
Specific comments on the draft report	We note that the authors are not cardiologists, nor even clinicians. Their interpretation of clinical science in this context is concerning and may well lack any real context.	Clinical expert perspective was obtained during topic refinement and available during report development to answer clinically relevant questions.
Introduction	In the introduction to the topic, the clinical and scientific description is generally accurate. There are some rather artificial black and white statements that do not reflect the true clinical continuum of coronary artery disease. The introduction paints medical therapy, PCI and CABG as separate and mutually exclusive treatments, and does not emphasize enough that guideline driven medical therapy is appropriate for all patients with CAD and use if PCI and CAGB are additional tools to optimize health status on top of GMT. The introduction	The use of medical therapy for ***all*** CAD patients is noted frequently throughout the report. Additional clarification/re-iteration that guideline directed medical therapy is used in all CAD patients has been added to the introduction/background.

	Comments	Response
	notes that advances have occurred in all CAD treatments without noticing that much of the advance that has been made, and realized in clinical practice, is better knowledge on application of PCI and CABG.	
Key Question 2	The exclusion of studies comparing first generation and second or third generation DES would be inappropriate, but seems to have been done.	The original 2009 report also focused on DES vs. BMS and did not compare different DES with each other. Our understanding from the literature and clinical experts is the first generation DES are no longer widely available; the purpose of the update was to evaluate the efficacy of FDA-approved newer generation DES compared with BMS.
Methods	We are disappointed that we were not notified in July 2014 as to the scope and key questions.	The key questions and proposed scope were publically published on the Washington State Health Technology Program Website and an email sent to stakeholders. Please contact the program to be placed on the stakeholder list: shtap@hca.wa.gov
Results	We applaud the attention to the Courage trial which has already markedly changed practice in the US. Not noted in the draft report was that there was a large crossover from medical therapy to PCI in the medical therapy arm.	Thank you for your comments. Cross over rates for all included trials of PCI + medical therapy vs. medical therapy alone in noted in table 17 of the full report; Cross over to PCI ranged from 1.5% immediately after randomization to 42% at 5 years with one study reporting Cross over of 14.3 % at 10 y ears.
Results	We fully agree that prevention of primary and secondary cardiovascular events is critical and cost effective and hope that the state would fully fund the provision of optimal medical therapy, tobacco cessation and prevention and cardiac rehabilitation.	Thank you for your comments
Clinical issues not addressed in the draft report	It is being increasingly recognized that patient choice and shared decision making is critical to the provision of health care in the US. We do not note any acknowledgement about this in the report. While PCI does not offer survival advantages in most situations of stable angina, it is clearly better in relieving angina. Some	Additional context has been added to the background regarding share decision making. We recognize the importance of outcomes and measures that are

	Comments	Response
	patients choose to avoid invasive procedures at the cost of linger lasting angina, some choose a procedure to more rapidly relieve their angina. As one of the original investigators who created the Seattle Angina Questionnaire, I appreciate the concept of quality of life better than many clinicians and most insurance companies. Since these patients do make decisions with financial "skin in the game", no insurance company or payer can mandate one approach over another. The important factor of patient choice in situations where science tells us we have multiple good options is not addressed here. When there is clinical equipoise between treatments, shared decision making is mandatory.	relevant to patients. To the extent that comparative data on relief of symptoms and improved quality of life were available, they were reported. Unfortunately, included studies did not frequently report on such outcomes.
Clinical issues not addressed in the draft report	Once the decision to proceed with PCI has been made in shared decision making with a patient, we need to consider all patient factors in deciding what type of stent. For the smallest vessels, only BMS are available. Absent issues of patient compliance, bleeding risk or upcoming major surgery, DES provide better outcomes (less target vessel revascularization) than BMS and are preferred. The FAME and FAME II trials were arbitrarily excluded from the draft report. These trials explored a new (and apparently better) technology for the assessment of coronary artery disease. Fractional Flow reserve (FFR) is a technique to measure the physiologic significance of specific coronary lesions. It is a much more accurate predictor of clinical outcomes than stenosis measured by coronary angiography. If the FFR for a specific lesion is non-ischemic, NOT stenting that lesion does not harm outcomes. Conversely, if a lesion is physiologically significant, then PCI treatment does improve hard outcomes. Overall this technology has diminished the need for PCI, and has been recognized in the AUC and guideline reports.	Thank you for your comments. Additional context has been added to regarding FFR in this section and section 2 of the report Exclusion of FFR studies was based on consultation with a clinical expert during topic refinement given that FFR is not routinely done, with an anecdotal estimate of FFR use in less than 10%-15% of procedures. A 2014 survey of interventionalists reported that the majority used FFR less than 1/3 of the time in patients without ACS, 15% never used it and 47% reported that FFR was not available in their institution (Hannawi, B, *Tex Heart Inst J 2014;41(6):579-84)* The 2014 update to the ACCF/AHA guideline on stable CAD (Fihn 2014) considered results newer date from the Fractional Flow Reserve versus Angiography for Multivessel Evaluation 2 Trial (FAME 2) but did not alter the recommendations in the full 2012 guideline text. The 2014 update states that: "FFR can assess the

	Comments	Response
		hemodynamic significance of angiographically "intermediate" or "indeterminant" lesions and allows one to decide when PCI may be beneficial or safely deferred" and that several studies suggest "a PCI strategy guided by FFR may be superior to a strategy guided by angiography alone." The initial FAME trial (and other studies of FFR) did not meet inclusion criteria as it (they) did not address comparators of interest which were determined *a priori*. Contextual information from the FAME 2 Trial is now described in "Key Considerations Highlighted by Experts" and abstraction of data relevant to our report's primary outcomes is presented in Appendix G, Table G10. There were no differences between FFR-guided PCI with medical therapy versus medical therapy alone up to 24 months for the following primary outcomes which were the focus of this HTA: All –cause mortality, cardiac death, MI (after the periprocedural period to 24 months, or stroke. With regard to the intermediate outcome of revascularization, FFR-guided PCI was associated with significantly lower risk of any revascularization and urgent revascularization (24 month HR 0.23, 95% CI 0.14 to 0 .38). Frequency of MI within the first seven days was 2% for FFR-PCI patients and 0.9% for medical therapy patients. The frequency of serious cardiovascular events was 17% in the FFR-PCI group compared with 25.4% of the medical therapy group. Authors did not report definite stent thrombosis or health-related quality of

	Comments	Response
		life measures
Clinical issues not addressed in the draft report	Please appreciate the marked reduction in Cardiovascular disease morbidity and mortality over the past decade. This is a result of the cardiology community learning what worked and implementing the science. As a result, in the face of a marked aging of the population (CAD is primarily a disease of aging and genetics), we have actually flattened both national spending on CCV disease and improved mortality and morbidity. It is rare for any medical field to accomplish this.	Thank you for your comments.
Unintended consequences of HTA decisions	While the committee's deliberation and intents are very well meaning, they have important unintended consequences. Excuse me for a few minutes while I step down from the perspective of an administrative organizational leader back to my day job, a clinical cardiologist. This context is critically important for the committee to understand the issue. One of my colleagues treated a STEMI patient with a DES in 2014. The insurer used the HTAC's 2009 deliberations as an excuse to deny payment for the patient's entire episode of care based solely on the size and type of stent used. This committee's well meaning deliberations, resulted in an unfortunate patient having both an acute heart attack (from which he recovered successfully) and a financial heart attack with a large bill (over $50, 000) because of this committee's actions. When a patient has an ST elevation myocardial infarction (STEMI), time is of the essence. There is no other medical condition where time is so important. Clinical science has shown that the sooner these patients are treated, the better their short and long term outcomes. Application of this science has significantly and materially improved long term outcomes of heart attack victims and markedly reduced subsequent heart failure. We are guilty of helping these patients living longer, which could possibly increase their health care costs. When I am called to care for a STEMI patient, I need to get to the hospital, meet and assess the patient (almost always not known to me and vice versa), perform a sterile coronary	Thank you for your comments. Comments related to the HTAP program process or decisions are not addressed by Spectrum as the evidence vendor. The study cited (Sarno 2014), which focuses on in stent thrombosis in those with STEMI, as well as the 2012 report from the same registry using a broader selection of the registry population were included in the report to the extent that safety outcomes, as defined in our methods, for second generation DES compared with BMS were described. This large observational registry study was rated as being at moderately high risk of bias (CoE III). The overall strength of evidence for outcomes from this registry study would be likely be graded low to insufficient; The strength of evidence from included RCTs for mortality was graded as moderate to high, depending on time frame. In the report, for the comparison of the newer (2nd generation) DES with BMS from the SCAAR study, Table 8 provides summary information on definite stent thrombosis, Table 30 provides demographic information

	Comments	Response
	angiogram, assess the coronary anatomy in the setting of the patient's acute and chronic illnesses and perform PCI to restore blood flow, all in as rapid time as possible. WA State as a whole does very well on average with a door-to-balloon time of (state wide average in 2013 is 57 minutes). Clinical data has consistently shown us that use of DES for STEMI provides significant benefit (see chart from J Am Coll Cardiol. 2014;64(1):16-24.) In the compressed time frame we function to care for a patient at risk of dying, we are not going to think about the HTACs deliberations in choosing a stent size and type to care for them.	and Table 34 provides information on definite stent thrombosis at various time points.
James Blankenship, MD, MHCM, FSCAI, On behalf of The Society for Cardiovascular Angiography and Interventions Foundation		
Clinical guidelines	We remain concerned that the draft document, while representing an in-depth review of the literature, adds little to established guidelines and appropriate use criteria that already exist, and which are much more likely to be read and followed by cardiologists than this review. As an example, a recently published article examining the impact of AUC shows convincing evidence of the impact of such documents on the utilization of PCI nationally and in Washington State (1,2). We would also like to point out that there have been recent updates to two important guideline documents that can be found at: http://www.scai.org/Assets/10542bc9-c8be-48d1-aa84-c647137878b7/635810359561230000/scai-2015-10-21-primarypciupdate-pdf and http://www.scai.org/Assets/d428d716-f835-4a7d-a169-8b2c8271aca5/635470782647170000/09017-fulltext-pdf.	The summary of guidelines contained in the report has been edited to reflect updated guidelines. Information from the references cited has been included in section 1.4.1 of the full report. Information related to citations has been included in the section on Key Considerations Highlighted by Experts.
Washington State utilization and cost data Tables 1-5 Page 45-47	There are several points to be made from these tables: 1. There is in general a decline in stenting overall, as noted in table 3, which is also reflected in national Medicare data as well. 2. The absolute number of patients receiving coronary stents is small compared to the population base covered by PEBB/UMP (0.03% in 2014)	These data were provided by the Health Technology Assessment Program, not by Spectrum Research as the evidence vendor.

	Comments	Response
	3. The impact of the prior document on savings is interestingly absent from the tables and 4. The potential clinical and financial impact of this HTA draft document on the population served is therefore likely to be very small.	
Key Question 1	Specific responses to the Key Questions follows; starting with Key Question 1. It is not surprising that no mortality benefit was found comparing stenting to medical therapy since medical therapy is the cornerstone of treatment of chronic stable ischemic heart disease and the studies reviewed by and large serve as the foundation for the current guidelines and AUC. Revascularization, be it by surgery or stenting, would not be expected to impact hard endpoints like mortality with a chronic disease like coronary artery disease given long enough follow up. With respect to quality of life it is important to understand that studies looking at that endpoint typically use "as randomized methodology", which while statistically valid, does not represent the way patients are treated with a chronic disease. In such studies, patients initially randomized to medical therapy but then cross over to revascularization because of worsened or uncontrolled symptoms are counted in the medical arm which "contaminates" follow up and potentially delivers and incorrect message, a message that in addition doesn't reflect how patients are cared for long term with a chronic disease. As an example, the crossover rate in COURAGE was about 25% from the medical to revascularization arm.	Thank you for your comments. Table 17 in the report provides information on cross over to PCI from medical therapy for comparison across studies.
Key Question 2	With respect to the review of the literature regarding Key Question 2, while extensive, it adds little important new information. As this body of data is reviewed it is important to remember that most of it was designed to determine any safety signals between DES and BMS and to be used by the companies developing the devices for FDA approval. The safety issue was looked at because there was a	Thank you for your comments.

	Comments	Response
	concern in the past (due to poorly designed meta analyses) that there might be excessive stent thrombosis with DES vs. BMS. Subsequent studies have confirmed that is not the case. The studies were not powered to determine if one device was superior to another with regard to stent thrombosis/MI. They were also not designed to evaluate mortality with respect to one device being superior to another. Looking for superiority of one device vs. another from these studies can be predicted to show no difference. This is exactly what has been shown in the draft document. These limitation exist with many of the other RCTs that were designed to lead to FDA approval of newer DES stents and not to show that DES was superior to BMS. Superiority of DES to BMS with respect to instent restenosis, in most cases, has been generally accepted by the cardiology community based on the totality of the evidence that has been generated from initial approval of the coronary stent in 1995 to date, not just since the prior HTA document in 2009. If one reviews the extensive evidence tables in the draft document it is clear that most of the evidence is of low to moderate strength which speaks to the evidence and raises concerns about the validity of any conclusions drawn from the review. As we stated in our 2009 HTA response we, as interventional cardiologist, have no vested interest in which stent type (DES vs. BMS) is chosen since physicians are not reimbursed based on the type of stent used. We are truly the patient's advocate when it comes to this aspect of their care. We would also like to point out that evaluations such as this will likely become more difficult in the future as the focus moves away from BMS vs. DES to studies looking at new platforms to deliver anti restenotic drugs to the coronaries. A prime example of this are bioreabsorable platforms that are on the near horizon for approval in the US. In addition, because of the prohibitive cost associated with bringing these devices to market in the US, trials have not and	

	Comments	Response
	will not be designed as superiority studies but as non-inferiority trials. This will add additional complexity to this type of literature review. It will also bring to question any attempt to draw inferences using meta analyses of future datasets based on these trials.	
Overall	We believe this review, while extensive, does not further inform the HTA process with respect to the key questions and adds little to the previous document. It is our opinion that, absent data to confirm otherwise, there will likely be little cost savings to the State from this exercise. We also firmly believe that going forward, reviews such as this will add little to guidelines and other documents produced by national organizations such as SCAI, ACC and the AHA. With all due respect the proper use of these devices and where they fit within the armamentarium used to treat coronary artery disease, a chronic disease with no cure, has been informed by the literature and not by reviews such as this.	Thank you for your comments

APPENDIX: Reviews And Comments Received

PEER REVIEW: Michael E. Ring

Thank you for your willingness to read and comment on the Comprehensive Evidence-Based Health Technology Assessment Review for the **Cardiac Stent Re-review Report** Your contribution and time are greatly appreciated. The general time commitment ranges between 2 and 4 hours; we are able to pay a maximum of 6 hours.

The report and appendices will be available after 10/13/15 at:
http://www.hca.wa.gov/hta/Pages/stent-rr.aspx

This form can be filled out electronically on your personal computer. Enter your identification information and comments directly into the shaded areas; use the **TAB** key to move from field to field. Please enter the section, page, and line numbers where relevant. The shaded comment field will expand as you type, allowing for unlimited text. You have been provided comment fields in each section. Should you have more comments than this allows for, please continue with a blank page. Additionally, we are very interested in your evaluation of the ease of use of our Peer Review Form. Please use the last field to enter suggestions for improvement.

We will be going through the draft for typographical errors as well as grammatical and minor edits, allowing you to focus on the substance/content of the report.

When the Peer Review form is complete, save it to your hard drive and return as an e-mail attachment to: **andrea@specri.com**

I will need your review by November 6, 2015 at the latest.

If you have questions or concerns please contact andrea@specri.com. Thanks!

Reviewer Identification Information

Reviewer Name	**Michael E. Ring**
Address	Street: 12604 S. Flying Goose Lane City: Spokane State WA Zip Code 99224
Phone	509-209-6895
Fax	
E-mail	michael.ring@providence.org

INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate?
- Topic of assessment is important to address?
- Public policy and clinical relevance are well defined?

Page 1 Line 2

Note that in Washington State, the leading cause of death has been cancer, not heart disease since 2004.

(http://www.doh.wa.gov/DataandStatisticalReports/VitalStatisticsandPopulationData/Death/DeathTablesbyTopic (table C2)

Page 1 Line 9

Note that in addition to plaque rupture, it is currently recognized that endothelial erosion is a major factor in myocardial infarction and ACS, especially in women.

Page 43 Line 11

Statement that most stents are used for stable CAD and asymptomatic patients is not correct. Currently about 2/3rds of PCI procedures performed in patients with ACS, at least for last 5 years (COAP can provide numbers for WA State).

Also the discussion on ad hoc PCI does not seem balanced; most non-ACS patients typically have had some sort of stress testing pre-procedure and cath is usually done to correlate anatomy with physiologic stress studies. Also, no discussion on role of FFR on evaluating intermediate lesions and helping to identify patients who would benefit from PCI versus optimal medical therapy alone. Would strongly consider reviewing and incorporating FAME and other pivotal FFR studies, particularly in reviewing evidence of PCI versus medical therapy in patients with stable CAD.

BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient?

Page 50 Line 7

Although most PCI currently performed by femoral approach, radial approach is increasing in popularity.

Page 52 Line

Table does not include the recently introduced Boston Scientific Synergy DES stent

Page Line

Enter Comments Here

REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue?
- Key questions clearly defined and adequate for achieving aims?

Page 82 Line 8

Although it stated that the primary focus of revascularization is improvement in clinical health outcomes (Mortality and freedom of MI), the main purpose of PCI in carefully selected patients with stable CAD is to relieve angina symptoms not responsive to medical therapy. In almost all patients with stable CAD who do not have LM disease, there is little argument that PCI prevents death or MI. As identified in the ACC AUC, there may be some stable CAD patients with high risk stress studies who may benefit from revascularization (currently being studied in the ISCHEMIA Study).

Page Line

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METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate?
- Criteria for the inclusion and exclusion of studies is appropriate?
- Method for Level of Evidence (LoE) rating is appropriate and clearly explained?
- Data abstraction and analysis/review are adequate?

Page Line

As indicated earlier, would consider including studies on the use of FFR to identify appropriate stable CAD patients for treatment with PCI and OMT or OMT alone.

Page Line

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RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate?
- Key questions are answered?
- Figures, tables and appendices clear and easy to read?
- Implications of the major findings clearly stated?
- Have gaps in the literature been dealt with adequately?
- Recommendations address limitations of literature?

Page Line

When interpreting the results of any study, it is obviously important to recognize the limitations of the results as a function of the study inclusions and exclusions. For the most part it was not clear what were the important inclusion/exclusions for each of the studies reviewed, nor how representative was each

study of the population studied. For instance, in the COURAGE study, less than 10% of the ~36,000 patients screened were enrolled in the study. I would suggest the following article for a more detailed criticism of the COURAGE Study: http://www.sciencedirect.com/science/article/pii/S0735109707026629

Page Line

An additional major limitation in assessing the studies of PCI/OMT vs OMT in stable CAD is how similar was the PCI performed in these studies to contemporary PCI practice. Since the primary purpose of PCI in these patients is to reduce angina, the high use of stand-alone PTCA and BMS in these studies is likely to result greater restenosis compared to NG DES which would limit long-term angina relief.

