Certificate of Need Program
Tertiary Service Review
Attn: Kyle Karinen, Office of Legal Services
Washington State Department of Health
P.O. Box 47873
Olympia, WA 98504-7873

February 26, 2015

Dear Mr. Karinen:

Please find attached a proposal (with appendix) to delete elective therapeutic cardiac catheterization, including percutaneous coronary interventions generally and elective percutaneous coronary angioplasty specifically (referred to collectively as "elective PCI"), from the list of services identified as tertiary under WAC 246-310-020(1)(d)(i).

This is in response to the Department's January, 2015 announcement, pursuant to WAC 246-310-035, of its review process to decide if any changes are necessary to the tertiary services list. It is being submitted on behalf of CHI Franciscan Health's Highline Medical Center, Capital Medical Center, Yakima Valley Memorial Hospital, Legacy Salmon Creek Medical Center and Walla Walla General Hospital.

The question before the Department is whether elective PCI meets the criteria established in WAC 246-310-035(2) for listing as a tertiary service. As detailed in this proposal, there is substantial, conclusive data indicating that it does not – and should therefore be removed from the list.

We look forward to the Department's favorable consideration. If you have any questions, or would like additional information, please let me know.

Sincerely,

Jonathan Seib

Jonathan Seib
Seib Policy and Public Affairs LLC

Proposal to Remove Elective PCI from the Listing of Tertiary Services Identified in Certificate of Need Rules WAC 246-310-020

1. Executive Summary/Key Findings:

For the reasons outlined in this proposal, both the current delivery model and published outcomes data render the inclusion of elective PCI inconsistent with the Department of Health's (Department) definition of tertiary services contained in WAC 246-310-035. With this nomination, we respectfully request that it be removed from the list.

This Proposal provides the rationale and supporting data to demonstrate that:

1) Elective PCI does not meet the criteria in WAC 246-310-035 for a determination of a tertiary service; and

2) Elective PCI is an outlier on the current listing of tertiary services found in WAC 246-310-020 because:

   - Elective PCI is the only service listed as tertiary that is provided on an outpatient basis (where it is performed nearly half the time).
   - PCI is the only service listed as tertiary for a small subset of cases. Emergent PCI are 77% of total cases but are not "tertiary" and require no CN. Notably, the remaining 23% that are regulated under CN are more stable, less complex, and lower risk.
   - With nearly one in three hospitals (34 total) in the state currently providing PCI, it is not characterized by relatively few providers.
   - PCI is a single procedure. Differences are limited to the type of stent used, the number of blood vessels involved and if a patient has existing complications.
   - The PCI use rate of 2.1 per 1,000 state residents places it at the very high end of services listed as tertiary.
   - Data shows the volume of PCI performed by a Washington hospital, or the availability of on-site surgery, have no significant bearing on outcomes.
   - Very rarely in the case of elective PCI does the need develop to immediately transfer a patient for more complex services. At one in every 1,000 cases, the immediate transfer rate is significantly lower than for many services not listed as tertiary.
   - Major complications from elective PCI are very low in comparison to the majority of services listed as tertiary (in-hospitality mortality rate of 0.6% compared to 3.0% for open heart surgery and up to 8.3% for heart transplants).

For these reasons, elective PCI is fundamentally different than the other services on the tertiary list and the data included within this proposal substantiates why it should be removed from the list. We respectfully request that this Proposal be approved and that elective PCI be removed from the listing of tertiary services found in WAC -246-310-020.

2. Background/Current Washington Environment:

Until 2008, elective PCI or elective therapeutic cardiac catheterization was defined in Washington's Certificate of Need rules as tertiary, and it could only be performed in hospitals that had secured CN approval or previously been grandfathered to operate an open heart program. Elective PCI was included on the list of tertiary services in 1989 primarily due to safety concerns. In the pre-stent era (pre 1995), the risk of major complication (death, MI (pre-troponin), or need for emergency bypass for elective PCI was about 5% and on-site surgical back-up was seen as necessary. The advent of stents, bailout devices, better pharmacotherapy and better equipment/technology has resulted in a dramatic reduction in risks and has allowed elective PCI to largely occur in the outpatient setting.

In 2008, while retaining the tertiary definition of elective PCI, the CN Program adopted rules to allow elective PCI to be performed in hospitals without on-site open heart surgery capability, as long as certain criteria were met to include minimum volumes. These volumes include both emergency and elective volumes. At the time the CN Program was developing these rules, the more robust, supportive data cited in this Proposal was not yet available.

The definition of elective PCI is found in two separate places in Chapter 246-310. WAC 246-310-020 (1)(d)(i)(E) reads:

> *E) Open heart surgery and/or elective therapeutic cardiac catheterization including elective percutaneous translumenal coronary angioplasty (PTCA). Open heart surgery includes the care of patients who have surgery requiring the use of a heart lung bypass machine.* ***Therapeutic cardiac catheterization means passage of a tube or other device into the coronary arteries or the heart chambers to improve blood flow. PTCA means the treatment of a narrowing of a coronary artery by means of inflating a balloon catheter at the site of the narrowing to dilate the artery****;*

WAC 246-310-675(2) and (4) defines both elective and PCI, as follows:

> *2) "Elective" means a PCI performed on a patient with cardiac function that has been stable in the days or weeks prior to the operation. Elective cases are usually scheduled at least one day prior to the surgical procedure.*
>
> *4) "Percutaneous coronary interventions (PCI)" means invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. These interventions include, but are not limited to:*

(a) Bare and drug-eluting stent implantation;
(b) Percutaneous transluminal coronary angioplasty (PTCA);
(c) Cutting balloon atherectomy;
(d) Rotational atherectomy;
(e) Directional atherectomy;
(f) Excimer laser angioplasty;
(g) Extractional thrombectomy.

Washington's Clinical Outcomes Assessment Program (COAP) was established to collect, analyze, report and provide hospitals with the clinical information needed to improve the quality of care provided to cardiac patients and to meet the growing demand for accountability in the health care industry. COAP started collecting data on PCIs in 1998, and provided the first annual report in 1999. Currently, data from cardiac revascularization programs is submitted to COAP by each hospital that performs such procedures. COAP's timely reporting mechanism provides hospitals with clinical feedback on at least a quarterly basis; it establishes quality standards by peer consensus and is transparently posted on COAP's interactive website.

This model has proven exceptionally effective, and the result is that COAP's data documents that there is **no significant difference in outcomes in Washington based on annual case volume or the availability of on-site surgery**. Current regulations define a minimum volume threshold of 300 PCI cases per year. It should be noted that in 2014, 18 or 53% of the 34 hospitals in Washington are performing less than 300 total PCIs per year, and, per COAP, each maintains excellent quality.

According to COAP, there were a total of 12,096 total PCIs performed in Washington's hospitals in the 12 month period ending June 30, 2014. Of this, 2,831 or 23% were "non-acute". Non-acute is the COAP definition that most closely correlates with the Department's elective PCI definition. Because of the slightly different definitions used within the industry, a glossary of terms is included as Attachment 1. Of the elective cases, 48% were performed on patients with an outpatient discharge status. In fact, Medicare currently requires elective PCI to be performed on an outpatient basis. The average length of stay for these outpatient PCIs is less than 24 hours, with over 200 cases being discharged the same day as the PCI procedure.