Page Line

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CONCLUSIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the conclusions reached valid?

Page Line

I am not sure how to answer this. There really are not any conclusions in this report but rather a summary of the review of the studies expressed as RR as associated p value for each variable examined

Page Line

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OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well structured and organized?
- Are the main points clearly presented?
- Is it relevant to clinical medicine?
- Is it important for public policy or public health?

Page Line

Page Line

Overall Presentation:

There was a great deal of repetition in the presentation of the studies and the Tables. Would consider a more succinct format, at least for the "average reader"

Page Line

Clinical Relevancy:

From a practical clinical viewpoint, almost all clinicians involved in the care of patients with CAD recognize the benefit of DES in reducing TLR/TVR in patients who do require PCI. The previous safety concerns about higher stent thrombosis with DES (compared to BMS) has been alleviated with the new generation DES. In fact as the review shows, there are strong signals that the NG DES may actually be safer long term than BMS.

The current clinical practice in PCI for the over-whelming majority of patients is to use DES unless the patient is not felt to be an appropriate patient for long-term DAPT.

From a financial viewpoint the difference in unit cost for DES and BMS is currently only a few hundred dollars. In addition the majority of coronary stent patients receive aspirin and clopidogrel for their DAPT. Since 2009, clopidogrel is now available generically which has resulted in a significant reduction in the cost of DAPT.

Regarding the use PCI for treatment of patients with stable CAD, I have concerns that this document does not capture the clinical decision making for these patients. The term "stable CAD" is an extremely broad term that incorporates a myriad of clinical situations and variables (age, severity of symptoms, response to medical therapy, lifestyle, occupation, comorbidities, coronary and lesion anatomy as well as personal preferences of the patient). There is currently a great deal of attention to proper selection and documentation when performing PCI in these patients as reflected to the development of the AUC

for PCI, which is captured on our regional and national registries. Note that institutional AUC data for WA State hospitals is currently publically reported (http://www.coap.org/). In fact there are currently few medical procedures that are as closely scrutinized and publicly reported as PCI.

Unlike the 2009 HTA Review on DES/BMS which could draw on multiple RCT to provide relatively straight forward recommendations for most clinical scenarios to guide appropriate use of DES versus BMS, it will be much more difficult (perhaps impossible) to achieve a binary recommendation regarding PCI for stable CAD.

QUALITY OF REPORT

Quality Of the Report
(Click in the gray box to make your selection)

Superior ☐

Good XXX

Fair ☐

Poor ☐

Page Line

The report covers an extremely large amount of material and studies and does a good job of organizing a large number of studies. Please see limitations above.

Page Line

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We would appreciate any feedback you have on the usability of this form. Please add comments in the field below.

There was a great deal of repetition in the presentation of the studies and the Tables. Would consider a more succinct format, at least for the “average reader”

PEER REVIEW: Rita F. Redberg

Thank you for your willingness to read and comment on the Comprehensive Evidence-Based Health Technology Assessment Review for the **Cardiac Stent Re-review Report** Your contribution and time are greatly appreciated. The general time commitment ranges between 2 and 4 hours; we are able to pay a maximum of 6 hours.

The report and appendices will be available after 10/13/15 at:
http://www.hca.wa.gov/hta/Pages/stent-rr.aspx

This form can be filled out electronically on your personal computer. Enter your identification information and comments directly into the shaded areas; use the **TAB** key to move from field to field. Please enter the section, page, and line numbers where relevant. The shaded comment field will expand as you type, allowing for unlimited text. You have been provided comment fields in each section. Should you have more comments than this allows for, please continue with a blank page. Additionally, we are very interested in your evaluation of the ease of use of our Peer Review Form. Please use the last field to enter suggestions for improvement.

We will be going through the draft for typographical errors as well as grammatical and minor edits, allowing you to focus on the substance/content of the report.

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I will need your review by November 6, 2015 at the latest.

If you have questions or concerns please contact andrea@specri.com. Thanks!

Reviewer Identification Information

Reviewer Name	Rita F. Redberg, MD
Address	Street
	City
	State
	Zip Code
Phone	
Fax	
E-mail	

INTRODUCTION Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Overview of topic is adequate?
- Topic of assessment is important to address?
- Public policy and clinical relevance are well defined?

Page Line

I would suggest adding some big picture statements. For example, as the trials do not show any advantage (no reduction in MI or death) for BMS versus medical therapy (GDMT) , it does not seem that showing no differences between DES and BMS is relevant, should be compared to GDMT. Same for cost –effectiveness, how can you do CEA when there is no clinical effectiveness. Should be infinity, unless you fudge the QALYs attributed to PCI.

Page Line

Would note limitations of the RCT are that none were blinded. As we know there is a significant placebo effect for procedures (up to 60%), it is not established that the short term symptom benefit seen in some of the unblinded RCTs with PCI is due to the actual stent, or due to just having a procedure. To answer that question, one would need a study where all of the patient got angiography and were told the same thing. Currently, one group was told they were going to be fixed by a procedure, and one was not. Lack of blinding is a major limitation for subjective symptoms endpoint.

Additionally, the endpoint of target vessel revascularizations, especially in trials with mandated 6 month post angiography, is a very soft outcome. It is not driven by symptoms, it is driven by the interventional cardiologists.

Page 10 Line 22-23

would delete "greater discomfort" this is unclear. could say - increasing frequency or intensity of usual pattern of angina – instead

Page 10 Line 22

would say decreasing levels of, instead of less

Page 11 Line 1

pts with stable CAD should be treated with medical therapy. there is no mortality risk reduction with revascularization.

Page 11 Line 2

this is nonspecific. should be defined, for example - acute coronary syndrome with troponin increases - would be high risk and considered for ICA.

Page 11 Line 26

Should remove the d from “updated”

Page 25 Line 15-18

Table 4, conclusion column

i am wondering how you could compute a cost per life year gained for PCI when there were no life years gained. and no symptom benefit over the lifetime horizon either.

Page Line

Table 9 row 1, column 2

How many were older than 75? (“STEMI (n=1498) reported post-hoc analysis on the effect of age…”)

BACKGROUND Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Content of literature review/background is sufficient?

Excellent review of the literature, very complete and clear.

Page 10 Line

I thought 70 -80% of CAD presents with chest pain

Page 68 Line

Table 6, row “I-A, I-B, II-CC”

what is data for this, which refs, i am not aware of these RCTs

Page 69 Line

Row 4 , "PCI may be reasonable as an alternative to CABG in selected stable patients"

this recommendation is unclear. i know of no RCT to support this statement, please explain. for what kind of patients.

Page 70 Line

Table 7, row 3

again this is confusing. Class C means expert opinion, no RCT. so what are these 3 RCTs. there is no benefit in asx ischemia.

Page 73 Line

Just above table 10 (Unstable angina/NSTEMI is defined as angina of increasing severity, duration, or onset, accompanied by ST depression or T wave inversion on EKG and troponin elevation.")

not the definition used in ACC/AHA guidelines, which are much broader, any new murmur, older than 75, LBBB, etc.

REPORT OBJECTIVES & KEY QUESTIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Aims/objectives clearly address relevant policy and clinical issue?
- Key questions clearly defined and adequate for achieving aims?

Page 15 Line

I think it is hard to

Page 52 Line

The data is strongest for STEMI. There is a lot of heterogeneity in the definition of ACS and would not include ACS in the high risk group where benefit is clearly shown. ACS is very loosely and variably defined, and many patient groups labeled as ACS get no benefit for PCI compared to GDMT.

Page 59 Line

1.9 – this description of PCI jumps around, would reorganize to start with a description of ICA, then what a PCI procedure entails, which would follow the diagnostic angiography.

p.60 1.9.1

this line is confusing - a 10% decrease in restenosis rates, 22% to 32%

would clarify that the stent is a foreign body and causes an inflammatory reaction, buildup of cells and fibrosis, which is what leads to the high restenosis rates

would clarify that there are no RCT showing any reduction of instent thrombosis with use of DAPT

similarly, it is not clear what the right duration of DAPT is. A recent study found that there was no benefit in extending past one year.

METHODS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Method for identifying relevant studies is adequate?
- Criteria for the inclusion and exclusion of studies is appropriate?
- Method for Level of Evidence (LoE) rating is appropriate and clearly explained?
- Data abstraction and analysis/review are adequate?

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RESULTS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Amount of detail presented in the results section appropriate?
- Key questions are answered?
- Figures, tables and appendices clear and easy to read?
- Implications of the major findings clearly stated?
- Have gaps in the literature been dealt with adequately?
- Recommendations address limitations of literature?

The literature review is excellent and appropriate. There are places (Table 15 for example) where the tables repeat what is said in the text, not sure that is necessary.

I may have missed it, but the rating system for the "strength of evidence" was not clear to me.

I would suggest adding a line on funding source for the RCTs listed to the tables.

Page 74	Line

Would note that AUC are not evidence based. They are the "expert opinion" of physicians, chosen by the various professional societies, who generally make their living from the procedures they are rating. For example, although there is no data of benefit for PCI on any objective outcomes, there are many situations where the AUC rate PCI in asymptomatic persons as appropriate. The evidence basis for this rating is lacking.

Page 64	Line 1.10.3

While it is true that reducing symptoms and mortality is always the goal of therapy, as there is no data that PCI accomplishes this goal, would delete this line.

GDMT should generally be continued unless patients have angina that cannot be controlled on maximal medical therapy.

Page 74	Line Table 11

Usually special populations refers to groups like women, or the elderly. can you report any analysis by sex or age?

Page	Line

CONCLUSIONS Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Are the conclusions reached valid?

Yes, they are clearly based on the evidence which is carefully collated and tabulated.

Page	Line

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Page	Line

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OVERALL PRESENTATION and RELEVANCY Comments

While reviewing this section please keep the following questions in mind, but please comment on any point:

- Is the review well structured and organized?
- Are the main points clearly presented?
- Is it relevant to clinical medicine?
- Is it important for public policy or public health?

The review is very high quality and well done. The information is clear. There is an overwhelming amount of information, due to the detailed presentation of results and multiple comparisons and key questions addressed. While the information is important, this full report takes many hours to read and absorb. The executive summary does summarize the key findings well and the main points are clear. It is relevant to clinical medicine. It may be helpful to have a few lines to try to help understand why actual

clinical practice seems to differ so widely from the evidence for PCI. Also, it is worth noting that most DES use is off-label, in the section where you list the FDA indications.

The findings are important for public policy and public health as there is clearly room for improvement in patterns of care for stable CAD. As the risks (and costs) of PCI are much greater than for medical therapy, treating more patients with medical tx would improve safety and effectiveness with equivalent or better outcomes and lower cost. This could be accomplished by a bundled payment policy for care of CAD, for example.

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QUALITY OF REPORT

Quality Of the Report
(Click in the gray box to make your selection)

Superior ☐

Good ☐

Fair ☐

Poor ☐

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We would appreciate any feedback you have on the usability of this form. Please add comments in the field below.

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PUBLIC COMMENTS:

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CHAPTER

November 18, 2015

Health Technology Assessment Program
P.O. Box 42712
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Submitted via email to shtap@hca.wa.gov

Response to WA State HTAC re coronary stenting

INTRODUCTION AND BACKGROUND:
On behalf of WA ACC (WA-ACC), I am submitting our comments on the Health Technology Assessment Committee's (HTAC) draft report on coronary stenting.

The Washington Chapter of the American College of Cardiology represents 625 professionals who care for patients with cardiovascular disease. Our members comprise physicians, pharmacists, nurse practitioners, physician assistants and cardiovascular administrators. The vast majority of cardiology physicians in the state are members. These comments are written on behalf of the ACC by a volunteer member whose full time job is the hands-on care of Washington state residents with Cardiovascular disease.

The Washington chapter is an independent organization tightly affiliated with the national American College of Cardiology (ACC), which has over 50,000 members and has been a leader in medicine in assessing the ever-evolving science of cardiovascular disease. The ACC works with other professional organizations to evaluate the science in various clinical areas of cardiology and publishes scientific, unbiased guidelines for care. These are appropriately referenced in the draft report. The ACC's conflict of interest policy is extremely stringent and transparent in guideline writing.
More recently, the ACC has used the guidelines and their scientific basis to publish appropriate use criteria based on scientific evidence. These guidelines and criteria are based on clinical care and the reality that every patient is unique and to help physicians use science as a guide in creating treatment plans. The draft report has also referenced those. It is very important to note that these internally created documents have significantly reduced stent use, both nationally (JAMA article), and in WA state as demonstrated in the draft report pages 45-47.

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Given the current environment described above, we are puzzled as to why the state would want to spend considerable resources looking at this topic again.

We commend the expertise and detailed work that went into the draft report by your expert consultants. The draft report is a single piece of data created to analyze cost and hard outcomes as mandated by the state. It does not attempt to delve into actual clinical care, and in fact, notes that in its preamble, specifically stating that "*Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability*." We entreat the committee (those making decisions) to very carefully consider this preamble in their discussions.

In the national picture, Washington State is both better at quality and less costly than averages on the country. Overall quality of health care, and specifically PCI, has been evaluated continuously by COAP (Clinical Outcomes Assessment Program) under the auspices of the Foundation for Health Care Quality since 1988. Their most recent executive summary is attached. Unlike HTAC, which by statute, is focused only on costly and expensive technologies, COAP actually looks at the quality of care and outcomes.

SPECIFIC COMMENTS ON THE DRAFT REPORT.
We note that the authors are not cardiologists, nor even clinicians. Their interpretation of clinical science in this context is concerning and may well lack any real context.

In the introduction to the topic, the clinical and scientific description is generally accurate. There are some rather artificial black and white statements that do not reflect the true clinical continuum of coronary artery disease. The introduction paints medical therapy, PCI and CABG as separate and mutually exclusive treatments, and does not emphasize enough that guideline driven medical therapy is appropriate for all patients with CAD and use if PCI and CAGB are additional tools to optimize health status on top of GMT. The introduction notes that advances have occurred in all CAD treatments without noticing that much of the advance that has been made, and realized in clinical practice, is better knowledge on application of PCI and CABG.

For Key question #2, the exclusion of studies comparing first generation and second or third generation DES would be inappropriate, but seems to have been done.
Methods. We are disappointed that we were not notified in July 2014 as to the scope and key questions.

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Results: We applaud the attention to the Courage trial which has already markedly changed practice in the US. Not noted in the draft report was that there was a large crossover from medical therapy to PCI in the medical therapy arm.

We fully agree that prevention of primary and secondary cardiovascular events is critical and cost effective and hope that the state would fully fund the provision of optimal medical therapy, tobacco cessation and prevention and cardiac rehabilitation.

CLINCAL ISSUES NOT ADDRESSED IN THE DRAFT REPORT:

It is being increasingly recognized that patient choice and shared decision making is critical to the provision of health care in the US. We do not note any acknowledgement about this in the report. While PCI does not offer survival advantages in most situations of stable angina, it is clearly better in relieving angina. Some patients choose to avoid invasive procedures at the cost of linger lasting angina, some choose a procedure to more rapidly relieve their angina. As one of the original investigators who created the Seattle Angina Questionnaire, I appreciate the concept of quality of life better than many clinicians and most insurance companies. Since these patients do make decisions with financial "skin in the game", no insurance company or payer can mandate one approach over another. The important factor of patient choice in situations where science tells us we have multiple good options is not addressed here. When there is clinical equipoise between treatments, shared decision making is mandatory.

Once the decision to proceed with PCI has been made in shared decision making with a patient, we need to consider all patient factors in deciding what type of stent. For the smallest vessels, only BMS are available. Absent issues of patient compliance, bleeding risk or upcoming major surgery, DES provide better outcomes (less target vessel revascularization) than BMS and are preferred.
The FAME and FAME II trials were arbitrarily excluded from the draft report. These trials explored a new (and apparently better) technology for the assessment of coronary artery disease. Fractional Flow reserve (FFR) is a technique to measure the physiologic significance of specific coronary lesions. It is a much more accurate predictor of clinical outcomes than stenosis measured by coronary angiography. If the FFR for a specific lesion is non-ischemic, NOT stenting that lesion does not harm outcomes. Conversely, if a lesion is physiologically significant, then PCI treatment does improve hard outcomes. Overall this technology has diminished the need for PCI, and has been recognized in the AUC and guideline reports.

Please appreciate the marked reduction in Cardiovascular disease morbidity and mortality over the past decade. This is a result of the cardiology community learning what worked and implementing the science. As a result, in the face of a marked aging of the population (CAD is primarily a disease of aging and genetics), we have actually flattened both national spending on CCV disease and improved mortality and morbidity. It is rare for any medical field to accomplish this.

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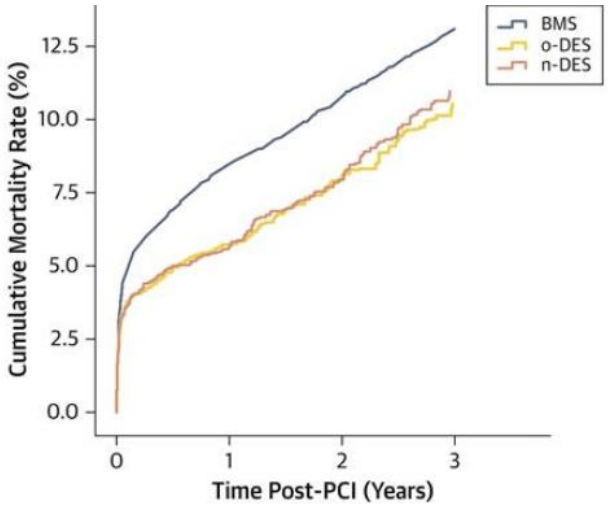
UNINTENDED CONSEQUENCES OF HTA DECISIONS

While the committee's deliberation and intents are very well meaning, they have important unintended consequences. Excuse me for a few minutes while I step down from the perspective of an administrative organizational leader back to my day job, a clinical cardiologist. This context is critically important for the committee to understand the issue.

One of my colleagues treated a STEMI patient with a DES in 2014. The insurer used the HTAC's 2009 deliberations as an excuse to deny payment for the patient's entire episode of care based solely on the size and type of stent used. This committee's well meaning deliberations, resulted in an unfortunate patient having both an acute heart attack (from which he recovered successfully) and a financial heart attack with a large bill (over $50, 000) because of this committee's actions.