3. Elective PCI Does Not Meet the Current Tertiary Services Definition:

The process for determining whether a service is tertiary and a listing of those services deemed to be tertiary has not been updated since 1993. The list of tertiary services has also not been updated since 1993.

The process for determining whether a service is tertiary is found at WAC 246-310-035 (2):

> *2) In determining whether a service is a tertiary service the department shall consider the degree to which the service meets the following criteria:*
>
> *(a) Whether the service is dependent on the skills and coordination of specialties and subspecialties. Including, but not limited to, physicians, nurses, therapists, social workers;*
> *(b) Whether the service requires immediate access to an acute care hospital;*
> *(c) Whether the service is characterized by relatively few providers;*
> *(d) Whether the service is broader than a procedure;*
> *(e) Whether the service has a low use rate;*
> *(f) Whether consensus supports or published research shows that sufficient volume is required to impact structure, process, and outcomes of care; and*
> *(g) Whether the service carries a significant risk or consequence.*

The list of services defined as tertiary since 1993 includes:

> *(a) Specialty burn services*
> *(b) Intermediate care nursery and/or obstetric services level II*
> *(c) Neonatal intensive care nursery and/or obstetric services level III*
> *(d) Transplantation of specific solid organs, including, but not limited to, heart, liver, pancreas, lung, small bowel and kidney and including bone marrow*
> *(e) Open heart surgery and/or elective therapeutic cardiac catheterization including elective percutaneous translumenal coronary angioplasty (PTCA)*
> *(f) Inpatient physical rehabilitation services level I*
> *(g) Specialized inpatient pediatric services*

On September 30, 2014, a group including cardiologists, physicians, service line administrators, regulators, COAP staff and consultants experts were convened with the sole purpose of discussing whether elective PCI as delivered today in Washington State meets the current tertiary services identification. After several hours of robust discussion, there was full consensus that the definition of tertiary is at best, not clear, and at worst, confusing. That said, there was also consensus that elective PCI is different than—an outlier---from the other services defined as tertiary.

Evaluation of Elective PCI against the Criteria Contained in WAC 246-310-035 Indicates that it does Not Meet the Criteria

Below we have responded to each criterion in WAC 246-310-035 to demonstrate the differences.

(a) Whether the service is dependent on the skills and coordination of specialties and subspecialties. Including, but not limited to, physicians, nurses, therapists, social workers;

- ✓ **Elective PCI is not differentiated from other acute care services, most of which are not defined as tertiary, by this criterion.**

The group convened on September 30 concurred that elective PCI is dependent on the skills of at least an interventional cardiologist and the catheterization lab team. That said, the group remarked that this criterion appears applicable to nearly every acute care service, and were not certain how this criterion would help establish whether the service is tertiary.

(b) Whether the service requires immediate access to an acute care hospital;

- ✓ **Elective PCI is not differentiated from other acute care services, most of which are not defined as tertiary, by this criterion.**

While elective PCI does require access to an acute care hospital, this is only because the equipment and staff that perform the procedure are hospital-based, not based on risk or transfer needs. Per COAP, the immediate need for transfer for CABG is 0.1%, or less than 1 person for every 1,000 elective cases. This rate of immediate transfer is significantly lower than for many other non-CN regulated procedures. The reality is that nearly 50% of elective PCI cases, while hospital-based, are performed in an outpatient setting with an average length of stay for elective cases of less than 24 hours.

(c) Whether the service is characterized by relatively few providers;

- ✓ **Elective PCI is not characterized as having few providers – 1 out of every 3 hospitals perform PCIs, and if Critical Access Hospitals are excluded from the count, virtually 100% of hospitals are performing PCI.**

According to COAP, in the 12 month timeframe ending September 30, 2014, 34 hospitals in the State, or approximately 40% of all non-pediatric, non-specialty acute care hospitals performed PCI[1]. Of these, only seven do not have certificate of need approval to perform elective PCI,[2] meaning that 27 current hospitals, or 31% of all non-pediatric, non-specialty acute care hospitals

[1] Excludes licensed psychiatric hospital, LTACHs and specialty hospitals such as SCCA. Dedicated children's hospitals and Group Health are also excluded.
[2] Highline, Walla Walla, Swedish Issaquah, Trios, Yakima Valley Memorial, St. Anthony and Harborview.

can provide both elective and emergent PCI. From our perspective nearly 1 out of every 3 hospitals cannot be characterized as "relatively few". In fact, if Washington's 38 Critical Access Hospitals are excluded from the count, virtually 100% of the non-pediatric, non-specialty acute hospitals are performing PCI.

Importantly, each of the seven hospitals that lack certificate of need approval to perform elective PCI are currently performing the more complicated and complex emergent (STEMI and UA/NSTEMI) cases. While they are prohibited from performing elective cases; by virtue of their emergent program and the fact that the procedures performed are the same (just the patient status differs), they maintain the staff, policies, equipment and resources to provide elective PCI. The reality is that, in many of these communities these hospitals are the safety net for both EMS and the community for emergency PCI. However, it is increasingly difficult to attract and retain board certified interventional cardiologists and trained catheterization laboratory staff in communities wherein these clinicians are prohibited from performing elective PCI. Several emergency PCI hospitals and the EMS systems in their communities are gravely concerned about the ability to sustain 24/7 emergency PCI without the ability to perform elective procedures.

The Department should be encouraging the providers with emergency programs to add elective capabilities, thereby increasing their ability to sustain these important safety net programs.

(d) Whether the service is broader than a procedure;

- ✓ **Elective PCI is a single procedure – and less than 25% of all PCIs are currently subject to CN review.**

PCI is also largely a single procedure. PCI is defined in WAC 246-310-710 as five DRGs (518 and 555-558). In 2008, CMS updated those DRGs, and they are now 246-251, defined below:

MS-DRG 246 Perc cardiovasc proc w drug-eluting stent w MCC or 4+ vessels/stents
MS-DRG 247 Perc cardiovasc proc w drug-eluting stent w/o MCC
MS-DRG 248 Perc cardiovasc proc w non-drug-eluting stent w MCC or 4+ ves/stents
MS-DRG 249 Perc cardiovasc proc w non-drug-eluting stent w/o MCC
MS-DRG 249 – Perc cardiovasc proc w non-drug-eluting stent w/o MCC
MS DRG 250 – Perc cardiovasc proc w/o coronary artery stent w MCC
MS DRG-251 – Perc cardiovasc proc w/o coronary artery stent w/o MCC

Each of these DRGs is exactly the same medical procedure—a percutaneous cardiovascular procedure. The procedure is performed in a cath lab, and usually completed in less than one hour's time. The only difference in the DRGs is whether a drug-eluting stent is used, the number of vessels involved and whether the patient has complications or co-morbidities. **It is also important to note that there is no distinction between elective or emergency procedures – the DRG codes are exactly the same. The difference is that currently only those procedures performed on an elective basis (on patients determined by the cardiologist to have cardiac function that has been stable in the days or weeks prior to the operation) are subject to review.**

Since 2007, the Department has mailed an Annual Outpatient Percutaneous Coronary Intervention Survey to hospitals. A copy of the DOH's survey instructions is included as Attachment 2. In the survey instructions, it states: *ICD-9 code 0.66 has been identified as the procedure code for these outpatient PCIs.* ICD-9 00.66 is defined as

00.66 - Percutaneous transluminal coronary angioplasty [PTCA]

Other possible codes include 36.07: Insertion of drug-eluting coronary artery stent(s) and code 00.43: Procedure on four or more vessels or code 00.48: Insertion of four or more vascular stents. Again, the difference is whether a drug-eluting stent is used and the number of vessels involved they are all a single procedure: a percutaneous cardiovascular procedure.

(e) Whether the service has a low use rate;

- ✓ **PCI is not characterized by a low use rate, instead with over 12,000 PCI cases performed in 2013, its use rate it significantly higher than almost all other tertiary services.**

While there is no definition of "low" in the rules, since over 12,000 PCI cases were performed in 2013, PCI clearly does not meet this criterion. Case in point, and as identified in Table 1 below, this volume results in the PCI use rate being significantly higher (2.12 per 1,000) than that of many other tertiary or quaternary services in Washington (be they regulated or not). These numbers do include all PCI procedures – whether performed on an elective or emergent basis because, again, the procedure is the same. The difference is simply the status of the patient – whether they are stable and need an elective procedure or if they are in an emergent situation. The standard for determining quality in a CN application for elective PCI recognizes this and requires all procedures (emergent and elective) be included. Therefore, we have also included all procedures in this use rate.

However, even if only looking at elective patients (less than 25% of the total procedures performed), the use rate of 0.50 procedures per 1,000 residents age 15+ still results in elective PCI being at the high end of many of the services on the tertiary list.

Table 1 Tertiary Service Discharges, 2013 for WA State Residents					
Tertiary Services	**# of Hospitals**	**Metric**	**2013 Volumes (Discharges), Age 15+**	**2013 Population, 15+**	**Use Rate**
Transplantation of Solid Organs (pancreas)	1	MSDRGs: 010	1	5,567,598	0.000
Transplantation of Solid Organs (kidney/pancreas)	3	MSDRG: 008	13	5,567,598	0.002
Transplantation of Solid Organs (lung)	1	MSDRGs: 007	35	5,567,598	0.006
Transplantation of Solid Organs (liver/intestine)	3[3]	MSDRGs: 005, 006	70	5,567,598	0.013
Transplantation of Solid Organs (heart)	3	MSDRGs: 001, 002	109	5,567,598	0.020
Transplantation of Solid Organs (bone marrow)	6[4]	MSDRG: 014, 016, 017	204	5,567,598	0.037
Transplantation of Solid Organs (kidney)	5[5]	MSDRG: 652	286	5,567,598	0.051
Specialty Burn Services	4[6]	MSDRGs : 927-929, 933-935	469	5,567,598	0.084
Open Heart Surgery (age 15+)	18	MSDRGs: 216-221, 228-236	5,330	5,567,598	0.957
Inpatient Rehabilitation Level I	4	50% of Rehab Discharges for Level I adult trauma facilities	1,200	5,567,598	0.215
PCI (age 15+)	34	COAP Non-Acute	11,828[7]	5,567,598	2.12
Neonatal Intensive Care and/or OB Level III	16	MSDRGs: 789, 790 (newborn DRGs)	2,452	86,819	242.71
Intermediate Care nursery or Level II OB	17	MSDRGs : 791, 792, 793, 794 (Newborn DRGs)	21,072	86,819[8]	28.24

[3] Count includes Seattle Children's (for discharges age >15).
[4] Ibid.
[5] Ibid.
[6] Only 4 had 5 or more discharges.
[7] Elective volume is 2,793 but since the procedures are the same (only patient status is different) and the total procedures are included in the methodology in determining appropriate volumes, it is appropriate to include the total volume as the comparison.
[8] Population is age 0 only.

(f) Whether consensus supports or published research shows that sufficient volume is required to impact structure, process, and outcomes of care; and

✓ **There is no correlation between volume and outcomes for Elective PCI.**

First and foremost, Washington State specific COAP data identifies no correlation between volume and outcomes.

As depicted in Table 2, actual data on Washington's hospitals identifies that for Washington volume is not a factor in quality. There is no significant difference in mortality or adverse events by size of program. Each of the seven "non-CN approved programs" operates below 200 cases annually, yet demonstrates outcomes at or above its peers with CN approval to perform elective cases. (Remember, these "non-CN approved programs" are currently performing only the higher risk emergency procedures, making the lack of difference in outcomes even more compelling!)

Table 2
2013 Q4 - 2014 Q3 COAP PCI Totals by Hospital

	Emergent		*Elective*			*Emergent*		*Elective*	*Mortality*			
Hospital	**STEMI**	**Non-STEMI**	**Non-ACUTE**	**Total**	**% Non-Acute**	**% Adverse Events STEMI**	**% Adverse Events Non-STEMI**	**% Adverse Events Non-Acute**	**STEMI**	**Non-STEMI**	**Non-Acute**	**All PCI**
Un-Named Hospital	1	2	1	4	25.0%	0.0%	50.0%	100.0%	0.0	0.0	0.0	0.0
St. Anthony	24	5	0	29	0.0%	8.3%	0.0%	No Data	2.5	0.0	No Data	1.9
Kennewick	12	28	4	44	9.1%	8.3%	3.6%	0.0%	1.5	3.2	0.0	2.1
Harborview	42	12	0	54	0.0%	24.0%	8.3%	No Data	1.3	0.0	No Data	1.0
Walla Walla	15	43	0	58	0.0%	13.0%	0.0%	No Data	1.0	0.0	No Data	0.9
Swedish-Issaquah	30	46	3	79	3.8%	23.0%	17.0%	0.0%	0.0	0.0	0.0	0.0
Capital	15	34	38	87	43.7%	27.0%	0.0%	0.0%	3.1	2.2	0.0	2.5
Sub-Total Under 100	139	170	46	355	13.0%	19.2%	6.1%	1.1%				
Auburn	56	48	3	107	2.8%	8.9%	10.0%	0.0%	1.5	0.7	0.0	1.2
Highline	58	78	0	136	0.0%	19.0%	2.6%	No Data	2.0	0.0	No Data	1.6
UWMC	8	90	41	139	29.5%	25.0%	8.9%	4.9%	0.0	1.5	2.3	1.6
PeaceHealth St. John	25	84	44	153	28.8%	4.0%	11.0%	6.8%	2.2	2.0	0.0	2.0
Yakima Valley	46	108	3	157	1.9%	24.0%	13.0%	0.0%	1.6	0.9	0.0	1.2
Yakima Regional	37	109	27	173	15.6%	22.0%	14.0%	19.0%	1.2	0.0	0.0	0.7
St. Francis	43	111	35	189	18.5%	9.3%	5.4%	0.0%	0.8	0.0	0.0	0.7
Sub-Total Under 200	273	628	153	1054	14.5%	16.1%	9.3%	4.8%				