N patients at risk	0 months	30 days	1 year	2 years	3 years
BMS	25065	23893 (4.8%)	22757 (8.0%)	20322 (11.0%)	16954 (12.8%)
o-DES	4271	4148 (3.8%)	3912 (5.0%)	2228 (8.0%)	1754 (10.3%)
n-DES	4811	4657 (3.7%)	4520 (5.0%)	2793 (8.0%)	1266 (10.6%)

When a patient has an ST elevation myocardial infarction (STEMI), time is of the essence. There is no other medical condition where time is so important. Clinical science has shown that the sooner these patients are treated, the better their short and long term outcomes. Application of this science has significantly and materially improved long term outcomes of heart attack victims and markedly reduced subsequent heart failure. We are guilty of helping these patients living longer, which could possibly increase their health care costs. When I am called to care for a STEMI patient, I need to get to the hospital, meet and assess the patient (almost always not known to me and vice versa), perform a sterile coronary angiogram, assess the coronary anatomy in the setting of the patient's acute and chronic illnesses and perform PCI to restore blood flow, all in as rapid time as possible. WA State as a whole does very well on average with a door-to-balloon time of (state wide average in 2013 is 57 minutes). Clinical data has consistently shown us that use of DES for STEMI provides significant benefit (see chart from *J Am Coll Cardiol*. 2014;64(1):16-24.) In the compressed time frame we function to care for a patient at risk of dying, we are not going to think about the HTACs deliberations in choosing a stent size and type to care for them.

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SUMMARY

While we appreciate that the state wants to get the most for its dollars (as do all purchasers of health care), we feel that this HTA approach is (to use our AUC terminology) rarely appropriate for CAD and PCI when clinical experts have already done the work. Furthermore, there is abundant evidence that utilization of high cost procedures has already declined with no clinical loss of benefit. Looking at only at health care spending, WA State is much better than nationally and efforts to curtail costs in Washington State by the mechanism of the HTAC threaten to inappropriately ration care. We would respectfully suggest that the HTAC spend its time, and our tax dollars, on areas of clinical concern where there does not exist such science and consensus as there does for PCI and CAD. Promulgation of decisions to limit the particular type of stent for treatment are unlikely to have any meaningful financial impact, and be potentially costly to the state if sued over these deliberations. We are happy to provide clinicians to attend committee meetings or other deliberations and explain further the clinical context and answer questions.

Respectfully submitted,

Tim Dewhurst MD FACC
President

CLINICAL **OUTCOMES ASSESSMENT** PROGRAM
A PROGRAM OF THE FOUNDATION FOR HEALTH CARE QUALITY

Participating Hospitals & Publicly Released COAP Data

Welcome to the hospital outcomes section of the Clinical Outcomes Assessment Program (COAP) web site where you can find detailed information on the performance of Washington State hospitals in the area of cardiac care. ***What you will learn on this site is that all Washington State hospitals are doing a very good job in cardiac care, and our state is out-performing the national average in many areas.*** We hope that this site will be used by hospitals for their internal quality improvement initiatives; and by heart patients and their loved ones as information to discuss with their doctor.

COAP is a truly unique and ground-breaking collaborative. This physician-led quality improvement activity is aimed at improving the quality of care for patients with heart disease who are treated in Washington hospitals. Through COAP, hospitals have been working together since 1997 to share and learn from comparative cardiac care performance information—and they have steadily improved. ***There have been significant improvements in many areas, and Washington State hospitals have much to be proud of!*** We are very fortunate to live in a state where we can be assured that every hospital is dedicated to making sure that you are getting the best possible care by participating in quality improvement efforts such as COAP. ***To keep the momentum going, and to work for even greater improvement, we are now making COAP data publicly available for several key clinical measures.***

In Washington State, there are 34 hospitals that perform Percutaneous Coronary Interventions (PCI), 18 of which also perform Coronary Artery Bypass Graft (CABG) and Valve surgeries. ***Hospitals have voluntarily agreed to make information about their performance available publicly. The few that are not disclosing data at this time may have chosen not to for a variety of reasons, which can be discussed with your physician or surgeon.*** Data from CABG & Valve surgeries and PCI are included on this site. COAP measures are all "outcomes" measures, meaning that they measure the end result of the treatment—how patients fared.

In the following table, you will see whether your hospital performed better, not as good as, or within the range of the state average for each of the measures. You will also see comparisons to the statewide average. ***It is very important to note that there are many reasons why one hospital's results might look different from another's and that while a hospital may not be currently performing within the range of the state average, they may still be significantly better than the national average.*** We encourage you to discuss this information with your physician or surgeon. The data reported is from the 2013 annual risk-adjusted clinical reports. It highlights outcomes from 2013 for PCI and CABG surgery. Because of the relatively small number of valve surgeries performed, valve surgery outcomes are reported as 3-year averages for 2011-2013.

For up to date results on a variety of metrics, see the COAP Public Reporting Platform accessed from the link on the left side of the home page, or visit:
http://www.coap.org/COAPPublicReporting/

If you are interested in information on select *general surgical procedures*, visit the Surgical Care & Outcomes Assessment Program (SCOAP) website: http://www.scoap.org/public/index.html

Updated June 2014

Volume of PCI Cases 2013

CLINICAL OUTCOMES ASSESSMENT PROGRAM
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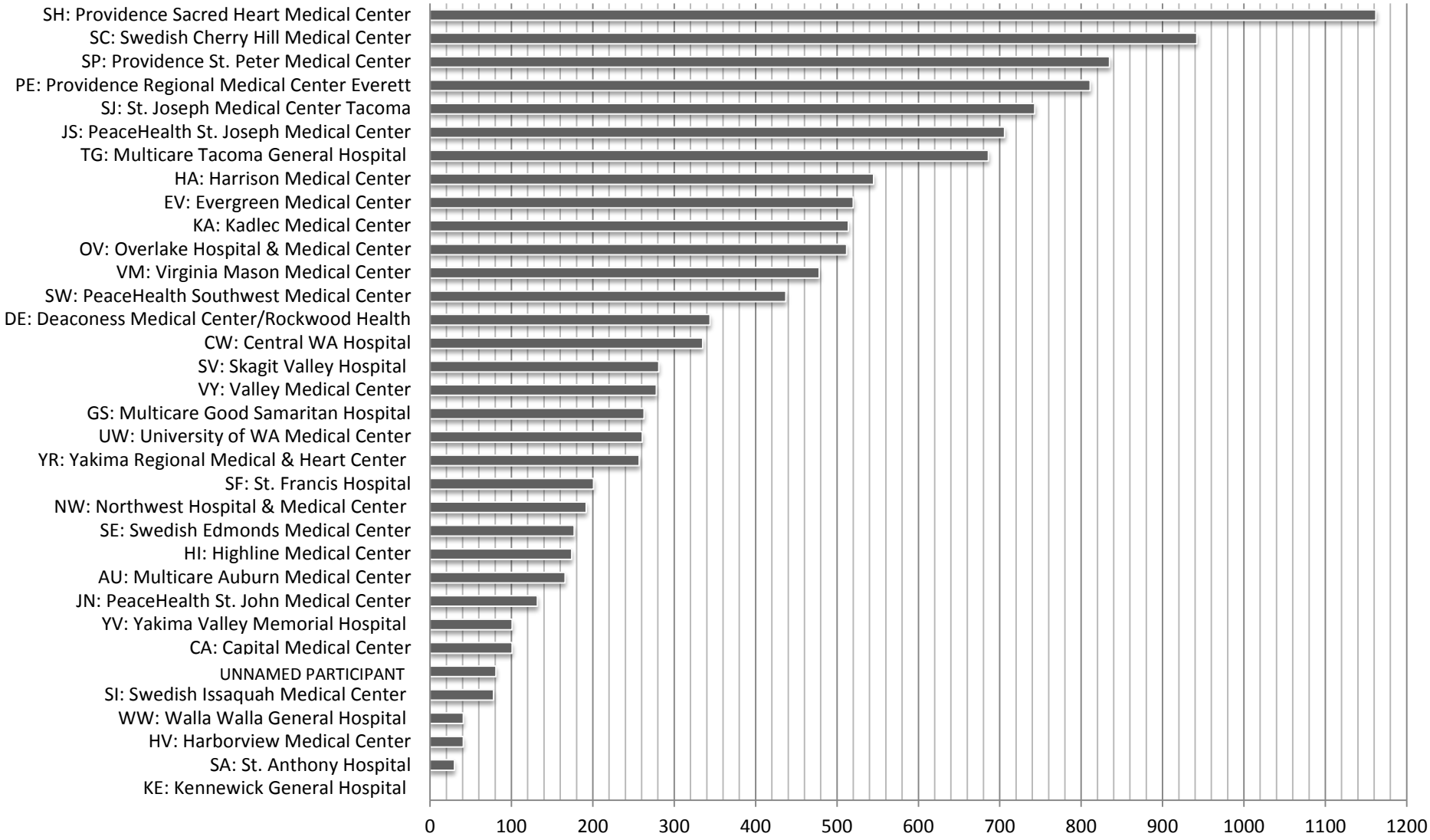


Percutaneous Coronary Intervention (PCI) Outcomes – 2013 Annual

① Risk-Adjusted Mortality - PCI 2013 State Average = **1.9%**
② Median Door to Balloon Time – PCI 2013- State Average = **57 Minutes**; Benchmark = **46 minutes**
③Insufficient Information – Non Acute PCI 2013 – State Average = **27%**

Symbols Key:	**PCI Metrics**	
⊙ Hospital results for 2013 are within the range of the statewide average for that metric ✚ Hospital results for 2013 are statistically **better** than the risk adjusted statewide average for that metric and/or have contributed to setting the **benchmark** for this measure ● Hospital results for 2013 are statistically **not as good** as the statewide average for that metric ◆ No data available for this hospital or no procedures done for this time period **xxx** Hospital is not currently releasing their data	① **Mortality**	② **Door to Balloon Time**
Black = Hospitals currently in full compliance with COAP's quality standards; ***Blue = hospitals currently in partial compliance with COAP's quality standards;*** ***Red = Hospitals currently out of compliance with COAP's quality standards***		
Auburn Regional Medical Center, Auburn	⊙	⊙
Capital Medical Center, Olympia	⊙	⊙
Central Washington Hospital, Wenatchee	⊙	⊙
Deaconess Medical Center, Spokane	⊙	⊙
Evergreen Hospital Medical Center, Kirkland	⊙	⊙
Good Samaritan Hospital, Puyallup	⊙	⊙
Harborview Medical Center, Seattle	⊙	⊙
Harrison Medical Center, Bremerton	⊙	⊙
Highline Medical Center, Burien	⊙	⊙
Kadlec Medical Center, Richland	✚	✚
Madigan Army Medical Center, Fort Lewis	xxx	xxx
Northwest Hospital & Medical Center, Seattle	⊙	⊙
Overlake Hospital Medical Center, Bellevue	⊙	⊙
PeaceHealth Southwest Washington Medical Center, Vancouver	⊙	⊙
Peace Health St. John, Longview	⊙	✚
Peace Health St. Joseph Hospital, Bellingham	⊙	⊙
Providence Regional Medical Center, Everett	⊙	⊙
Providence Sacred Heart Medical Center, Spokane	⊙	⊙
Providence St. Peter Hospital, Olympia	⊙	✚
Skagit Valley Hospital, Mt. Vernon	✚	⊙
St. Anthony Hospital, Gig Harbor	⊙	⊙
St. Francis Hospital, Federal Way	⊙	⊙
St. Joseph Medical Center, Tacoma	⊙	⊙
Swedish Health Services, Cherry Hill, Seattle	⊙	✚
Swedish Health Services, Edmonds	⊙	⊙
Swedish Health Services, Issaquah	⊙	
Tacoma General Hospital, Tacoma	⊙	⊙
University of Washington Medical Center, Seattle	⊙	⊙
Valley Medical Center, Renton	⊙	⊙
Veteran's Affairs Medical Center, Seattle	**xxx**	**xxx**
Virginia Mason Medical Center, Seattle	⊙	✚
Yakima Regional Medical & Heart Center, Yakima	⊙	⊙
Yakima Valley Memorial Hospital, Yakima	⊙	⊙
Walla Walla Hospital, Walla Walla	⊙	✚

Updated June 2014

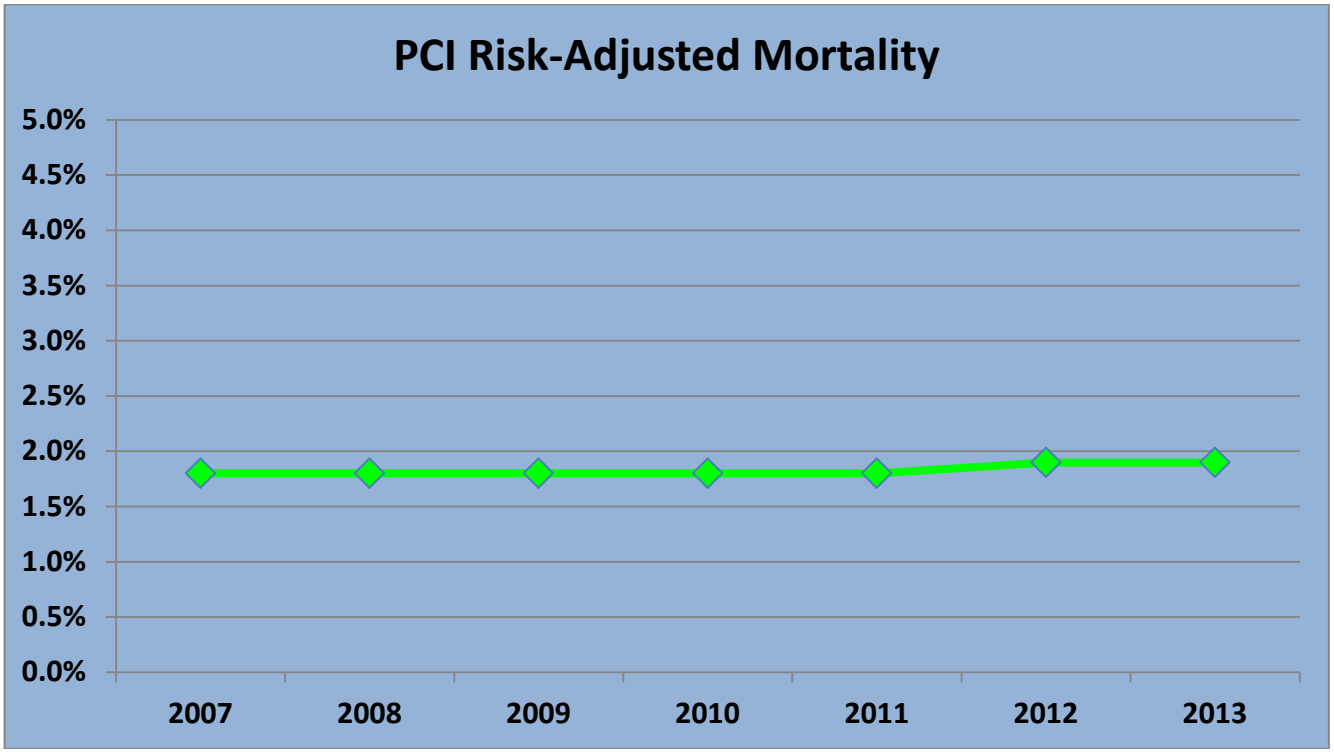
Percutaneous Coronary Intervention (PCI) Outcomes

PCI Risk-Adjusted Mortality Rate

34 hospitals in Washington State perform percutaneous coronary interventions, or PCI. PCI is a method of restoring blood flow to the heart muscle by reopening clogged arteries. Mortality rate is the percentage of patients who died before being discharged from the hospital following PCI for both elective and emergent procedures. All surgical procedures involve some risk. Additionally, all patients have their own particular risk factors such as previous medical and family history, current state of overall health, how long they have had their coronary disease, how long it has taken between onset of symptoms to treatment in an acute situation, and many others. Mortality rates for a hospital can be impacted by many things. For example, if a hospital does a low volume of this particular type of surgery, even one unavoidable death can make a significant impact on their mortality rate.

Results for this measure refer to the percentage of patients in Washington State that died during or following percutaneous coronary intervention (PCI). ***Since 2007, the risk-adjusted statewide average has stayed very steady.*** Overall, hospitals in Washington State are doing a very good job in keeping their mortality rates low. Individual hospital risk-adjusted results for 2013 range from a low of 0.0% to a high of 3.8%.

TRENDS:



Ask your physician about mortality rates for percutaneous coronary interventions at your hospital and specific risks associated with your particular case. Encourage them to examine their COAP report regarding mortality rates so they know you care!

Updated June 2014

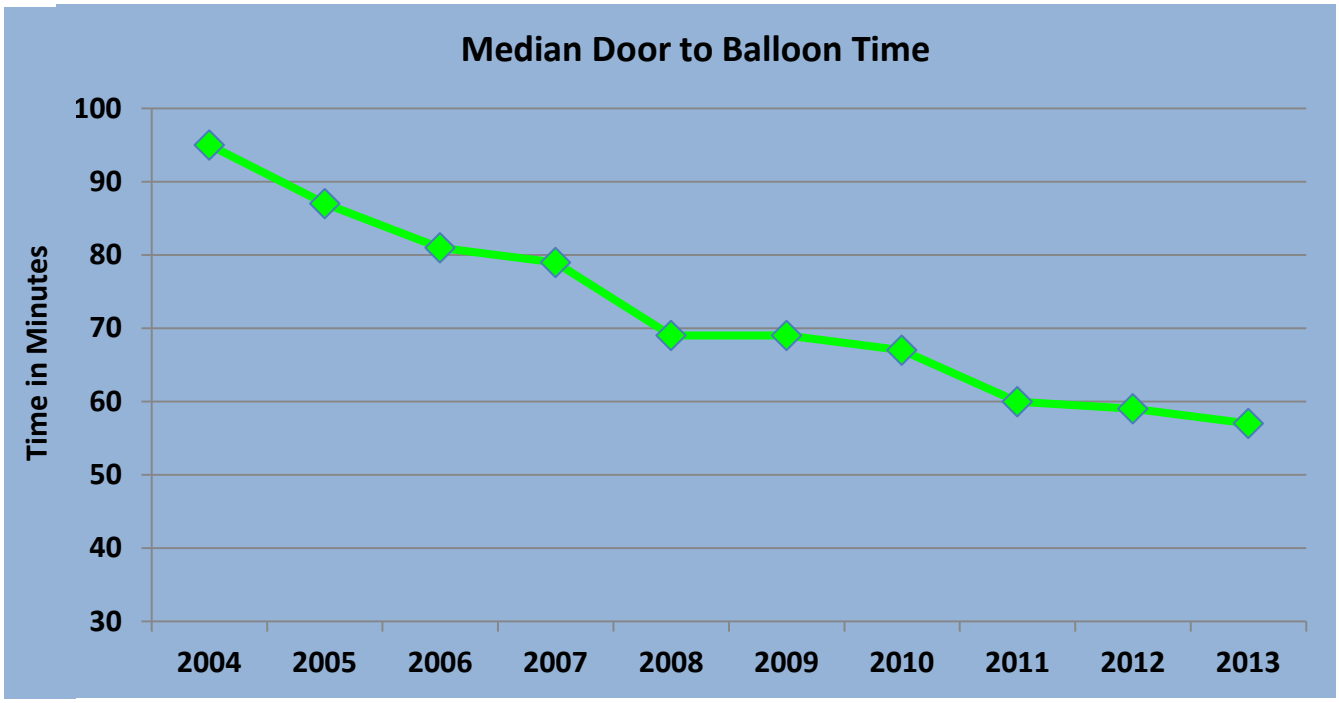
Median Time from Emergency Room Arrival to Balloon Inflation: "Door-to-Balloon Time"

34 hospitals in Washington State perform percutaneous coronary interventions, or PCI. PCI is a method of restoring blood flow to the heart muscle by reopening clogged arteries. This is often done by inflating a tiny balloon at the site of the blockage, and sometimes putting in a small metal device called a stent to hold the artery open. Experts agree that when a patient is having an acute heart attack, the quicker this happens, the better. The longer blood does not flow to the heart muscle during a heart attack, the more likely there could be damage to that muscle.