	Emergent		*Elective*			*Emergent*		*Elective*	*Mortality*			
Hospital	**STEMI**	**Non-STEMI**	**Non-ACUTE**	**Total**	**% Non-Acute**	**% Adverse Events STEMI**	**% Adverse Events Non-STEMI**	**% Adverse Events Non-Acute**	**STEMI**	**Non-STEMI**	**Non-Acute**	**All PCI**
Swedish-Edmonds	66	95	49	210	23.3%	9.1%	11.0%	4.1%	0.0	1.4	0.0	0.8
Northwest	47	129	54	230	23.5%	4.3%	7.8%	11.0%	1.2	2.1	0.0	1.4
Good Samaritan	109	162	12	283	4.2%	6.4%	3.7%	0.0%	1.2	3.8	0.0	1.7
Valley	88	173	28	289	9.7%	18.0%	10.0%	11.0%	0.9	0.9	0.0	0.9
Skagit Valley	68	208	30	306	9.8%	7.4%	2.4%	3.3%	0.2	0.0	0.0	0.1
Central WA	82	154	82	318	25.8%	32.0%	8.4%	8.5%	1.4	0.4	8.1	1.3
Deaconess	73	239	56	368	15.2%	23.0%	14.0%	11.0%	1.2	0.4	2.2	1
Sub-Total Under 400	533	1,160	311	2,004	15.5%	15.4%	8.3%	7.2%				
PeaceHealth Southwest	147	255	13	415	3.1%	19.0%	3.5%	0.0%	2.9	1.0	0.0	2.3
Kadlec	115	240	120	475	25.3%	18.0%	6.7%	5.0%	0.6	1.9	0.0	0.8
Evergreen	100	277	122	499	24.4%	10.00%	4.30%	4.1%	0.6	0.4	2.2	0.6
Virginia Mason	42	191	274	507	54.0%	14.0%	5.8%	4.7%	0.6	0.9	1.3	0.8
Overlake	67	329	113	509	22.2%	9.0%	5.5%	7.1%	1.3	0.8	0.0	0.9
Harrison	140	307	81	528	15.3%	12.0%	7.2%	7.4%	0.8	0.6	0.0	0.7
Tacoma General	62	429	142	633	22.4%	16.0%	8.4%	4.9%	0.9	0.9	0.0	0.9
PeaceHealth St. Joseph	104	383	198	685	28.9%	31.0%	13.0%	11.0%	1.3	1.7	2.6	1.5
St. Joseph MC	98	479	139	716	19.4%	12.0%	4.8%	5.0%	1.4	1.1	2.2	1.3
Providence St. Peter	219	456	167	842	19.8%	11.0%	6.8%	6.6%	0.7	0.5	1.8	0.7
Providence Everett	206	316	325	847	38.4%	15.0%	9.2%	8.9%	0.4	0.8	0.7	0.5
Swedish-Cherry Hill	112	263	513	888	57.8%	26.0%	20.0%	17.0%	0.9	1.1	0.8	1.0
Sacred Heart	235	790	114	1,139	10.0%	16.0%	9.9%	7.0%	0.9	1.4	0.0	1.0
Sub-Total Over 400	1,647	4,715	2,321	8,683	26.7%	16.4%	8.8%	7.5%				
TOTAL	**2,592**	**6,673**	**2,831**	**12,096**	**23.4%**	**16.3%**	**8.7%**	**7.0%**				

Source: Raw Data from COAP Website for 2013 Q4 - 2014 Q3; aggregated without risk-adjusting.

COAP recently published a report on PCI activity in 2013. This document is included in Attachment 3. The Report provides comparisons of mortality, CABG, Transfer for CABG and Composite Adverse events and its conclusions further substantiate that outcomes in Washington do not vary by program size. Specifically:

> Slide 3: Provides a comparison based of three PCI subgroups. (STEMI, N-STEMI and Non-Acute). This slide demonstrates that Non-Acute (elective) procedures have statistically significantly lower risk in all 4 measures.
>
> Slide 5: Compares outcomes by hospital PCI volume. This slide demonstrates no volume outcome relationship.
>
> Slide 6: Demonstrates that 48% of non-acute (elective) PCI are outpatient - not part of a hospital stay (at discharge).

Further, COAP has developed Level I and II outcome indicators, and every program in the State meets these indicators. A copy of the indicators is included as Attachment 4.

Nationally, recommendations are also focusing less on volume and more on quality metrics and outcomes. Washington is unique in that it has already put into place quality metrics that the national bodies are currently recommending.

In 2007, the American Heart Association/American College of Cardiology (AHA/ACC) and the Society of Cardiac Angiography and Interventions (SCAI) each published expert consensus statements regarding the provision of PCI. These statements served, in significant part, as the basis for the Department's 2007 elective PCI certificate of need rules. Since 2007, seven studies and two meta-analyses of PCI have been published that have shown no difference for in-hospital or 30 day mortality between sites with and without on-site surgery.

The newest AHA/ACC and SCAI consensus documents, coupled with the data being published by COAP, demonstrate neither increased mortality nor greater need for emergency CABG at sites without on-site cardiac surgery or with low volumes. This is directly attributable to the quality review that has been put in place and is actively overseen by COAP.

Further, in 2011 the AHA/ACC upgraded elective PCI to Class IIa (weight of evidence/opinion is in favor of usefulness/efficacy) at facilities without on-site surgery. In 2013, the AHA/ACC again updated its Consensus statement. The SCAI did the same in early 2014. Both of those documents placed decreasing focus on volumes and increasing focus on quality review and reporting. The 2013 AHA/ACC document states *the use of PCI volume as a surrogate for quality and the adoption of arbitrarily-defined annual volume standards, despite the lack of definitive evidence, have generated much controversy*. The 2014 SCAI document noted f*acility requirements are similar to those presented in past documents but now include a greater emphasis on the presence of quality review programs for facilities and operators.*

The published literature, including most recently the updated ACC/AHA (*Update of the Clinical Competence Statement on Coronary Artery Intervention Procedures,* May 8, 2013) and SCAI

(May 2014) include volume recommendations, but explicitly state that factors such as quality reporting are equally or more important. Washington is unique in that it invested in, and has put into place the mechanisms that are most consistently demonstrated to improve quality outcomes.

In March 2012, the AHA issued a policy statement on PCI without surgical backup defining two major reasons for providing PCI without on-site surgery.

> *First, PCI without on-site surgery is considered reasonable if the intent is to provide high quality timely primary PCI for patients with STEMI. The statement recommended that each community and facility in the community have an agreed-upon plan for how STEMI patients are to be treated. The plan should indicate hospitals that should receive STEMI patients from EMS units capable of obtaining diagnostic electrocardiograms, the management at the initial receiving hospital and written criteria and agreements for the expeditious transfer of patients from non PCI-capable to PCI-capable facilities. Second, PCI without on-site surgery is a reasonable consideration for providing local care to patients and families who do not want to travel significant distances or who have certain preferred local physicians. This is an important consideration, but the policy statement emphasized that evolving evidence suggests that such centers should have mechanisms in place to ensure high quality care.*

In 2014, the SCAI went further. Its statement indicated:

> *Facility requirements are similar to those presented in* ***past documents but now include a greater emphasis on the presence of quality review programs for facilities and operators, as described in the 2013 PCI competency document***[4] *Diagnostic modalities such as IVUS and especially fractional flow reserve previously considered desirable for facilities without on-site surgery have now increased in importance and are necessary for all PCI centers.*

Copies of the most recent AHA/ACC and SCAI reports are included as Attachment 5 and 6 respectively.

(g) Whether the service carries a significant risk or consequence.

- ✓ **Elective PCI is not characterized by this criterion; and in fact carries significantly lower risk than emergency PCI which is not defined as tertiary.**

Again, significant risk or consequence is not defined. Table 3 provides summary statistics presented by COAP at the September 30 stakeholder meeting and demonstrates that major complications from elective PCI are very low and in line with other elective outpatient procedures. It also confirms that the procedures currently performed on emergent patients (which are not subject to the tertiary services definition) carry a higher risk than the elective cases that are subject review. The data is for CY2013.