Door-to-Balloon Time is a measurement of the time between when a patient having an acute heart attack comes through the "door" of the emergency room and when the "balloon" is first inflated in the clogged artery. The *American Heart Association* and the *American College of Cardiology* along with many other national agencies recommend that this time interval be no more than 90 minutes. All 34 of these hospitals participate in COAP, a statewide cardiac quality improvement program, and they are working to reduce their door-to-balloon times.

Results for this measure refer to the median door-to-balloon time for all Washington hospitals that perform PCI. ***The statewide median has decreased from 95 minutes in 2004 to 57 minutes in 2013, which is outstanding!*** Individual hospital results for Washington State in 2013 range from a low of 42.5 minutes to a high of 85 minutes. ***Six hospitals in Washington have significantly lower door to balloon times than the state average, and as such have set what we call a "benchmark" for all hospitals to try to achieve.***

TRENDS:



Ask your physician about door-to-balloon times at your hospital. Encourage them to examine their COAP report regarding door-to-balloon time so they know you care!

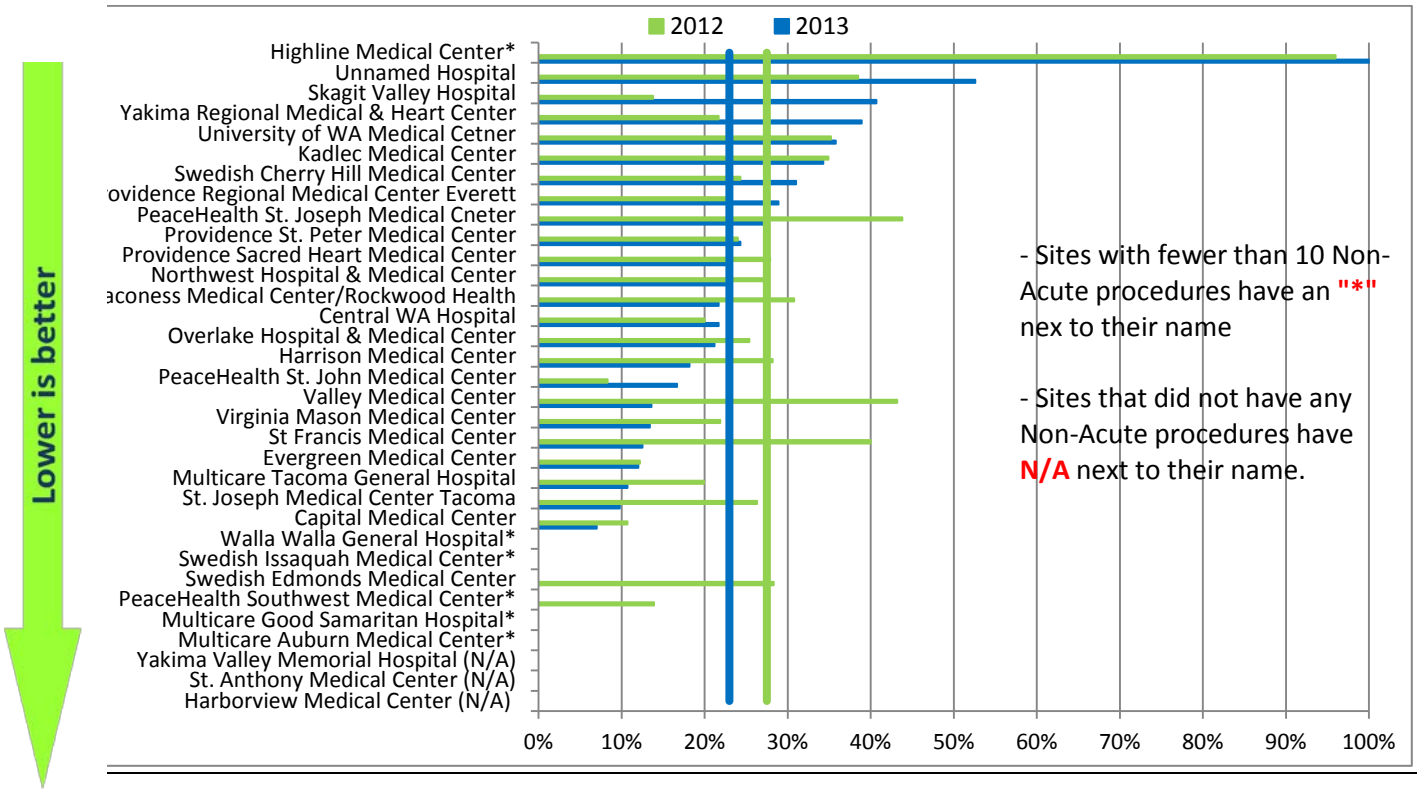
Appropriate Use Measures for Percutaneous Coronary Intervention (PCI)

PCI is a critical tool in the management of coronary disease. For patients experiencing an acute MI (myocardial infarction or "heart attack"), PCI is known to reduce mortality and recurrent MI. In patients with stable coronary artery disease, PCI offers significant symptom relief in appropriately selected patients. PCI is considered "appropriate" when the expected benefits, in terms of survival or health outcomes (reduction of symptoms, improvement in the quality of life, etc), exceed the expected negative consequences of the procedure. COAP, along with other national organizations, has begun using a complex process based on widely agreed upon criteria, to evaluate the appropriateness of each PCI procedure done in the state of Washington.

The majority of PCI's are done for acute reasons and in Washington State as well as nationally, this is almost always (99% of the time) the most appropriate form of treatment. For the non-acute, or "elective" procedures however, PCI is not always the best option for treatment at that time. In this case, those procedures would be classified as "inappropriate". There is wide variation among hospitals as to the frequency that this occurs. Reducing the incidence of those "inappropriate" procedures is a goal that Washington hospitals have set, and COAP is helping them work on this.

Certain information must be available in order to evaluate whether a procedure can be classified as "appropriate" and it should be collected for every patient and every procedure. Again, there is wide variation among hospitals as to whether all of that information is routinely collected and/or documented. *Put simply, if the data used to evaluate the appropriateness of the procedure is missing, the appropriateness of the procedure can't be measured.*

One of the ways that COAP is helping hospitals to work toward the goal of reducing inappropriate procedures is to help them reduce the amount of "insufficient information". The following graph represents the percentage of non-acute or elective PCI procedures that were "not able to be classified" or in other words, did not have enough information documented in order to be evaluated. All PCI centers in Washington are represented on this graph. The hospitals that have agreed to share their data with the public are listed here. Those that are not sharing their data publicly at this time say "un-named". Hospitals are ranked below in order of their performance for 2013…in this instance, the lower the better. The comparison with 2012 is provided so that you can see whether that hospital is improving. If the blue line (2013) is shorter than the green line (2012), the hospital has made improvements in the collection and documentation of the data needed to determine whether a non-acute PCI Procedure was appropriate.



Updated June 2014

Volume of Isolated CABG Cases 2013

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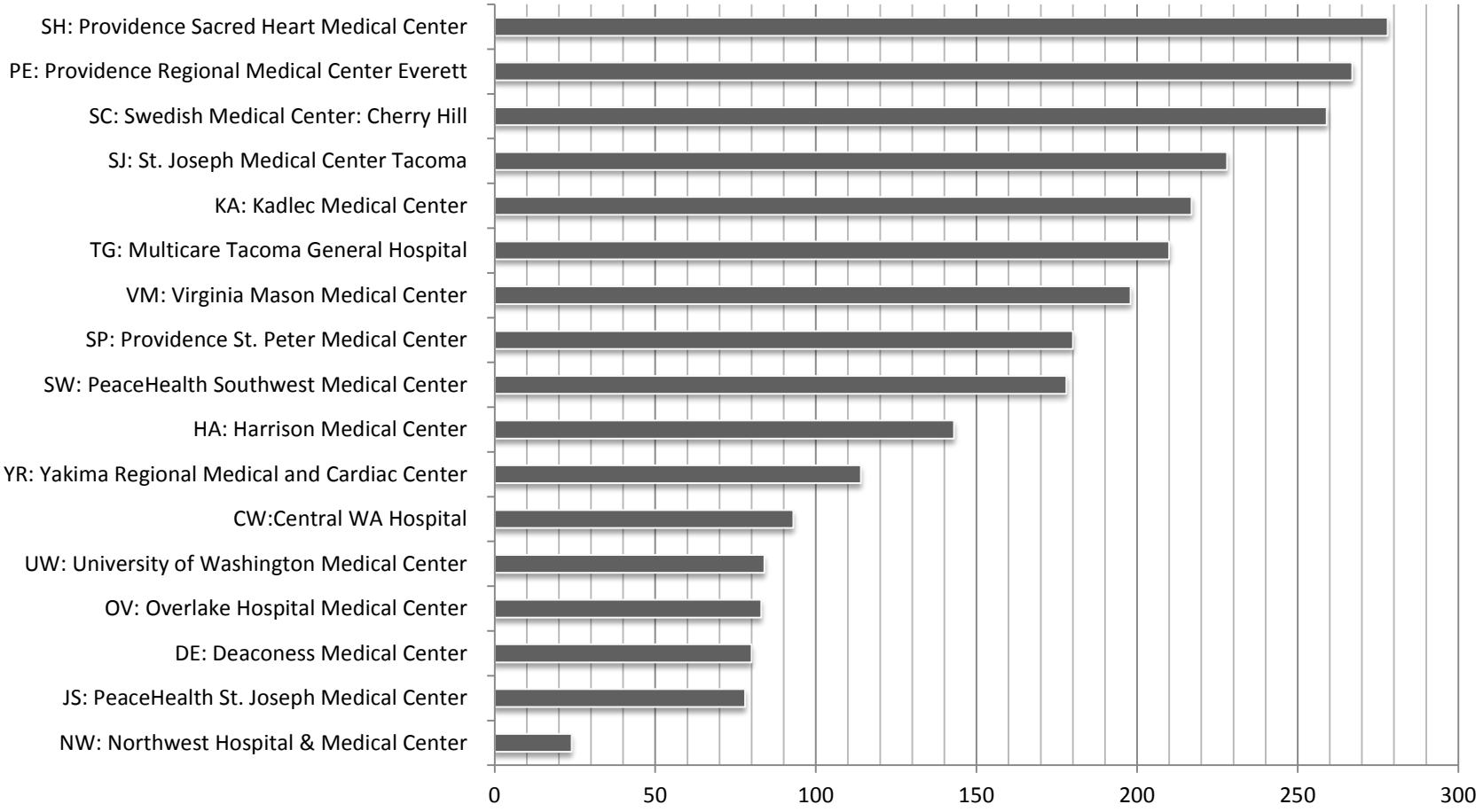


Coronary Artery Bypass Graft (CABG) Surgery Outcomes - 2013 Annual

❶ Mortality - CABG Surgery 2013 State Average = **2.0%**
❷ Renal Insufficiency – CABG Surgery 2013 State Average = **1.5%**; Benchmark = **0.6%**
❸ Stroke – CABG Surgery 2013 State Average = **2.0%**; Benchmark = **0.9%**
❹ Arterial Graft Use – CABG Surgery 2013 State Average = **99.8%**; Benchmark = **100%**
❺ Deep Sternal Wound Infection – CABG Surgery 2013 State Average = **0.2%**; Benchmark = **0%**
❻ Blood Use – CABG Surgery 2013 State Average = **23.1%**; Benchmark = **12.4%**

Symbols Key:

- ⊙ Hospital results for 2013 are within the range of the statewide average for that metric
- ✚ Hospital results for 2013 are statistically **better** than the risk adjusted Statewide average for that metric and/or have contributed to setting the **benchmark** for this measure
- ⭘ Hospital results for 2013 are statistically **not as good** as the statewide average for that metric

Black = Hospitals in full compliance with COAP's quality standards;
Blue = hospitals in partial compliance with COAP's quality standards;
Red = Hospitals out of compliance with COAP's quality standards

	CABG Metrics					
	❶ Mortality	❷ Renal Insufficiency	❸ Stroke	❹ Arterial Graft Use	❺ Wound Infection	❻ Blood Use
Central Washington Hospital, Wenatchee	⊙	✚	⊙	✚	✚	⊙
Deaconess Medical Center, Spokane	⊙	⊙	⊙	✚	⊙	⊙
Harrison Medical Center, Bremerton	⊙	⊙	⊙	✚	✚	⊙
Kadlec Medical Center, Richland	⊙	⊙	⭘	✚	✚	⊙
Multicare Tacoma General Hospital, Tacoma	⊙	✚	✚	⊙	✚	⊙
Northwest Hospital & Medical Center, Seattle	⊙	✚	⭘	✚	✚	⊙
Overlake Hospital Medical Center, Bellevue	⊙	⊙	⊙	✚	✚	⊙
PeaceHealth Southwest Washington Medical Center, Vancouver	⊙	⊙	✚	⊙	✚	⊙
PeaceHealth St. Joseph Hospital, Bellingham	⊙	⊙	⊙	✚	⭘	⊙
Providence Regional Medical Center, Everett	⊙	⊙	⊙	✚	⊙	✚
Providence Sacred Heart Medical Center, Spokane	⊙	⊙	⊙	⊙	✚	⊙
Providence St. Peter Hospital, Olympia	⊙	⊙	⊙	✚	✚	⊙
St. Joseph Medical Center, Tacoma	⊙	✚	⊙	✚	✚	✚
Swedish Health Services, Cherry Hill, Seattle	⊙	✚	⊙	✚	⊙	⊙
University of Washington Medical Center, Seattle	⊙	⊙	⊙	✚	✚	⊙
Veteran's Affairs Medical Center, Seattle	XXX	XXX	XXX	XXX	XXX	XXX
Virginia Mason Medical Center, Seattle	⊙	✚	⊙	✚	✚	⊙
Yakima Regional Medical & Heart Center, Yakima	⊙	✚	⊙	✚	✚	⊙

Updated June 2014

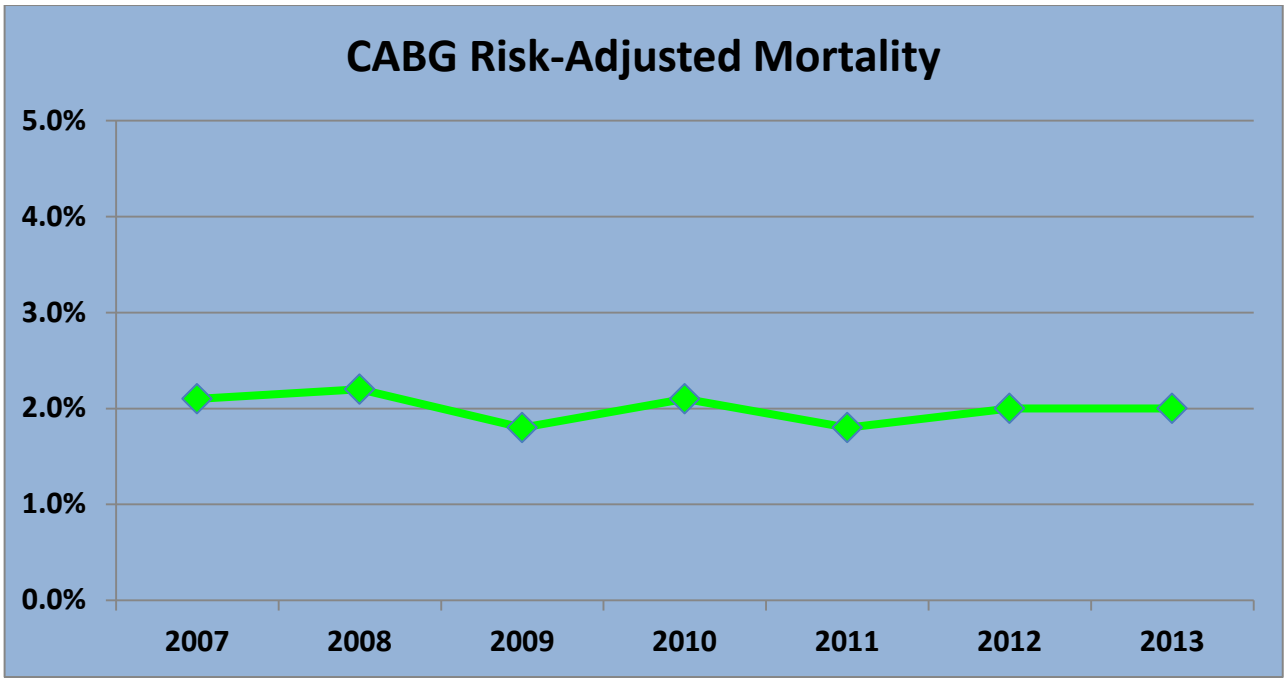
Coronary Artery Bypass Graft (CABG) Surgery Outcomes

CABG Risk-Adjusted Mortality Rate

Mortality rate is the percentage of patients who died before being discharged from the hospital following Coronary Artery Bypass Graft Surgery (CABG) for both elective and emergent procedures. All surgical procedures involve some risk. Additionally, all patients have their own particular risk factors such as previous medical and family history, current state of overall health, how long they have had their coronary disease, how long it has taken between onset of symptoms to treatment in an acute situation, and many others. Mortality rates for a hospital can be impacted by many things. For example, if a hospital does a low volume of this particular type of surgery, even one unavoidable death can make a significant impact on their mortality rate.

Results for this measure refer to the percentage of patients in Washington State that died during or following coronary artery bypass graft (CABG) surgery before being discharged from the hospital. ***The statewide risk-adjusted average has varied between 1.8% and 2.2% since 2007.*** Overall, hospitals in Washington State are doing a good job in keeping their mortality rates low, and are consistent with the national averages. Individual hospital results for Washington State in 2013 range from a low of 0.0% to a high of 4.1%. When adjusted for high risk cases, all Washington hospitals fall within the statewide mean for 2013.