Table 3 Mortality, Transfer to CABG and Adverse Events: Non-Acute and STEMI PCI			
	Elective	Emergent	
Metric	Non-Acute PCI	STEMI	N-STEMI
Mortality	0.6%	6.5%	1.3%
To OR for CABG	0.7%	2.2%	0.9%
Transfer for CABG	0.1%	0.4%	0.1%
Composite Adverse Events	5.2%	11.9%	4.1%

Source: COAP, CY 2013

Table 4 provides the in-hospital mortality rates for all currently defined tertiary services.

Table 4 In-Hospital Mortality Rates for Tertiary Services	
Tertiary Services	In-Hospital Mortality
Specialty Burn Services	1.3%
Intermediate Care nursery or Level II OB	0.0%
Neonatal Intensive Care and/or OB Level III	7.8%
Transplantation of Solid Organs (heart)	8.3%
Transplantation of Solid Organs (liver/intestine)	2.9%
Transplantation of Solid Organs (pancreas)	0.0%
Transplantation of Solid Organs (kidney/pancreas)	0.0%
Transplantation of Solid Organs (lung)	2.9%
Transplantation of Solid Organs (kidney)	0.0%
Transplantation of Solid Organs (bone marrow)	2.9%
Open Heart Surgery (age 15+)	3.0%
Elective PCI (age 15+)	0.6%
Inpatient Rehabilitation Level I	0.2%

Source: WA State CHARS

4. Factors Differentiating Elective PCI from Other Services Defined as Tertiary:

Elective PCI is inherently different than any other service on the CN Program's list of tertiary services found in WAC 246-310-020 most relevantly because:

Elective PCI is the only tertiary service wherein hospitals are allowed to perform a procedure on higher level/more complex/higher risk patients (emergent PCI) without prior CN review but are required to undergo CN review to perform the same procedure on less complex, lower risk patients.

PCIs can be divided into three general groupings: 1) PCI for STEMI (ST Elevated Myocardial infarction) a heart attack which is treated as a life threatening emergency, 2) PCI for N-STEMI/ UA (Non-ST Elevated Myocardial Infarction or Unstable Angina) are acute events usually necessitating PCI within 24 hours; and 3) Elective PCI, usually scheduled as an Outpatient procedure in advance Washington hospitals are currently allowed to perform emergent PCIs (STEMI and NSTEMI/UA PCIs) which are more complex, and higher risk without prior CN review. CN review is only required for elective PCI, the same procedure, but on less complex, and lower risk patients. Only about 23% of the total PCI procedure volume falls into the category of "elective" and is subject to certificate of need review.

COAP data proves conclusively that emergent PCI is higher risk and more complex (see Table 2); yet Washington has always allowed these procedures to be done without the restrictions of a prior CN review. If this philosophy were extended to other services on the list, hospitals would need a CN to provide Level 1 neonatal care, but not Level 2 or 3; or hospitals would need CN approval to establish Level 2 and 3 rehabilitation services, but not Level 1. This is not the case, because in these examples, the Department fundamentally understood that the purpose of the tertiary service definition is to regulate only the most complex and highest risk services. The reality is that technology has changed the face of cardiac care to such an extent that elective PCI no longer fits within the definition of a tertiary service.

No Other Tertiary Service Has Any Activity Occurring on an Outpatient Basis

According to COAP, in 2013, 48% of all non-acute PCIs were performed on patients with an outpatient discharge status. As depicted in Table 5, not one of the other tertiary services has even a 1% outpatient rate.

Table 5 Current Tertiary Services and Percent Outpatient			
Tertiary Services	**Metric**	**2013 Volumes (Discharges), Age 15+**	**% Outpatient**
Specialty Burn Services	MSDRGs : 927-929, 933-935	469	0.00%
Intermediate Care nursery or Level II OB	MSDRGs : 791, 792, 793, 794 (Newborn DRGs)	21,072	0.00%
Neonatal Intensive Care and/or OB Level III	MSDRGs: 789, 790 (newborn DRGs)	2,452	0.00%
Transplantation of Solid Organs (heart)	MSDRGs: 001, 002	109	0.00%
Transplantation of Solid Organs (liver/intestine)	MSDRGs: 005, 006	70	0.00%
Transplantation of Solid Organs (pancreas)	MSDRGs: 010	1	0.00%
Transplantation of Solid Organs (kidney/pancreas)	MSDRG: 008	13	0.00%
Transplantation of Solid Organs (lung)	MSDRGs: 007	35	0.00%
Transplantation of Solid Organs (kidney)	MSDRG: 652	286	0.00%
Transplantation of Solid Organs (bone marrow)	MSDRG: 014, 015	204	0.00%
Open Heart Surgery (age 15+)	MSDRGs: 216-221, 228-236	5,330	0.00%
Inpatient Rehabilitation Level I	All Rehab Discharges for Level I Facilities (MHS Good Sam, Harborview, St. Luke & UWMC)	1,200	0.00%
Specialized Inpatient Pediatric Services (complex pediatric cases w/LOS > 24 hours)	By definition; none are outpatient		0.00%
Total PCI (age 15+)	MSDRGs: 246-251	2,793	48%

Source: 2013 CHARS Database and 2013 DOH PCI OP Surveys

A very effective and proven Washington program, COAP, establishes quality standards, holds institutions accountable for performing to those standards and publicly and transparently reports data by individual hospital.

Ongoing participation in COAP by all facilities that perform PCI procedures will ensure that a continuous monitoring process is in place which will immediately identify variations in care and make certain that the quality of care remains high across the state. In fact the ideal way for the state to move forward would be to have regular updates from COAP about outcomes from the various facilities to determine if programs should continue or if new programs should be started.

The COAP program has provided a written statement regarding their ability and willingness to work with the Department to establish a working relationship for quality assessment (Attachment 7).

5. Conclusion:

In conclusion, the data demonstrates convincingly that elective PCI does not meet the criteria contained in WAC 246-310-035 used to determine whether a service is tertiary. Most importantly, data provided by Washington State's nationally renowned COAP Program shows no correlation between volume and outcome. We attribute this to COAP's commitment to report and provide hospitals with the clinical information needed to improve the quality of care and the shared commitment to work together to improve care and outcomes.

PCI is also clearly an outlier compared to the other services currently reviewed. Most notably, 76% of PCI procedures in Washington are currently not subject to the tertiary services definition and are not subject to CN review. Only those PCI procedures performed on more stable patients with less risk and better outcomes are subject to review. However, when the Department evaluates a certificate of need, its review criteria in WAC 246-310 (700-755), includes all PCI procedures in the volumes necessary to demonstrate a quality program.

This distinction in the tertiary services definition is arbitrary and not supported by the current data. Washington has the mechanisms in place to ensure quality of all PCI providers without CN review. Elective PCI should be removed from the tertiary services definition.

6. Next Steps:

Per the Department's notice on the tertiary service update, the review process will consist of three phases:

Phase 1: January 1, 2015 – February 28, 2015
The first phase consists of this announcement and a two month period for people to propose changes to the current list of tertiary services. At the end of this phase the department will consolidate the suggestions into a report of proposed changes. This report will then be broadly distributed through the program's general communications listserv and posted to the program's webpage. **This proposal represents our compliance with Phase 1 of this process.**

Phase 2: March 16, 2015 – April 15, 2015
The second phase is a 30 day comment period when the department will accept comments on the report of proposed changes. All proposed changes must address whether the service meets or partially meets the criteria listed below for continued status as a tertiary service or inclusion as a new tertiary service. The criteria are[1]:

a) Whether the service is dependent on the skills and coordination of specialties and subspecialties, including, but not limited to, physicians, nurses, therapists, social workers;
b) Whether the service requires immediate access to an acute care hospital;
c) Whether the service is characterized by relatively few providers;
d) Whether the service is broader than a procedure;
e) Whether the service has a low use rate;

[1] WAC 246-310-035(2)

f) Whether consensus supports or published research shows that sufficient volume is required to impact structure, process, and outcomes of care; and
g) Whether the service carries a significant risk or consequence.