TRENDS:



Ask your surgeon about mortality rates for coronary artery bypass surgery at your hospital and specific risks associated with your particular case. Encourage them to examine their COAP report regarding mortality rates so they know you care!

Volume of Aortic Valve Cases 2013

COAP
CLINICAL OUTCOMES ASSESSMENT PROGRAM
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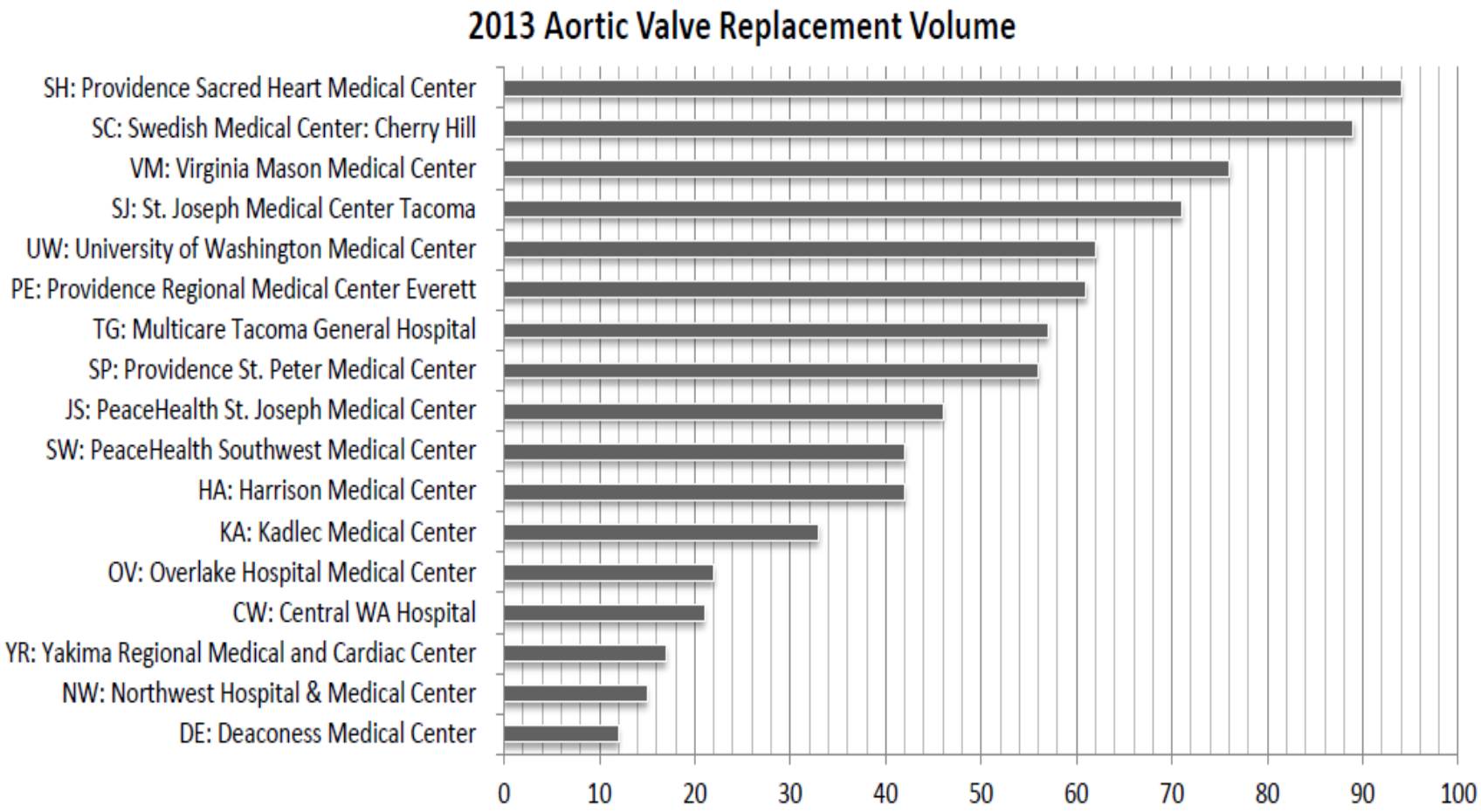

Aortic Valve Replacement (AVR) Surgery 3-Year Outcomes 2011 - 2013

❶ Mortality - AVR Surgery 3 Year Average = **1.8%**
❷ Renal Failure – AVR Surgery 3 Year Average = **2.5%**
❸ Stroke – AVR Surgery 3 Year Average = **1.6%**
❹ Deep Sternal Wound Infection – AVR Surgery 3 Year Average = **0.1%**
❺ Blood Use – AVR Surgery 3 Year Average = **27.3%**

Symbols Key:

⊙ Hospital results for 3 year average are within the range of the statewide average for that metric
✚ Hospital results for 3 year average are statistically **better** than the risk adjusted Statewide average for that metric
⊙ Hospital results for 3 year average are statistically **not as good** as the statewide average for that metric

Black = Hospitals in full compliance with COAP's quality standards;
Blue = hospitals in partial compliance with COAP's quality standards;
Red = Hospitals out of compliance with COAP's quality standards

	AVR Metrics				
	❶ Mortality	❷ Renal Failure	❸ Stroke	❹ Wound Infection	❺ Blood Use
Central Washington Hospital, Wenatchee	⊙	⊙	⊙	⊙	⊙
Deaconess Medical Center, Spokane	⊙	⊙	⊙	⊙	⊙
Harrison Medical Center, Bremerton	⊙	⊙	⊙	⊙	⊙
Kadlec Medical Center, Richland	⊙	⊙	⊙	⊙	⊙
Northwest Hospital & Medical Center, Seattle	⊙	⊙	⊙	⊙	⊙
Overlake Hospital Medical Center, Bellevue	⊙	⊙	⊙	⊙	⊙
Providence Regional Medical Center, Everett	⊙	⊙	⊙	⊙	✚
Providence Sacred Heart Medical Center, Spokane	✚	⊙	⊙	⊙	⊙
Providence St. Peter Hospital, Olympia	⊙	⊙	⊙	⊙	✚
St. Joseph Hospital, Bellingham	⊙	⊙	⊙	⊙	⊙
St. Joseph Medical Center, Tacoma	⊙	⊙	⊙	⊙	⊙
Southwest Washington Medical Center, Vancouver	⊙	⊙	⊙	⊙	⊙
Swedish Health Services, Cherry Hill, Seattle	⊙	⊙	⊙	⊙	⊙
Tacoma General Hospital, Tacoma	⊙	⊙	⊙	⊙	⊙
University of Washington Medical Center, Seattle	✚	✚	⊙	⊙	⊙
Veteran's Affairs Medical Center, Seattle	XXX	XXX	XXX	XXX	XXX
Virginia Mason Medical Center, Seattle	⊙	✚	⊙	⊙	⊙
Yakima Regional Medical & Heart Center, Yakima	⊙		⊙	⊙	⊙

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Volume of Aortic Valve + CABG Cases 2013

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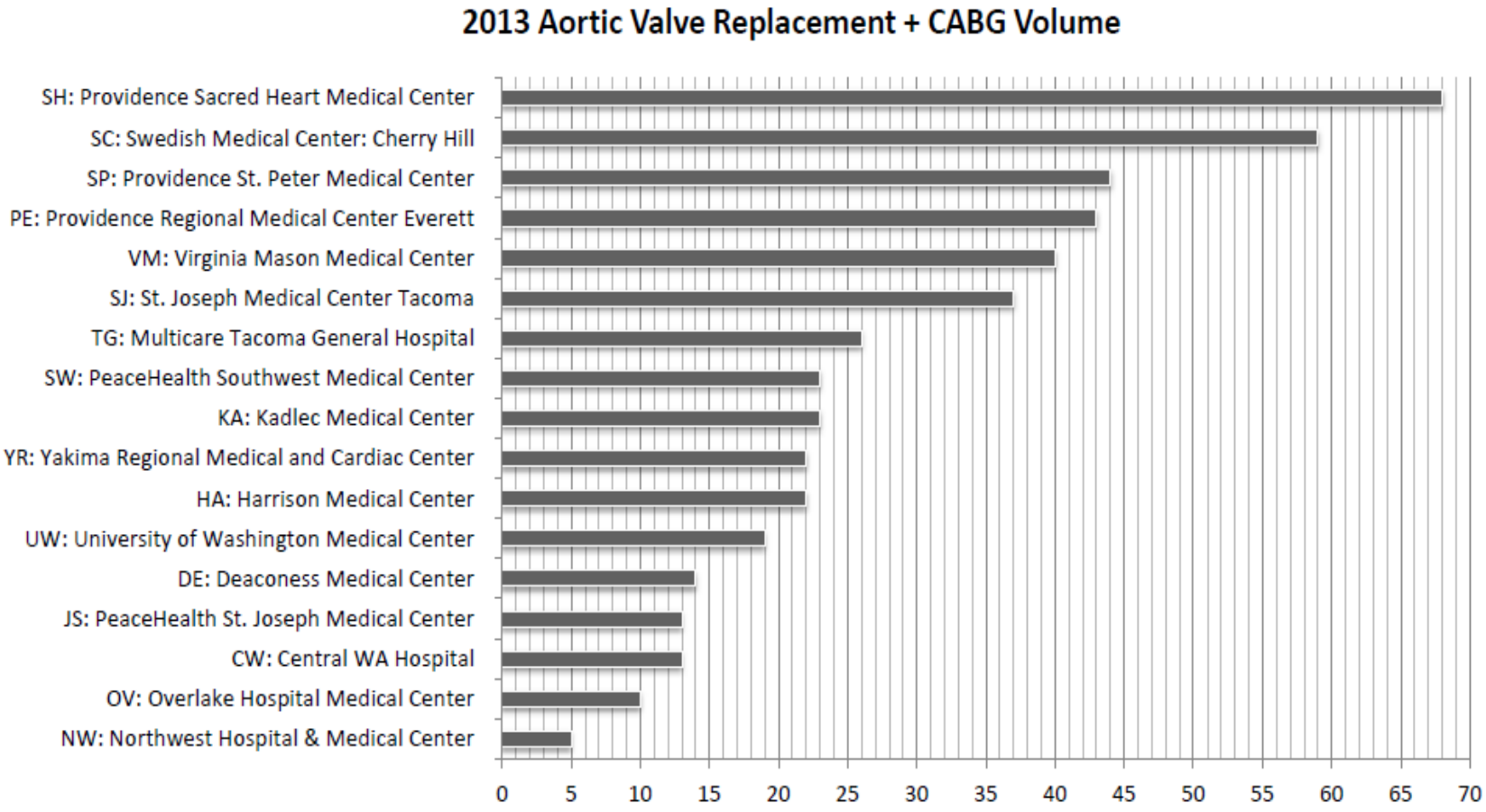

CABG + Aortic Valve Replacement (AVR) Surgery 3-Year Outcomes 2011-2013

❶ Mortality – CABG + AVR Surgery 3 Year Average = **3.5%**
❷ Renal Failure – CABG + AVR Surgery 3 Year Average = **3.9%**
❸ Stroke – CABG + AVR Surgery 3 Year Average = **2.6%**
❹ Arterial Graft Use – CABG + AVR Surgery 3 Year Average = **92.5%**
❺ Deep Sternal Wound Infection – CABG + AVR Surgery 3 Year Average = **0.5%**
❻ Blood Use – CABG + AVR Surgery 3 Year Average = **46.5%**

Symbols Key:	**CABG + AVR Metrics**					
⊙ Hospital results for 3 year average are within the range of the statewide average for that metric ✚ Hospital results for 3 year average are statistically **better** than the risk adjusted Statewide average for that metric ● Hospital results for 3 year average are statistically **not as good** as the statewide average for that metric	❶ Mortality	❷ Renal Failure	❸ Stroke	❹ Arterial Graft Use	❺ Wound Infection	❻ Blood Use
Black = Hospitals in full compliance with COAP's quality standards; ***Blue = hospitals in partial compliance with COAP's quality standards;*** ***Red = Hospitals out of compliance with COAP's quality standards***						
Central Washington Hospital, Wenatchee	⊙	⊙	⊙	⊙	⊙	⊙
Deaconess Medical Center, Spokane	⊙	⊙	⊙	⊙	⊙	⊙
Harrison Medical Center, Bremerton	⊙	⊙	⊙	⊙	⊙	⊙
Kadlec Medical Center, Richland	⊙	⊙	⊙	⊙	⊙	⊙
Northwest Hospital & Medical Center, Seattle	⊙	⊙	●	⊙	⊙	⊙
Overlake Hospital Medical Center, Bellevue	⊙	⊙	⊙	⊙	⊙	⊙
Providence Regional Medical Center, Everett	⊙	⊙	⊙	⊙	⊙	✚
Providence Sacred Heart Medical Center, Spokane	✚	✚	⊙	⊙	⊙	⊙
Providence St. Peter Hospital, Olympia	⊙	⊙	⊙	⊙	⊙	✚
St. Joseph Hospital, Bellingham	⊙	⊙	⊙	⊙	⊙	⊙
St. Joseph Medical Center, Tacoma	⊙	⊙	⊙	⊙	⊙	⊙
Southwest Washington Medical Center, Vancouver	⊙	⊙	⊙	✚	⊙	⊙
Swedish Health Services, Cherry Hill, Seattle	⊙	⊙	⊙	⊙	⊙	⊙
Tacoma General Hospital, Tacoma	⊙	✚	⊙	⊙	⊙	⊙
University of Washington Medical Center, Seattle	⊙	⊙	⊙	⊙	⊙	⊙
Veteran's Affairs Medical Center, Seattle	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**
Virginia Mason Medical Center, Seattle	⊙	✚	⊙	✚	⊙	⊙
Yakima Regional Medical & Heart Center, Yakima	⊙	✚	⊙	⊙	⊙	⊙

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Volume of Mitral Valve Cases 2013

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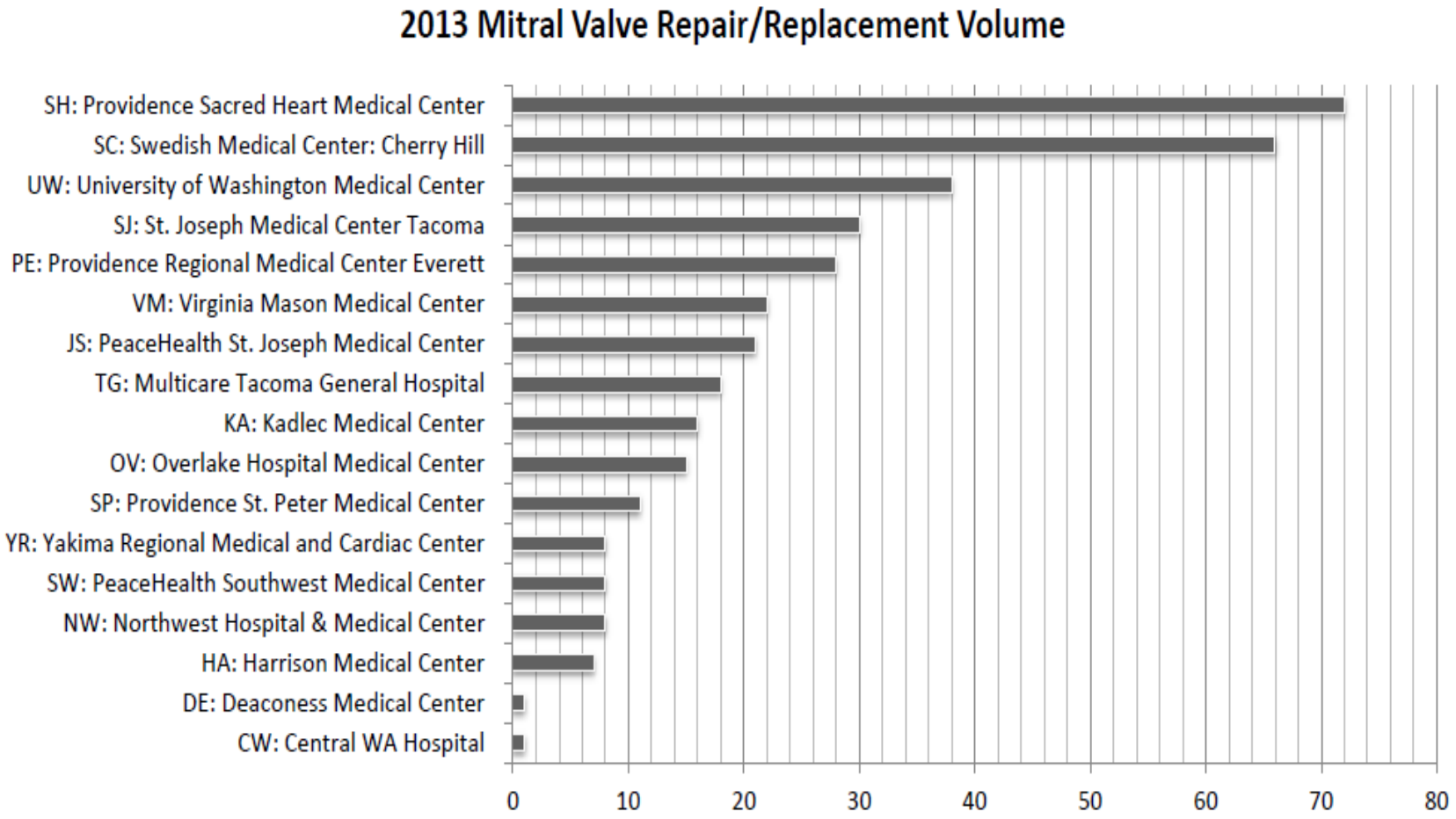

Mitral Valve Repair or Replacement (MVRR) Surgery 3-Year Outcomes 2011 - 2013

❶ Mortality - MVRR Surgery 3 Year Average = **2.1%**
❷ Renal Failure – MVRR Surgery 3 Year Average = **2.3%**
❸ Stroke – MVRR Surgery 3 Year Average = **0.8%**
❹ Deep Sternal Wound Infection – MVRR Surgery 3 Year Average = **0.2%**
❺ Blood Use – MVRR Surgery 3 Year Average = **25.9%**

Symbols Key:	**MVRR Metrics**				
⊙ Hospital results for 3 year average are within the range of the statewide average for that metric ✚ Hospital results for 3 year average are statistically **better** than the risk adjusted Statewide average for that metric ⊙ Hospital results for 3 year average are statistically **not as good** as the statewide average for that metric	❶ Mortality	❷ Renal Failure	❸ Stroke	❹ Wound Infection	❺ Blood Use
Black = Hospitals in full compliance with COAP's quality standards; ***Blue = hospitals in partial compliance with COAP's quality standards;*** ***Red = Hospitals out of compliance with COAP's quality standards***					
Central Washington Hospital, Wenatchee	⊙	⊙	⊙	⊙	⊙
Deaconess Medical Center, Spokane	⊙	⊙	⊙	⊙	⊙
Harrison Medical Center, Bremerton	⊙	⊙	⊙	⊙	⊙
Kadlec Medical Center, Richland	⊙	⊙	⊙	⊙	⊙
Northwest Hospital & Medical Center, Seattle	⊙	⊙	⊙	⊙	⊙
Overlake Hospital Medical Center, Bellevue	⊙	⊙	⊙	⊙	⊙
Providence Regional Medical Center, Everett	⊙	⊙	⊙	⊙	✚
Providence Sacred Heart Medical Center, Spokane	⊙	⊙	⊙	⊙	✚
Providence St. Peter Hospital, Olympia	⊙	⊙	⊙	⊙	⊙
St. Joseph Hospital, Bellingham	⊙	⊙	⊙	⊙	⊙
St. Joseph Medical Center, Tacoma	⊙	⊙	⊙	⊙	⊙
Southwest Washington Medical Center, Vancouver	⊙	⊙	⊙	⊙	⊙
Swedish Health Services, Cherry Hill, Seattle	⊙	⊙	⊙	⊙	⊙
Tacoma General Hospital, Tacoma	⊙	⊙	⊙	⊙	⊙
University of Washington Medical Center, Seattle	⊙	⊙	⊙	⊙	⊙
Veteran's Affairs Medical Center, Seattle	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**
Virginia Mason Medical Center, Seattle	⊙	⊙	⊙	⊙	⊙
Yakima Regional Medical & Heart Center, Yakima	⊙	⊙	⊙	⊙	⊙

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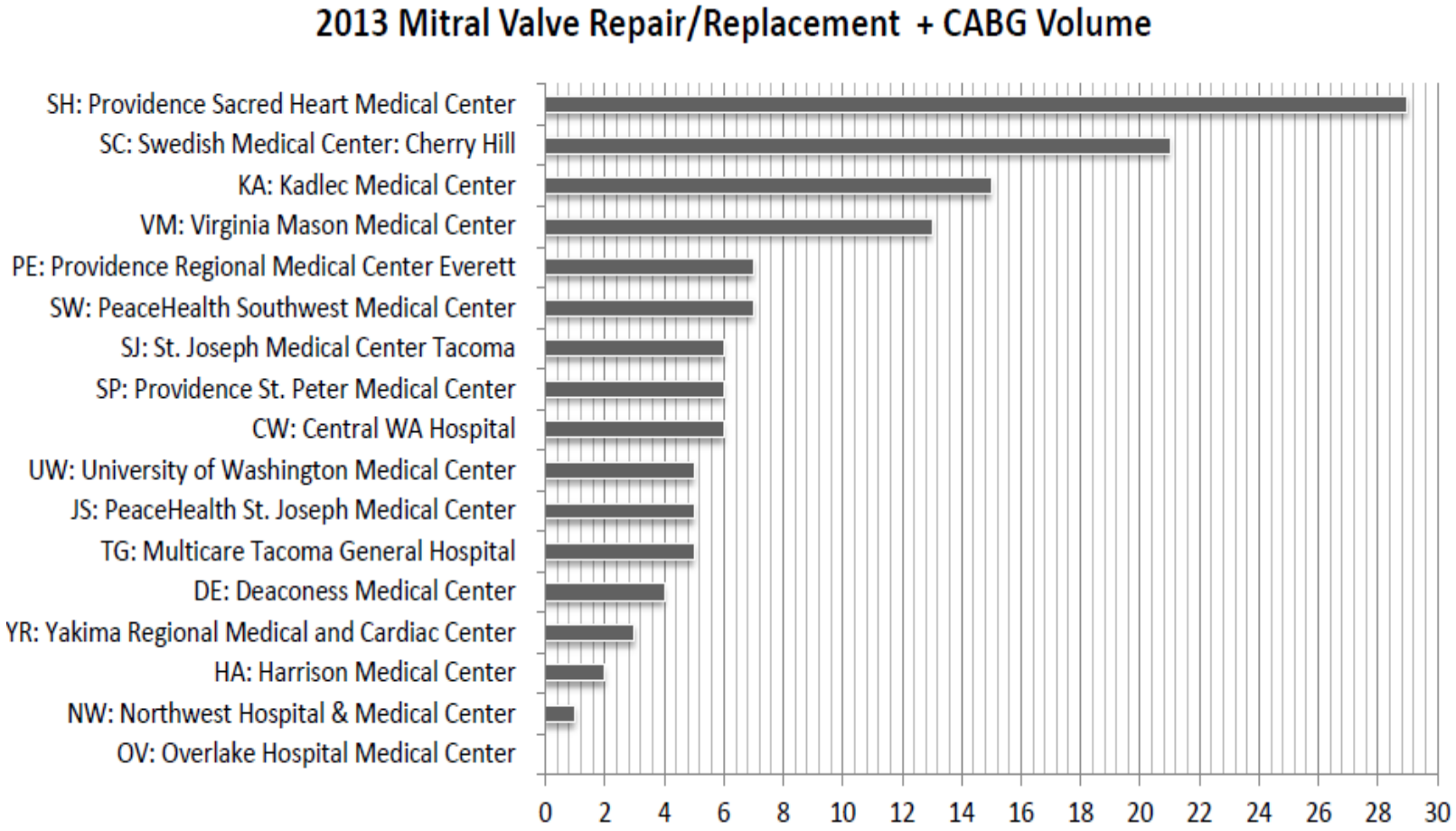

CABG + Mitral Valve Repair or Replacement (MVRR) Surgery 3-Year Outcomes 2011-2013

❶ Mortality – CABG + MVRR Surgery 3 Year Average = **6.0%**
❷ Renal Failure – CABG + MVRR Surgery 3 Year Average = **8.9%**
❸ Stroke – CABG + MVRR Surgery 3 Year Average = **2.3%**
❹ Arterial Graft Use – CABG + MVRR Surgery 3 Year Average = **96.7%**
❺ Deep Sternal Wound Infection – CABG + MVRR Surgery 3 Year Average = **0.0%**
❻ Blood Use – CABG + MVRR Surgery 3 Year Average = **47.3%**

Symbols Key:

⊙ Hospital results for 3 year average are within the range of the statewide average for that metric
✚ Hospital results for 3 year average are statistically **better** than the risk adjusted Statewide average for that metric
● Hospital results for 3 year average are statistically **not as good** as the statewide average for that metric

Black = Hospitals in full compliance with COAP's quality standards;
Blue = hospitals in partial compliance with COAP's quality standards;
Red = Hospitals out of compliance with COAP's quality standards

	CABG + MVRR Metrics					
	❶ Mortality	❷ Renal Failure	❸ Stroke	❹ Arterial Graft Use	❺ Wound Infection	❻ Blood Use
Central Washington Hospital, Wenatchee	⊙	⊙	⊙	⊙	⊙	⊙
Deaconess Medical Center, Spokane	⊙	⊙	⊙	⊙	⊙	⊙
Harrison Medical Center, Bremerton	⊙	⊙	⊙	⊙	⊙	⊙
Kadlec Medical Center, Richland	⊙	⊙	⊙	⊙	⊙	⊙
Northwest Hospital & Medical Center, Seattle	⊙	⊙	⊙	⊙	⊙	✚
Overlake Hospital Medical Center, Bellevue	⊙	⊙	⊙	⊙	⊙	⊙
Providence Regional Medical Center, Everett	⊙	⊙	⊙	⊙	⊙	✚
Providence Sacred Heart Medical Center, Spokane	⊙	⊙	⊙	⊙	⊙	✚
Providence St. Peter Hospital, Olympia	⊙	⊙	⊙	⊙	⊙	⊙
St. Joseph Hospital, Bellingham	⊙	⊙	⊙	⊙	⊙	⊙
St. Joseph Medical Center, Tacoma	⊙	⊙	⊙	⊙	⊙	⊙
Southwest Washington Medical Center, Vancouver	⊙	⊙	⊙	⊙	⊙	⊙
Swedish Health Services, Cherry Hill, Seattle	⊙	⊙	⊙	⊙	⊙	⊙
Tacoma General Hospital, Tacoma	⊙	⊙	⊙	⊙	⊙	⊙
University of Washington Medical Center, Seattle	⊙	⊙	⊙	⊙	⊙	⊙
Veteran's Affairs Medical Center, Seattle	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**
Virginia Mason Medical Center, Seattle	⊙	⊙	⊙	⊙	⊙	⊙
Yakima Regional Medical & Heart Center, Yakima	⊙	⊙	⊙	⊙	⊙	⊙

Updated June 2014

Original Investigation

Appropriate Use Criteria for Coronary Revascularization and Trends in Utilization, Patient Selection, and Appropriateness of Percutaneous Coronary Intervention

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IMPORTANCE Appropriate Use Criteria for Coronary Revascularization were developed to critically evaluate and improve patient selection for percutaneous coronary intervention (PCI). National trends in the appropriateness of PCI have not been examined.

OBJECTIVE To examine trends in PCI utilization, patient selection, and procedural appropriateness following the introduction of Appropriate Use Criteria.

DESIGN, SETTING, AND PARTICIPANTS Multicenter, longitudinal, cross-sectional analysis of patients undergoing PCI between July 1, 2009, and December 31, 2014, at hospitals continuously participating in the National Cardiovascular Data Registry CathPCI registry over the study period.

MAIN OUTCOMES AND MEASURES Proportion of nonacute PCIs classified as inappropriate at the patient and hospital level using the 2012 Appropriate Use Criteria for Coronary Revascularization.

RESULTS A total of 2.7 million PCI procedures from 766 hospitals were included. Annual PCI volume of acute indications was consistent over the study period (377 540 in 2010; 374 543 in 2014), but the volume of nonacute PCIs decreased from 89 704 in 2010 to 59 375 in 2014. Among patients undergoing nonacute PCI, there were significant increases in angina severity (Canadian Cardiovascular Society grade III/IV angina, 15.8% in 2010 and 38.4% in 2014), use of antianginal medications prior to PCI (at least 2 antianginal medications, 22.3% in 2010 and 35.1% in 2014), and high-risk findings on noninvasive testing (22.2% in 2010 and 33.2% in 2014) ($P < .001$ for all), but only modest increases in multivessel coronary artery disease (43.7% in 2010 and 47.5% in 2014, $P < .001$). The proportion of nonacute PCIs classified as inappropriate decreased from 26.2% (95% CI, 25.8%-26.6%) to 13.3% (95% CI, 13.1%-13.6%), and the absolute number of inappropriate PCIs decreased from 21 781 to 7921. Hospital-level variation in the proportion of PCIs classified as inappropriate persisted over the study period (median, 12.6% [interquartile range, 5.9%-22.9%] in 2014).

CONCLUSIONS AND RELEVANCE Since the publication of the Appropriate Use Criteria for Coronary Revascularization in 2009, there have been significant reductions in the volume of nonacute PCI. The proportion of nonacute PCIs classified as inappropriate has declined, although hospital-level variation in inappropriate PCI persists.

Editorial

Supplemental content at jama.com

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In 2009, the American College of Cardiology and the American Heart Association, along with other professional societies, released Appropriate Use Criteria for Coronary Revascularization to critically examine and improve patient selection for percutaneous coronary intervention (PCI) as well as address concerns about potential overuse.[1,2] Prior studies demonstrated that 1 in 6 nonacute PCIs were classified as inappropriate (new Appropriate Use Criteria documents use the term "rarely appropriate"), indicating that the benefits of the procedure were unlikely to outweigh the risks.[3,4] Furthermore, there was substantial variation in the proportion of nonacute PCIs considered inappropriate across hospitals.[3,4] These findings received considerable attention in both the academic literature and media,[5,6] prompting numerous efforts to improve the appropriateness of PCI.

In 2011, the National Cardiovascular Data Registry's CathPCI registry (NCDR CathPCI) began providing hospitals information about their performance on PCI appropriateness, which was benchmarked against other participating hospitals. Simultaneously, national quality improvement campaigns, such as the American Board of Internal Medicine's Choosing Wisely Initiative, identified PCI appropriateness as a key area for intervention,[7] insurers incorporated measures of PCI appropriateness into pay-for-performance programs,[8] and some payers declined reimbursement for certain PCIs classified as inappropriate.[9]

Despite the attention that the appropriateness of PCI has received, there has been no comprehensive, national examination of trends in the indications, patient characteristics, and appropriateness of PCI procedures after the introduction of the Appropriate Use Criteria. Similarly, the extent of hospital-level variation in the proportion of nonacute PCI considered inappropriate has not been systematically examined over time. To address these gaps in knowledge, we examined national trends in patient selection for PCI, changes in PCI appropriateness, and hospital variation in inappropriate PCI using the NCDR CathPCI Registry.

Methods

Data Source and Appropriate Use Criteria

Details of the registry have been described previously.[10,11] In brief, the NCDR CathPCI registry is the largest national registry of diagnostic cardiac catheterization and PCI, with more than 1500 participating institutions. Detailed information on clinical characteristics, cardiac testing, angiographic findings, and in-hospital management and clinical outcomes are collected by trained staff at participating hospitals using a standardized data collection form (http://cvquality.acc.org/en/NCDR-Home/Data-Collection/What-Each-Registry-Collects.aspx). All data submissions must meet specified quality standards, and randomly identified sites are monitored through annual audits. The Human Investigation Committee of the Yale University School of Medicine approved the use of a limited data set from the registry for research without requiring informed consent.

Box. An Overview of the 2012 Appropriate Use Criteria for Coronary Revascularization and Methodology for Determination of the Appropriateness of PCI

The methodology for developing the Appropriate Use Criteria for Coronary Revascularization, which are based on the modified RAND methodology and reflect a synthesis of contemporary clinical trial evidence, clinical practice guidelines, and expert opinion, has been described.[12]

Using a modified Delphi approach, a 17-member expert panel adjudicated the appropriateness of coronary revascularization, compared with medical therapy, for 198 distinct clinical indications, which were categorized by clinical indication, angiographic severity, magnitude of ischemia, severity of angina symptoms, and intensity of medical therapy.

From the individual ratings of the technical panel members, each clinical indication was classified as appropriate, uncertain, or inappropriate. An "appropriate" rating denotes that coronary revascularization, compared with medical therapy, would likely improve a patient's health status (symptoms, function, or quality of life) or survival; an "uncertain" rating implies that more research, patient information, or both is needed to further classify the indication; and an "inappropriate" rating suggests that the benefits of coronary revascularization are unlikely to outweigh the risks.

For additional details see 2012 Appropriate Use Criteria for Coronary Revascularization.[13]

The methodology used to develop the Appropriate Use Criteria for Coronary Revascularization has been described (see the **Box** for additional details).[1,13,14] The registry has developed validated algorithms mapping data collected using version 4 of the data collection form (beginning July 2009) to the Appropriate Use Criteria.[3] The Appropriate Use Criteria for Coronary Revascularization were revised in 2012 to provide greater specificity in defining nonacute indications.[13] For this analysis, we exclusively used the 2012 Appropriate Use Criteria.

Study Population and Definitions

The study cohort included all PCIs in the NCDR registry between July 1, 2009, and December 31, 2014. To accurately assess trends in appropriateness, we restricted our cohort to PCIs performed at hospitals that participated continuously in the registry during the entire study period. For patients undergoing multiple PCIs in a single visit, only the first PCI was included. We excluded hospitals that performed an average of fewer than 10 nonacute PCIs in each calendar year to provide more robust estimates of hospital performance.

Each PCI in our study cohort was initially classified as acute, nonacute, or nonmappable. Acute PCIs were defined as those performed in the setting of an acute coronary syndrome. Nonmappable PCIs were PCIs that could not be classified because of missing data elements (typically because noninvasive testing was not performed or not available). All other PCIs were considered nonacute. Each mappable PCI was then assigned a rating of procedural appropriateness (appropriate, uncertain, or inappropriate) based on the 2012 Appropriate Use Criteria for Coronary Revascularization.[13]

Statistical Analysis

All analyses were performed either at the patient level, using all PCIs to calculate an estimate, or at the hospital level, aggregating each hospitals' data to calculate a hospital-specific estimate.

PCI volume and the relative proportions of acute, nonacute, and nonmappable PCIs were examined at the patient level by year. Hospital-level variation in the proportions of PCIs for acute, nonacute, and nonmappable indications was examined across calendar year. Median hospital-level proportions with interquartile ranges were used to characterize the distribution and are displayed using box plots.

Baseline demographic and clinical characteristics as well as clinical presentation, background medical therapy, and results from noninvasive and angiographic studies were compared over time for all patients undergoing PCI and among those undergoing nonacute PCI. The proportions of appropriate, inappropriate, and uncertain PCIs at the patient level were calculated for each 6-month interval and compared over time. The proportion of nonacute PCIs considered inappropriate at the hospital level was calculated by aggregating all nonacute PCIs in the calendar year and displayed using box plots.

To identify the presence of different subgroups of hospital-level change in proportion of inappropriate PCI, we performed a latent growth curve analysis.[15,16] Latent-class growth curve analysis, using growth mixture modeling, serves to identify distinct patterns of change over time using each hospital's observed trajectory of the proportion of nonacute PCIs classified as inappropriate. Hospitals with similar patterns over time are grouped together and considered to form a latent class. The use of growth mixture modeling estimates a mean growth curve for each latent class while allowing for individual variation around the growth curve within each class. We fit 4 models: 2-group, 3-group, 4-group, and 5-group. For each model we evaluated the change in the Bayesian information criterion and calculated the approximated Bayes factor. We also plotted the observed vs the predicted values to evaluate model fit. The average posterior probabilities were used to ensure that the model adequately distinguished between identified groups. We chose the 4-group model because it performed best on these criteria. We performed this secondary analysis among hospitals in the highest quartile of proportion of inappropriate PCI between July 2009 and December 2010 to understand the trajectories of hospitals with the greatest opportunity for improvement. For each hospital, we then examined the proportion of inappropriate nonacute PCI from January 2011 to December 2014, grouping hospitals with similar patterns over time together. Last, we compared hospital characteristics across groups to identify hospital features associated with various patterns.

Statistical testing of trends was performed using the Cochran-Armitage test[17,18] for binary variables and the Jonckheere-Terpstra test[19] for categorical variables. To further assess sensitivity of hospital-level results to the aggregation of estimates within hospitals, we confirmed all test results using weighted general linear models, weighting estimates by hospital volume. Absolute changes in PCI volume and patient characteristics were calculated using 2010 and 2014 data, because the study interval began July 1, 2009. All tests for statistical significance were 2-tailed and evaluated at a significance level of .05, corrected for multiple comparisons using the Šidák correction.[20] All statistical analyses were performed using SAS version 9.3 (SAS Institute).

Results

More than 3.5 million PCIs were performed at 1561 hospitals between July 2009 and December 2014. We excluded 550 836 patients treated at 583 hospitals that did not participate continuously in the registry during the study period and an additional 273 167 cases performed at 212 facilities that performed an average of fewer than 10 nonacute PCIs in each calendar year, leaving 2 685 683 PCI procedures from 766 hospitals as the primary study cohort. Characteristics of the hospitals in the primary study cohort are shown in eTable 1 in the Supplement.