Phase 3: April 16, 2015 – June 15, 2015

The third phase is the department's assessment of comments or proposals. The Department will decide if any changes to the current list of tertiary services in necessary. During this phase information may be exchanged between the Department and persons proposing changes.

Attachment 1
Glossary of Terms

Attachment 1
Glossary of Terms

1. **Adverse events**
   As defined by COAP, Adverse event rates for PCI include: vascular complications; new renal failure (new requirement for dialysis OR creatinine increase to >2.0 AND creatinine increase to twice the baseline level); unplanned CABG; surgery for other PCI complications; tamponade; new cardiogenic shock; occlusion of the treated lesion, unsuccessful procedure (post-procedure stenosis > 50% or decrease of < 20% from pre-procedure stenosis).

2. **In-Hospital Mortality**
   COAP defines in-hospital mortality as any death during hospitalization

3. **Level I Clinical Outcome Indicators**
   Measures selected by COAP as quality standards because for each indicator, a persistent outlier may signal a serious program deficiency.

4. **Level II Clinical Outcome Indicators**
   Measures selected by COAP as process and quality measures focus on specific areas of patient management. A pattern of persistent outliers in three or more of these measures may also suggest a serious program deficiency.

5. **Level III Clinical Outcome Indicators**
   Indicators selected by COAP that comprise both new measures that are being tested as well as prior Level II measures that should continue to be encouraged as good practice but which will not be subject to sanctions.

6. **NCDR CathPCI Registry**
   National Cardiovascular Data Registry developed by the American College of Cardiology which serves as a quality improvement resource though the capture and reporting of trusted and reliable data. CathPCI collects data on PCI as well as diagnostic cardiac catheterizations. NCDR currently has 7 other registries, in addition to CathPCI, such as ACTION for Acute MI and Implantable Cardioverter Defibrillator (ICD).

7. **PCI - Percutaneous Coronary Intervention**

Different terms exist in the regulations to define basically the same procedure – a Percutaneous Coronary Intervention or PCI.

a) WAC 246-310-605 (4) defines PCI, as follows:
   "Percutaneous coronary interventions (PCI)" means invasive but nonsurgical mechanical procedures and devices that are used by cardiologists for the revascularization of obstructed coronary arteries. These interventions include, but are not limited to:

   (a) Bare and drug-eluting stent implantation;
   (b) Percutaneous transluminal coronary angioplasty (PTCA);
   (c) Cutting balloon atherectomy;
   (d) Rotational atherectomy;
   (e) Directional atherectomy;
   (f) Excimer laser angioplasty;
   (g) Extractional thrombectomy.

b) WAC 246-310-020 (1)(d)(i)(E) reads:
Open heart surgery and/or elective therapeutic cardiac catheterization including elective percutaneous translumenal coronary angioplasty (PTCA). Open heart surgery includes the care of patients who have surgery requiring the use of a heart lung bypass machine. ***Therapeutic cardiac catheterization means passage of a tube or other device into the coronary arteries or the heart chambers to improve blood flow. PTCA means the treatment of a narrowing of a coronary artery by means of inflating a balloon catheter at the site of the narrowing to dilate the artery****;*

7. PCI - Elective

WAC 246-310-705 defines Elective as a PCI performed on a patient with cardiac function that has been stable in the days or weeks prior to the operation. Elective cases are usually scheduled at least one day prior to the surgical procedure.

a) Non-Acute

COAP does not use the same classifications as used in the regulations (emergent and elective. Instead it has three classifications: non-acute, STEMI, and N-STEMI. Non-acute is the category that is most similar to the elective PCI definition contained in WAC

8. PCI - Emergent

WAC 246-310-705 defines Emergent as a patient needs immediate PCI because, in the treating physician's best clinical judgment, delay would result in undue harm or risk to the patient. COAP has two classifications that fit within this definition of "emergent": STEMI and N-STEMI.

a) PCI for STEMI (ST Elevated Myocardial infarction) - a heart attack which is treated as a life threatening emergency

b) PCI for N-STEMI/UA (Non-ST Elevated Myocardial Infarction or Unstable Angina) - acute events usually necessitating PCI within 24 hours.

8. Tertiary Health Service

WAC 246-310-010 (59) defines "Tertiary health service" as a specialized service meeting complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care.

Attachment 2
DOH Annual PCI Survey Instructions

Washington State Department of Health

Washington State Certificate of Need Program
2014 Annual Outpatient Percutaneous Coronary Intervention Survey
For Calendar Year 2013

Survey Instructions:

- **ICD-9 code 00.66** has been identified as the procedure code for these outpatient PCIs. However, if ICD-9 code 00.66 does not capture all outpatient PCIs performed at your facility, please include the additional PCI counts and identify the ICD-9 code associated with them.
- If your facility did not perform any outpatient PCI procedures in calendar year 2013, please answer with a zero.
- If you have more than one hospital licensed under the same license, provide the information below for **each site separately** where PCIs are performed.
- Add more tables if needed. Blank tables attached at the end of this form.

Below is the response format sample. **The actual survey is on page two of this form.**

Calendar Year 2013	
Zip Code	**Number of Outpatient PCIs**
Sample	XXX
Sample	XXX
Sample	XXX
Total	

ICD-9 Codes used in this Response	
00.66	XX.XX
XX.XX	XX.XX

The responses provided on the next page are in accordance with provisions in Revised Code of Washington 70.38 and Washington Administrative Code 246-310 adopted by the Washington State Department of Health. I hereby certify that the statements made in this survey are correct to the best of my knowledge and belief.

Person Completing Survey, include title (*if any*): _____
TYPE or PRINT

Signature of Person Completing Survey: _____

Phone #: _____

Washington State Department of Health

Name of Facility: _____

UBI Number: _____

Facility Address: _____

_____

Calendar Year 2013			
Zip Code	Number of Outpatient PCIs	Zip Code	Number of Outpatient PCIs
Total		Total	

List of all ICD 9 codes used in this response									
00.66									

There are many ways you can provide your information:

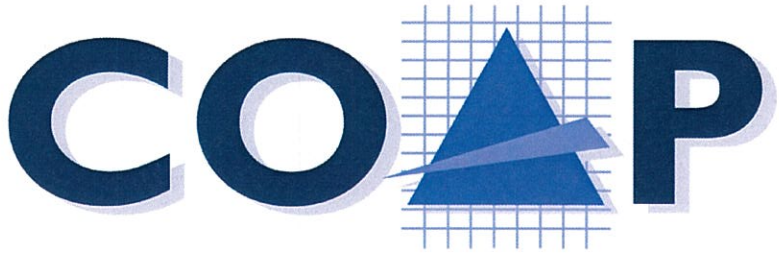
- You can mail this completed survey using the enclosed, self-addressed envelope.
- You can e-mail it to the Certificate of Need Program at fslcon@doh.wa.gov
- You can fax it to the Certificate of Need Program at (360) 236-2901.
- You can send it to one of the following addresses.