PCI Indication Over Time

Of the PCI procedures included in the analysis, 76.3% (95% CI, 76.2%-76.3%) were for acute indications, 14.8% (95% CI, 14.8%-14.9%) were for nonacute indications, and 8.9% (95% CI, 8.9%-9.0%) were nonmappable (**Table 1**). Annual PCI volume declined over the study period, from 538 076 in 2010 to 456 507 in 2014. The volume of acute PCI was relatively stable over time (377 540 in 2010; 374 543 in 2014), but there were significant declines in the volume of nonacute PCI (89 704 in 2010 and 59 375 in 2014; $P < .001$) and nonmappable PCI (70 832 in 2010 and 22 589 in 2014; $P < .001$). As a consequence, the proportion of PCIs performed for acute indications increased from 69.1% (95% CI, 68.8%-69.3%) in 2009 to 82.0% (95% CI, 81.9%-82.2%) in 2014. The proportion of PCIs for nonacute indications declined from 16.8% (95% CI, 16.7%-17.0%) to 13.0% (95% CI, 12.9%-13.1%), whereas the proportion of nonmappable PCIs declined from 14.0% (95% CI, 13.9%-14.2%) in 2009 to 4.9% (95% CI, 4.9%-5.0%) in 2014. Similar findings were noted at the hospital level (**Figure 1**).

Baseline Characteristics

Baseline demographic and clinical characteristics as well as the presence of angina symptoms, background antianginal medical therapy, results of noninvasive testing, and angiographic findings are reported in eTable 2 in the Supplement for the entire study cohort and in **Table 2** for patients undergoing nonacute PCI.

Among patients in the overall study cohort, the absolute number and relative proportion of patients undergoing PCI with Canadian Cardiovascular Society (CCS) grade I or II angina decreased over time, while the absolute number and relative proportion of patients with CCS grade IV angina increased over the study period. The numbers of patients undergoing PCI in the setting of an acute coronary syndrome (unstable angina,

Table 1. Acute, Nonacute, and Nonmappable Percutaneous Coronary Interventions From July 1, 2009–December 31, 2014

		Year					
PCI Indication/Year	Total	2009[a]	2010	2011	2012	2013	2014
Overall, No.	2 685 683	243 580	538 076	502 995	481 889	462 636	456 507
Acute							
No.	2 047 853	168 366	377 540	373 423	380 331	373 650	374 543
% (95% CI)	76.3 (76.2-76.3)	69.1 (68.9-69.3)	70.2 (70.0-70.3)	74.2 (74.1-74.4)	78.9 (78.8-79.0)	80.8 (80.7-80.9)	82.0 (81.9-82.2)
Nonacute							
No.	397 737	41 024	89 704	78 328	66 849	62 457	59 375
% (95% CI)	14.8 (14.8-14.9)	16.8 (16.7-17.0)	16.7 (16.6-16.8)	15.6 (15.5-15.7)	13.9 (13.8-14.0)	13.5 (13.4-13.6)	13.0 (12.9-13.1)
Nonmappable							
No.	240 093	34 190	70 832	51 244	34 709	26 529	22 589
% (95% CI)	8.9 (8.9-9.0)	14.0 (13.9-14.2)	13.2 (13.1-13.3)	10.2 (10.1-10.3)	7.2 (7.1-7.3)	5.7 (5.7-5.8)	4.9 (4.9-5.0)

Abbreviation: PCI, percutaneous coronary intervention.

[a] Includes July 1, 2009, to December 31, 2009.

ST-segment elevation myocardial infarction, non-ST-segment elevation myocardial infarction [NSTEMI]) were stable (367 253 in 2010 to 368 574 in 2014), with increases in the number of patients with NSTEMI (94 097 in 2010 to 107 225 in 2014) and decreases in the number of patients with unstable angina (194 008 in 2010 to 183 735 in 2014). Use of antianginal therapy increased over the study period, whereas use of noninvasive testing remained stable. The number and relative proportion of patients with unavailable or low-risk results on stress testing declined, whereas there was an increase in the number and relative proportion of patients with intermediate- and high-risk findings. The burden of coronary artery disease on angiography was similar over the study period.

Among patients undergoing nonacute PCI, the absolute number and relative proportion of patients without symptoms or with CCS grade I or II angina decreased over time. There was an increase in both the absolute number and relative proportion of patients undergoing nonacute PCI with CCS grade III angina (13 442 [15.0%] in 2010 to 20 727 [34.9%] in 2014). There was an increase in the use of antianginal therapy, with 80.6% of patients undergoing nonacute PCI in 2014 reported to be receiving at least 1 antianginal medication and 35.1% receiving 2 or more antianginal medications as compared with 69.8% and 22.3%, respectively, in 2010. Performance of noninvasive testing and fractional flow reserve testing increased over the study interval, from 64.6% and 8.1%, respectively, in 2010 to 72.5% and 30.8% in 2014. Moreover, the extent of ischemia with noninvasive testing changed over time, with 64.7% of patients having intermediate- or high-risk findings in 2010 as compared with 78.1% in 2014. The proportion of patients with multivessel coronary artery disease was 43.7% in 2010 and 47.5% in 2014.

Trends in Inappropriate PCI

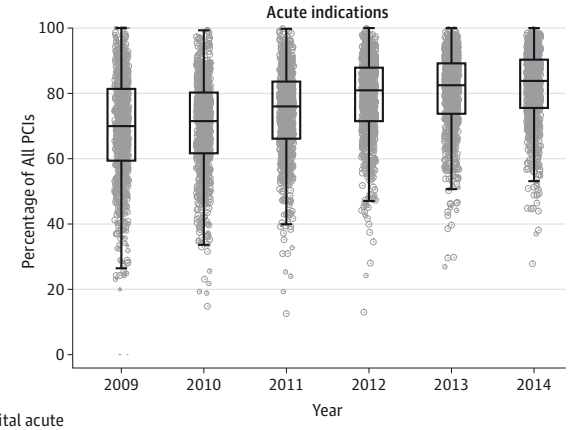
Between July 2009 and December 2014, the proportion of nonacute PCIs classified as inappropriate decreased from 26.2% (95% CI, 25.8%-26.6%) to 13.3% (95% CI, 13.1%-13.6%) ($P < .001$) (**Figure 2**A). The absolute number of inappropriate PCIs decreased from 21 781 in 2010 to 7921 in 2014. The percentage of nonacute PCIs classified as appropriate increased from 30.1% (95% CI, 29.7%-30.6%) to 53.6% (95% CI, 53.2%-54.0%), and those considered uncertain decreased from 43.7% (95% CI, 43.2%-44.2%) to 33.0% (95% CI, 32.6%-33.4%) (Figure 2A). Hospital-level trends in the proportion of inappropriate nonacute PCIs are shown in Figure 2B. The median hospital proportion of nonacute PCIs considered inappropriate decreased from 25.8% in 2009 to 12.6% in 2014. There was persistent variation in hospital-level proportion of nonacute PCIs classified as inappropriate over the study interval (interquartile range, 16.7%-37.1% in 2009 and 5.9%-22.9% in 2014).

Temporal Patterns Across Hospitals

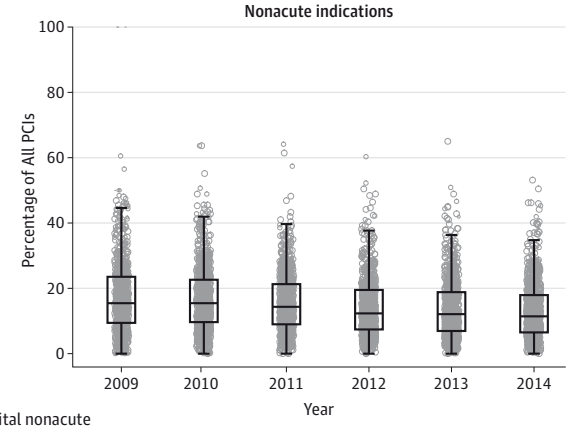
Among hospitals in the highest quartile for proportion of nonacute PCI deemed inappropriate from July 2009 to December 2010 (n = 191), we observed 4 distinct trajectories in changes in rates of inappropriate PCI from January 2011 to December 2014 (**Figure 3**). Hospitals in groups 1, 2, and 4 had similar baseline rates of inappropriate PCI; however, hospitals in group 4 (n = 108) demonstrated immediate and steady declines in rates of inappropriate PCI, from 43.9% (95% CI, 42.4%-45.3%) in 2009-2010 to 15.5% (95% CI, 14.0%-17.0%) in 2014. In contrast, hospitals in group 1 (n = 18) had minimal change in the first 2 years but demonstrated lower rates of inappropriate PCI in the last 2 years of the study period.

Hospitals in group 2 (n = 50) demonstrated steady but smaller absolute declines in rates of inappropriate PCI over the study period than groups 1 and 4, with the proportion of inappropriate nonacute PCIs decreasing from 40.9% (95% CI, 39.7%-42.1%) in 2009-2010 to 32.2% (95% CI, 30.4%-34.1%) in 2014. Last, hospitals in group 3 (n = 15) had the highest initial rates of inappropriate PCI but also the largest absolute decline over the study period, from 70.6% (95% CI, 68.5%-72.7%) in 2009-2010 to 9.4% (95% CI, 7.6%-11.1%) in 2014. There were no systematic differences in hospital characteristics, geographic location, financial status, or teaching status across hospital groups (eTable 3 in the Supplement).

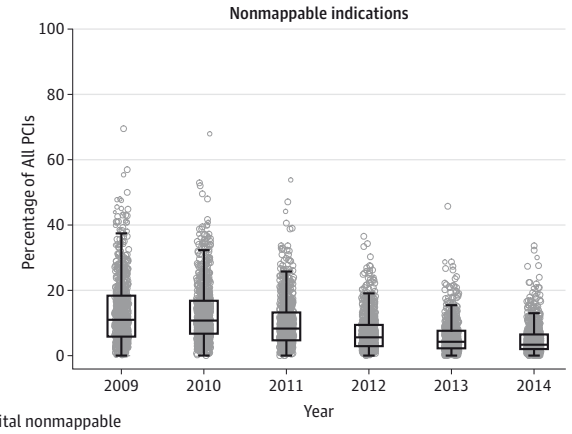
Figure 1. Proportion of PCIs for Acute, Nonacute, and Nonmappable Indications at the Hospital Level From 2009 to 2014



Hospital acute PCI volume, median No. (IQR)	2009	2010	2011	2012	2013	2014
	177 (101-289)	402 (246-629)	389 (255-614)	407 (264-627)	401 (262-620)	403 (265-620)



Hospital nonacute PCI volume, median No. (IQR)	2009	2010	2011	2012	2013	2014
	39 (20-72)	84 (46-151)	72 (39-127)	60 (34-107)	55 (29-100)	53 (27-98)



Hospital nonmappable PCI volume, median No. (IQR)	2009	2010	2011	2012	2013	2014
	30 (13-58)	61 (32-117)	44 (21-84)	28 (14-56)	22 (10-44)	18 (9-38)

All percutaneous coronary inteventions (PCIs) performed July 1, 2009, to December 31, 2014, at 766 hospitals participating continuously in the National Cardiovascular Disease Registry CathPCI Registry over study period. The horizontal line in the center of each box indicates the median; lower and upper bounds of each box, the 25th and 75th percentiles; error bars, 1.5 times the interquartile range. Each hospital is represented as a point; size of point reflects hospital volume. Results for 2009 include 6 months of data.

Discussion

Among patients undergoing PCI between July 2009 and December 2014, we found that volumes of nonacute PCIs declined significantly from 89 704 in 2010 to 59 375 in 2014, while the volume of acute PCIs remained stable, 377 540 in 2010 to 374 543 in 2014. In addition, we observed significant reductions in the proportion of nonacute PCIs classified as inappropriate, from 26.2% in 2009 to 13.3% in 2014. However, there was persistent hospital-level variation in the rate of inappropriate PCIs, with an interquartile range of 5.9% to 22.9% in 2014. Collectively, these findings suggest that the practice of interventional cardiology has evolved since the introduction of Appropriate Use Criteria in 2009.

This analysis provides details about changes in the clinical profiles of patients undergoing PCI and suggests that the observed reductions in inappropriate PCI in part reflect improvements in patient selection and clinical decision making as well as better documentation of the key elements used to determine procedural appropriateness. Trends consistent with improvements in patient selection include the reduction in nonacute PCI volume and changes in the clinical profile of patients undergoing nonacute PCI. We observed significant declines in the proportions of patients undergoing nonacute PCI who were asymptomatic or had minimal symptoms; who were not receiving or receiving only minimal antianginal therapy; and who had low- or intermediate-risk findings on noninvasive testing. We identified increased use of fractional flow reserve among patients with intermediate stenosis. These findings may indicate that clinicians are doing a better job of identifying and limiting nonacute PCI procedures to those patients most likely to benefit from revascularization.

We cannot exclude the possibility that reductions in inappropriate PCI may reflect changes in documentation or even intentional up-coding, particularly of subjective data elements such as symptom severity. Temporal trends in anginal symptom burden raise the possibility that this data element may be overestimated. Specifically, despite significant reductions in the volume of nonacute PCI, we observed increases in the numbers and proportions of patients reported to have CCS grade III and IV angina but minimal change in extent of coronary artery disease. Nevertheless, we did not see evidence that patients were being systematically shifted from nonacute to acute indications for PCI. The number of acute PCIs were stable over time, and the proportion of patients undergoing acute PCI reported to have unstable angina decreased.

The appropriateness of PCI has garnered attention from clinicians, insurers, and policy makers. It has been the subject of national quality improvement initiatives and incorporated into pay-for-performance programs. In our analysis, the observed reductions in inappropriate PCI appeared to accelerate in 2011, which coincided with the publication of a high-profile report on PCI appropriateness, the National Cardiovascular Data Registry's inclusion of procedural appropriateness in its benchmarking reports, and the launch of

Table 2. Baseline Characteristics of Patients Undergoing Nonacute Percutaneous Coronary Intervention (PCI) From July 1, 2009–December 31, 2014

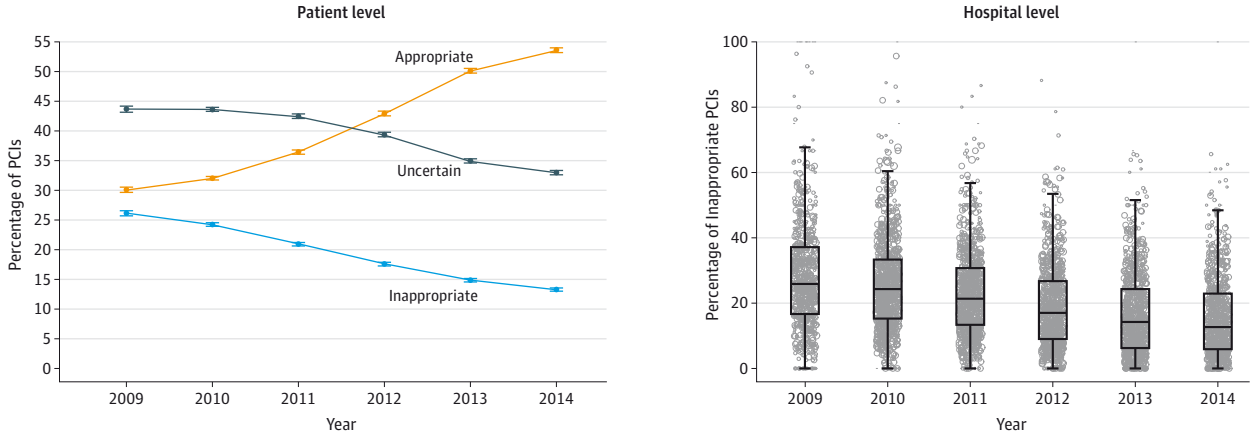
	No. (%)						
Patient Characteristics	Total	2009[a]	2010	2011	2012	2013	2014
No.	397 737 (100.0)	41 024 (10.3)	89 704 (22.6)	78 328 (19.7)	66 849 (16.8)	62 457 (15.7)	59 375 (14.9)
Age, mean (SD)	66.5 (10.9)	65.9 (11.1)	66.1 (11.0)	66.3 (10.9)	66.6 (10.8)	66.9 (10.8)	67.1 (10.8)
Male sex	275 469 (69.3)	27 574 (67.2)	60 902 (67.9)	53 801 (68.7)	46 433 (69.5)	44 457 (71.2)	42 302 (71.3)
White race	350 988 (88.3)	36 376 (88.7)	79 591 (88.7)	68 884 (87.9)	58 822 (88.0)	55 124 (88.3)	52 191 (87.9)
Insurance							
Private	278 236 (70.1)	27 640 (67.5)	61 789 (69.0)	54 489 (69.7)	47 129 (70.7)	44 514 (71.4)	42 675 (72.0)
Public only	109 827 (27.7)	12 432 (30.4)	25 723 (28.7)	21 734 (27.8)	17 909 (26.9)	16 417 (26.3)	15 612 (26.3)
Non-US citizens	266 (0.1)	33 (0.1)	57 (0.1)	46 (0.1)	37 (0.1)	40 (0.1)	53 (0.1)
None	8607 (2.2)	854 (2.1)	2004 (2.2)	1872 (2.4)	1600 (2.4)	1349 (2.7)	928 (1.6)
Clinical risk factors and comorbidities							
Current/recent smoker (<1 y)	77 355 (19.5)	8528 (21.0)	18 437 (20.6)	15 522 (19.8)	12 822 (19.2)	11 352 (18.2)	10 694 (18.0)
Hypertension	344 698 (86.7)	34 932 (85.2)	77 378 (86.3)	67 532 (86.3)	58 262 (87.2)	54 656 (87.5)	51 938 (87.5)
Dyslipidemia	341 445 (85.9)	34 755 (84.8)	77 123 (86.0)	67 145 (85.8)	57 191 (85.6)	53 981 (86.5)	51 250 (86.4)
Family history of CAD	93 873 (23.6)	10 084 (24.6)	21 969 (24.5)	18 789 (24.0)	16 194 (24.2)	14 450 (23.1)	12 387 (20.9)
Prior PCI	173 734 (43.7)	17 075 (41.6)	38 785 (43.2)	34 273 (43.8)	29 323 (43.9)	27 794 (44.5)	26 484 (44.6)
Prior CABG surgery	57 394 (14.4)	5096 (12.4)	11 615 (13.0)	10 877 (13.9)	9986 (14.9)	10 116 (16.2)	9704 (16.3)
Diabetes mellitus	156 865 (39.5)	15 505 (37.8)	34 023 (37.9)	30 794 (39.3)	26 627 (39.8)	25 467 (40.8)	24 449 (41.2)
CAD presentation							
No symptoms, no angina	91 046 (22.9)	11 899 (29.0)	23 889 (26.6)	18 367 (23.5)	13 902 (20.8)	12 301 (19.7)	10 688 (18.0)
Symptoms unlikely to be ischemic	41 247 (10.4)	4145 (10.1)	9577 (10.7)	8301 (10.6)	7179 (10.7)	6165 (9.9)	5880 (9.9)
Stable angina	265 444 (66.7)	24 980 (60.9)	56 238 (62.7)	51 660 (66.0)	45 768 (68.5)	43 991 (70.4)	42 807 (72.1)
Angina							
No symptoms	102 920 (25.9)	12 443 (30.3)	26 313 (29.3)	20 541 (26.2)	16 313 (24.4)	14 420 (23.1)	12890 (21.7)
CCS class I	44 889 (11.3)	6297 (15.4)	12 752 (14.2)	10 070 (12.9)	6484 (9.7)	4934 (7.9)	4352 (7.3)
CCS class II	148 898 (37.4)	15 824 (38.6)	34 958 (39.0)	31 366 (40.0)	25 842 (38.7)	21 571 (34.5)	19 337 (32.6)
CCS class III	89 909 (22.6)	5575 (13.6)	13 442 (15.0)	14 454 (18.5)	16 299 (24.4)	19 412 (31.1)	20 727 (34.9)
CCS class IV	11 121 (2.8)	885 (2.2)	2239 (2.5)	1897 (2.4)	1911 (2.9)	2120 (3.4)	2069 (3.5)
No. of antianginal medications							
0	102 655 (25.8)	13 811 (33.7)	27 076 (30.2)	21 306 (27.2)	15 719 (23.5)	13 222 (21.2)	11 521 (19.4)
1	187 154 (47.1)	19 272 (47.0)	42 610 (47.5)	37 427 (47.8)	31 930 (47.8)	28 884 (46.3)	27 031 (45.5)
≥2	107 885 (27.1)	7928 (19.3)	20 011 (22.3)	19 585 (25.0)	19 195 (28.7)	20 350 (32.6)	20 816 (35.1)
Stress or imaging test performed	273 237 (68.7)	26 720 (65.1)	57 942 (64.6)	53 045 (67.7)	47 420 (70.9)	45 041 (72.1)	43 069 (72.5)
Stress test results[b]							
Unavailable	40 046 (15.1)	5053 (19.6)	10 328 (18.4)	8373 (16.3)	6442 (14.0)	5142 (11.7)	4708 (11.2)
Low risk	37 316 (14.0)	4272 (16.5)	9548 (17.0)	7855 (15.2)	5953 (12.9)	5171 (11.8)	4517 (10.7)
Intermediate risk	116 078 (43.7)	10 756 (41.6)	23 920 (42.5)	22 416 (43.5)	20 319 (44.1)	19 709 (44.8)	18 958 (44.9)
High risk	72 463 (27.3)	5759 (22.3)	12 460 (22.2)	12 893 (25.0)	13 373 (29.0)	13 960 (31.7)	14 018 (33.2)
Fractional flow reserve among patients with 40%-70% lesions	14 636 (18.0)	706 (8.1)	1987 (10.2)	2285 (13.8)	2824 (21.6)	3369 (28.2)	3465 (30.8)
No. of diseased vessels (≥70% stenosis)							
0	2758 (0.7)	350 (0.9)	741 (0.8)	587 (0.8)	407 (0.6)	358 (0.6)	315 (0.5)
1	214 960 (54.1)	23 162 (56.5)	49 732 (55.4)	42 445 (54.2)	35 963 (53.8)	32 790 (52.5)	30 868 (52.0)
2	116 447 (29.3)	11 656 (28.4)	25 908 (28.9)	23 008 (29.4)	19 578 (29.3)	18 539 (29.7)	17 758 (29.9)
3	63 572 (16.0)	5856 (14.3)	13 323 (14.9)	12 288 (15.7)	10 901 (16.3)	10 770 (17.2)	10 434 (17.6)