Mailing Address:
Department of Health
Certificate of Need Program
PCI Survey-2014
Mail Stop 47852
Olympia, WA 98504-7852

FedEx and UPS:
Department of Health
Certificate of Need Program
PCI Survey-2014
111 Israel Road SE
Tumwater, WA 98501

Thank you for your cooperation

Attachment 3
COAP Program Review



CLINICAL **OUTCOMES ASSESSMENT** PROGRAM

A PROGRAM OF THE FOUNDATION FOR HEALTH CARE QUALITY

Shilpen Patel, MD; Medical Director, COAP
Kristin Sitcov; Program Director, COAP & OB COAP

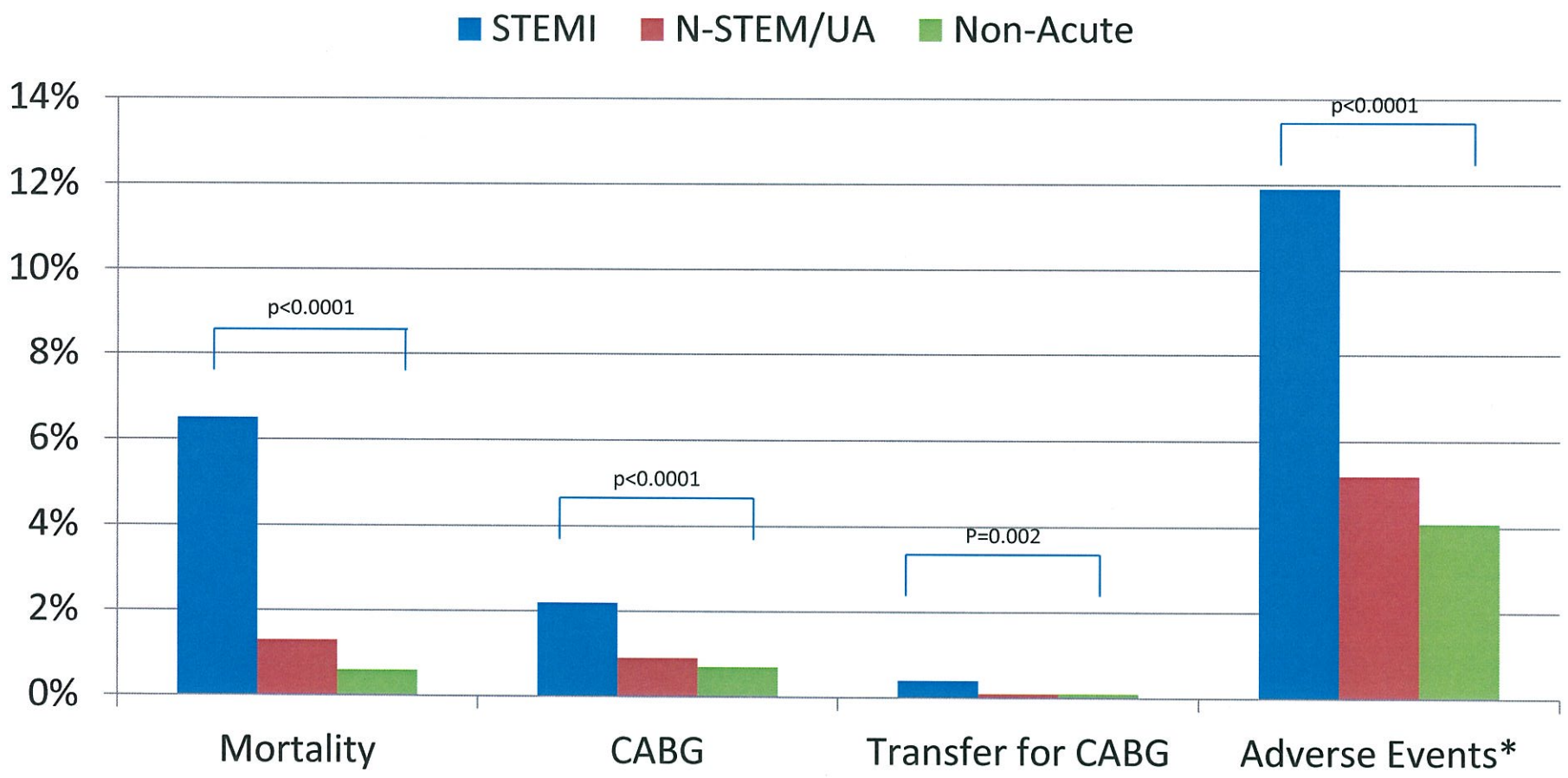
CABG: coronary artery bypass graft
STEMI: ST elevation myocardial infarction
NSTEMI: non ST elevation myocardial infarction
UA: unstable angina
PCI: percutaneous coronary intervention

*** Expected Mortality:**
From COAP PCI mortality model

**** Adverse Events:**
Defined as one or more of the following: stroke; new renal failure; dialysis; cardiogenic shock; CVA or stroke; hemorrhagic stroke; tamponade; RBC or whole blood transfusion; bleeding event within 72 hours; bleeding at access site; hematoma at access site; retroperitoneal bleeding; gastrointestinal bleeding; genital-urinary bleeding; other bleeding; or other vascular complications; occlusion of a treated lesion; or unsuccessful procedure.