Abbreviations: CABG, coronary artery bypass graft; CAD, coronary artery disease; CCS, Canadian Cardiovascular Society.

[a] Includes July 1, 2009, to December 31, 2009.

[b] Low risk (<1% annual mortality rate): low-risk treadmill score (≥5); normal or small myocardial perfusion defect at rest or with stress; normal stress echocardiographic wall motion or no change of limited resting wall motion abnormalities during stress. Intermediate risk (1%- 3% annual mortality rate): mild or moderate resting left ventricular dysfunction (left ventricular ejection fraction [LVEF] 35%-49%); intermediate-risk treadmill score (−11 to <5); stress-induced moderate perfusion defect without left ventricular dilation or increased lung intake (thallous chloride Tl 201); limited stress echocardiographic ischemia with wall motion abnormality only at higher doses of dobutamine involving ≤2 segments. High risk (>3% annual mortality rate): severe resting left ventricular dysfunction (LVEF <35%); high-risk treadmill score (≤−11); severe exercise left ventricular dysfunction (LVEF <35%); stress-induced large perfusion defect (particularly if anterior); stress-induced multiple perfusion defects of moderate size; large, fixed perfusion defect with left ventricular dilation or increased lung uptake (thallous chloride Tl 201); stress-induced moderate perfusion defect with left ventricular dilation or increased lung uptake (thallous chloride Tl 201); echocardiographic wall motion abnormality (>2 segments) developing at low dose of dobutamine (≤10 mg/kg/min) or at low heart rate (<120/min); stress echocardiographic evidence of extensive ischemia.

Figure 2. Proportions of Appropriate, Inappropriate, and Uncertain Percutaneous Coronary Intervention (PCI) at the Patient Level and at the Hospital Level Among Nonacute PCIs From July 1, 2009, to December 31, 2014



Nonacute PCI volume, No.	2009	2010	2011	2012	2013	2014
	41024	89704	78328	66849	62457	59375

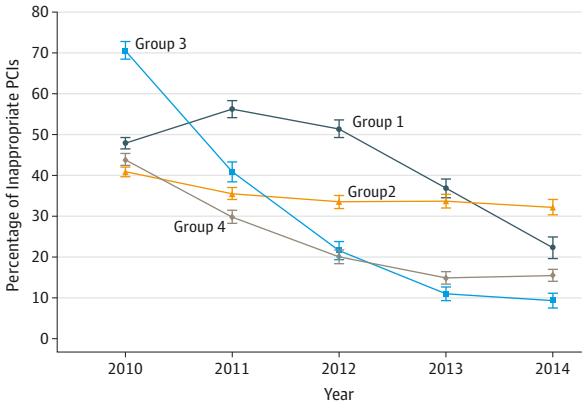
Hospital nonacute PCI volume, median No. (IQR)	2009	2010	2011	2012	2013	2014
	39 (20-72)	84 (46-151)	72 (39-127)	60 (34-107)	55 (29-100)	53 (27-98)

Rates of at the patient and hospital level among nonacute PCIs performed July 1, 2009, to December 31, 2014, at 766 hospitals participating continuously in the National Cardiovascular Disease Registry CathPCI Registry over study period. A, Point estimates for each classification of procedural appropriateness. Error bars indicate 95% CIs. B, The horizontal line in the center of each box indicates the median; the bottom and top box boundaries indicate the 25th and 75th percentiles, respectively; error bars indicate 1.5 times the interquartile range. Each hospital is represented as a point in the box plot; the size of the point reflects the hospital volume. Results from 2009 include 6 months of data.

national performance improvement campaigns.[3,7] Our findings are consistent with an analysis of PCI appropriateness in Washington State.[21] However, because the registry was not configured to characterize PCI appropriateness until July 2009, our analyses are limited to cases performed after the release of the Appropriate Use Criteria. As such, we could not evaluate the impact of the criteria, and our findings are best considered a description of changes in patterns of care and procedural appropriateness over this period. It is likely that many factors such as the publication of the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) and BARI 2D (Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes) trials influenced clinical practice during this time frame.[22,23]

We observed persistent variation in hospital-level performance of inappropriate PCI. Among better-performing hospitals (lowest quartile), fewer than 6% of nonacute PCIs in 2014 were classified as inappropriate. In contrast, among worse-performing hospitals (highest quartile), more than 22% of nonacute PCIs were classified as inappropriate. These findings suggest the need for ongoing performance improvement initiatives and hospital benchmarking. Among hospitals with the highest rates of inappropriate nonacute PCI from July 2009 to December 2010, we observed distinct trajectories from January 2011 to December 2014. Although the majority of hospitals with the highest baseline rates of inappropriate PCI demonstrated large reductions in the proportion of PCIs classified as inappropriate, we identified a group of hospitals with less than 10% absolute reduction in the proportion of inappropriate PCI over the study period.

Figure 3. Trends in Inappropriate Nonacute Percutaneous Coronary Intervention at Hospitals With the Highest Initial Proportion of Inappropriate PCI (>34% From July 2009 to December 2010)



Hospital nonacute PCI volume, median (IQR)	2010	2011	2012	2013	2014
Group 1 (n = 18)	49 (25-85)	42 (17-63)	43 (19-72)	38 (24-87)	31 (16-68)
Group 2 (n = 50)	73 (36-130)	67 (41-114)	53 (29-84)	39 (26-88)	33 (21-80)
Group 3 (n = 15)	29 (11-70)	27 (20-47)	37 (27-50)	38 (25-83)	37 (24-75)
Group 4 (n = 108)	63 (35-93)	57 (36-92)	47 (33-83)	51 (28-80)	49 (28-81)

Observed rates of inappropriate nonacute percutaneous coronary intervention (PCI) for 4 groups of hospitals identified by latent growth curve analysis. Error bars indicate 95% CIs. The analysis was restricted to hospitals with the highest initial rates of inappropriate nonacute PCI performed July 2009 to December 2010 (>34%, n = 191). Results shown for 2010 include data for 2009 and 2010.

The observed differences in timing and pace of change suggest both that Appropriate Use Criteria–related quality metrics are actionable and that the specific approach adopted by a hospital affects its performance. Identifying the organizational strategies and structures most strongly associated with lower rates of inappropriate PCI remains a potentially important area for future research.

There are several limitations to our analysis. First, not all hospitals that perform PCI in the United States participate in the registry. Furthermore, we excluded hospitals that did not participate in the registry throughout the entire study period, and these hospitals may have different rates of inappropriate PCI. Regardless, our analysis included nearly 2.7 million procedures performed across 766 facilities and to our knowledge represents the most comprehensive examination of PCI appropriateness to date. In addition, only including hospitals participating in the registry over the entire study period enabled us to more rigorously investigate temporal changes in PCI utilization, clinical characteristics, and appropriateness. Second, our analysis focused mostly on trends in potential overuse (ie, inappropriate PCI). Understanding whether Appropriate Use Criteria have introduced new barriers to the performance of medically necessary procedures remains an important topic that could not be addressed in our study. Relatedly, we only have information on patients undergoing PCI, rather than the larger population of patients with coronary artery disease who might be considered for revascularization. As such, we cannot determine whether the observed changes truly reflect improved patient selection or overestimation of patient symptoms. The integration of more objective assessments of patient-reported health status into routine clinical care may provide a way to reduce the chances of misclassifying symptom burden.[24]

Conclusions

Since the publication of the Appropriate Use Criteria in 2009, there have been significant reductions in volume of nonacute PCI. The proportion of nonacute PCIs classified as inappropriate has declined, although hospital-level variation in inappropriate PCI persists.

ARTICLE INFORMATION

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Author Contributions: Drs Desai and Curtis had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Desai, Bradley, Parzynski, Spertus, Ader, Curtis.
Acquisition, analysis, or interpretation of data: Desai, Bradley, Parzynski, Nallamothu, Chan, Patel, Ader, Soufer, Krumholz, Curtis.
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Obtained funding: Desai, Krumholz, Curtis.
Administrative, technical, or material support: Desai, Ader, Curtis.
Study supervision: Desai, Curtis.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Drs Desai and Krumholz reported being recipients of a research agreement from Johnson & Johnson, through Yale University, to develop methods of clinical trial data sharing. Drs Desai, Krumholz, and Curtis reported receiving funding from the Centers for Medicare & Medicaid Services to develop and maintain performance measures used for public reporting. Dr Spertus reported receiving funding from the American College of Cardiology to analyze the National Cardiovascular Disease Registry (NCDR) registries; serving as a member of the United Healthcare cardiac scientific advisory board; and holding an equity interest in Health Outcomes Sciences. Dr Patel reported receiving research grants, through Duke University, from Johnson & Johnson, AstraZeneca, Maquet, the Agency for Healthcare Research and Quality, and the National Heart, Lung, and Blood Institute; and serving on the advisory board of Bayer Healthcare, Jansen, and Genzyme. Dr Krumholz reported receiving research support from Medtronic, through Yale University, to develop methods of clinical trial data sharing; receiving a grant from the US Food and Drug Administration to develop methods for postmarket surveillance of medical devices; and chairing a cardiac scientific advisory board for UnitedHealth. Dr Curtis reported holding equity interest in Medtronic. No other disclosures were reported.

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November 18, 2015

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Olympia, WA 98504-2712

RE: Cardiac Stents – Re-Review: Draft Evidence Report, October 19,2015

Dear Mr. Morse

Thank you for the opportunity to comment on this draft report. We hope that we can work with the Health Technology Assessment Program (HTAP) to arrive at the optimal outcome for cardiovascular patients and taxpayers in Washington State. This report is the result of extensive research into the literature in this field.

The Society for Cardiovascular Angiography and Interventions is a 4,500-member professional organization representing invasive and interventional cardiologists in approximately 70 countries. SCAI's mission is to promote excellence in invasive/interventional cardiovascular medicine through physician education and representation, and advancement of quality standards to enhance patient care. SCAI's public education program, SecondsCount, offers comprehensive information about cardiovascular disease. For more information about SCAI and SecondsCount, visit www.SCAI.org or www.SecondsCount.org.

We remain concerned that the draft document, while representing an in-depth review of the literature, adds little to established guidelines and appropriate use criteria that already exist, and which are much more likely to be read and followed by cardiologists than this review. As an example, a recently published article examining the impact of AUC shows convincing evidence of the impact of such documents on the utilization of PCI nationally and in Washington State (1,2). We would also like to point out that there have been recent updates to two important guideline documents that can be found at: http://www.scai.org/Assets/10542bc9-c8be-48d1-aa84-c647137878b7/635810359561230000/scai-2015-10-21-primarypciupdate-pdf and http://www.scai.org/Assets/d428d716-f835-4a7d-a169-

8b2c8271aca5/635470782647170000/09017-fulltext-pdf. It is clear from the review that these and prior similar documents have already had an impact on the frequency of coronary stenting both nationally and more locally in the State of Washington (see our comments in the next paragraph).

In the draft document beginning on page 45 and continuing to page 47 are tables 1 to 5. There are several points to be made from these tables:

1. There is in general a decline in stenting overall, as noted in table 3, which is also reflected in national Medicare data as well.
2. The absolute number of patients receiving coronary stents is small compared to the population base covered by PEBB/UMP (0.03% in 2014)
3. The impact of the prior document on savings is interestingly absent from the tables and
4. The potential clinical and financial impact of this HTA draft document on the population served is therefore likely to be very small.

Specific responses to the Key Questions follows; starting with Key Question 1. It is not surprising that no mortality benefit was found comparing stenting to medical therapy since medical therapy is the cornerstone of treatment of chronic stable ischemic heart disease and the studies reviewed by and large serve as the foundation for the current guidelines and AUC. Revascularization, be it by surgery or stenting, would not be expected to impact hard endpoints like mortality with a chronic disease like coronary artery disease given long enough follow up. With respect to quality of life it is important to understand that studies looking at that endpoint typically use “as randomized methodology”, which while statistically valid, does not represent the way patients are treated with a chronic disease. In such studies, patients initially randomized to medical therapy but then cross over to revascularization because of worsened or uncontrolled symptoms are counted in the medical arm which “contaminates” follow up and potentially delivers and incorrect message, a message that in addition doesn’t reflect how patients are cared for long term with a chronic disease. As an example, the crossover rate in COURAGE was about 25% from the medical to revascularization arm.

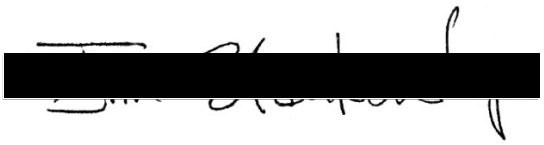
With respect to the review of the literature regarding Key Question 2, while extensive, it adds little important new information. As this body of data is reviewed it is important to remember that most of it was designed to determine any safety signals between DES and BMS and to be used by the companies developing the devices for FDA approval. The safety issue was looked at because there was a concern in the past (due to poorly designed meta analyses) that there might be excessive stent thrombosis with DES vs. BMS. Subsequent studies have confirmed that is not the case. The studies were not powered to determine if one device was superior to another with regard to stent thrombosis/MI. They were also not designed to evaluate mortality with respect to one device being superior to another. Looking for superiority of one device vs. another from these studies can be predicted to show no difference. This is exactly what has been shown in the draft document. These limitation exist with many of the other RCTs that were designed to lead to FDA approval of newer DES stents and not to show that DES was superior to BMS. Superiority

of DES to BMS with respect to instent restenosis, in most cases, has been generally accepted by the cardiology community based on the totality of the evidence that has been generated from initial approval of the coronary stent in 1995 to date, not just since the prior HTA document in 2009. If one reviews the extensive evidence tables in the draft document it is clear that most of the evidence is of low to moderate strength which speaks to the evidence and raises concerns about the validity of any conclusions drawn from the review. As we stated in our 2009 HTA response we, as interventional cardiologist, have no vested interest in which stent type (DES vs. BMS) is chosen since physicians are not reimbursed based on the type of stent used. We are truly the patient's advocate when it comes to this aspect of their care.

We would also like to point out that evaluations such as this will likely become more difficult in the future as the focus moves away from BMS vs. DES to studies looking at new platforms to deliver anti restenotic drugs to the coronaries. A prime example of this are bioreabsorable platforms that are on the near horizon for approval in the US. In addition, because of the prohibitive cost associated with bringing these devices to market in the US, trials have not and will not be designed as superiority studies but as non-inferiority trials. This will add additional complexity to this type of literature review. It will also bring to question any attempt to draw inferences using meta analyses of future datasets based on these trials.

We believe this review, while extensive, does not further inform the HTA process with respect to the key questions and adds little to the previous document. It is our opinion that, absent data to confirm otherwise, there will likely be little cost savings to the State from this exercise. We also firmly believe that going forward, reviews such as this will add little to guidelines and other documents produced by national organizations such as SCAI, ACC and the AHA. With all due respect the proper use of these devices and where they fit within the armamentarium used to treat coronary artery disease, a chronic disease with no cure, has been informed by the literature and not by reviews such as this.

Sincerely,



James C. Blankenship, MD, MHCM, FSCAI
President

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