Association Between Outcomes & *PCI Indication*

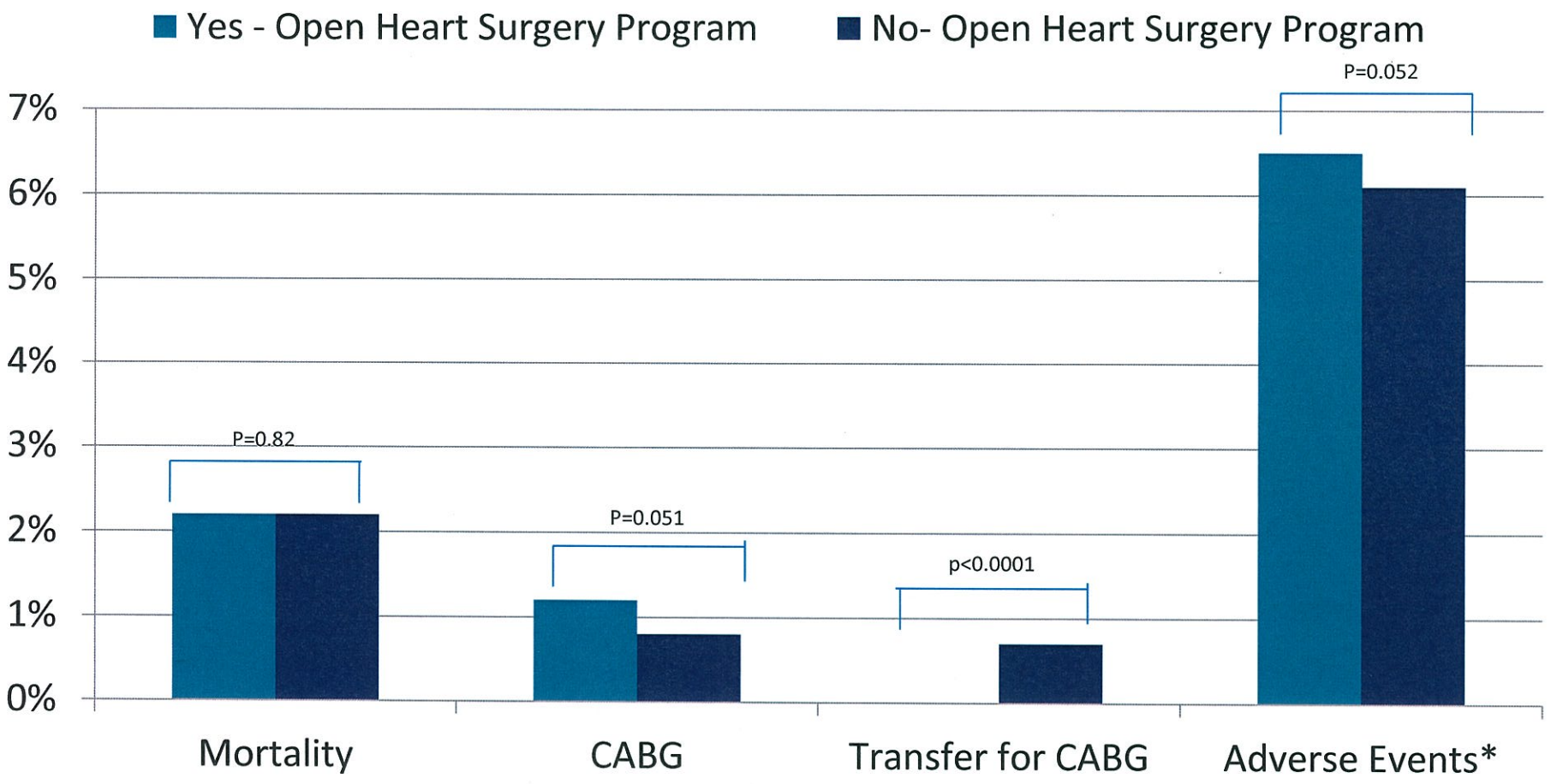
CLINICAL OUTCOMES ASSESSMENT PROGRAM
A PROGRAM OF THE FOUNDATION FOR HEALTH CARE QUALITY



	Outcomes				
PCI indication	Observed mortality	Expected mortality*	CABG	Transfer for CABG	Adverse event**
STEMI(n=2537)	165 (6.5%)	6.8%±16.0%	57 (2.2%)	11 (0.4%)	302 (11.9%)
NSTEMI/UA (n=6575)	86 (1.3%)	1.2%±5.2%	57 (0.9%)	8 (0.1%)	343 (5.2%)
Non-acute (n=2855)	16 (0.6%)	0.5%±3.4%	20 (0.7%)	2 (0.1%)	117 (4.1%)
P	<0.0001	<0.0001	<0.0001	0.002	<0.0001

Association Between Outcomes & *On-Site Open Heart Surgery Program*

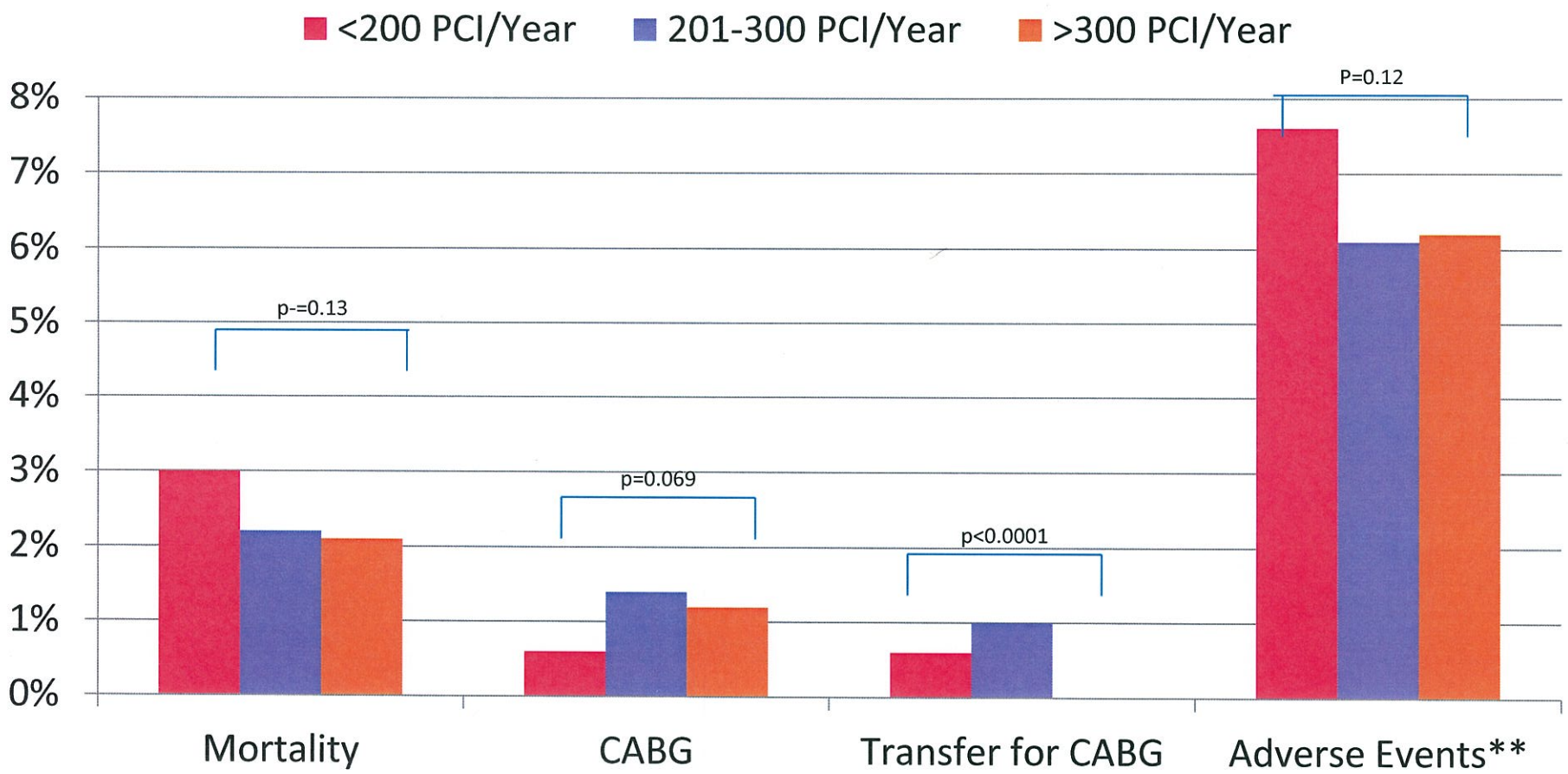
CLINICAL OUTCOMES ASSESSMENT PROGRAM
A PROGRAM OF THE FOUNDATION FOR HEALTH CARE QUALITY



	Outcomes				
Open heart surgery program	Observed mortality	Expected mortality*	CABG	Transfer for CABG	Adverse event**
Yes (n=8756)	70 (2.2%)	2.1%±8.6%	108 (1.2%)	0 (0.0%)	565 (6.5%)
No (n=3212)	197 (2.2%)	2.5%±9.2%	26 (0.8%)	21 (0.7%)	197 (6.1%)
P	0.82	0.043	0.051	<0.0001	0.52

Association Between Outcomes & *PCI Procedure Volume*

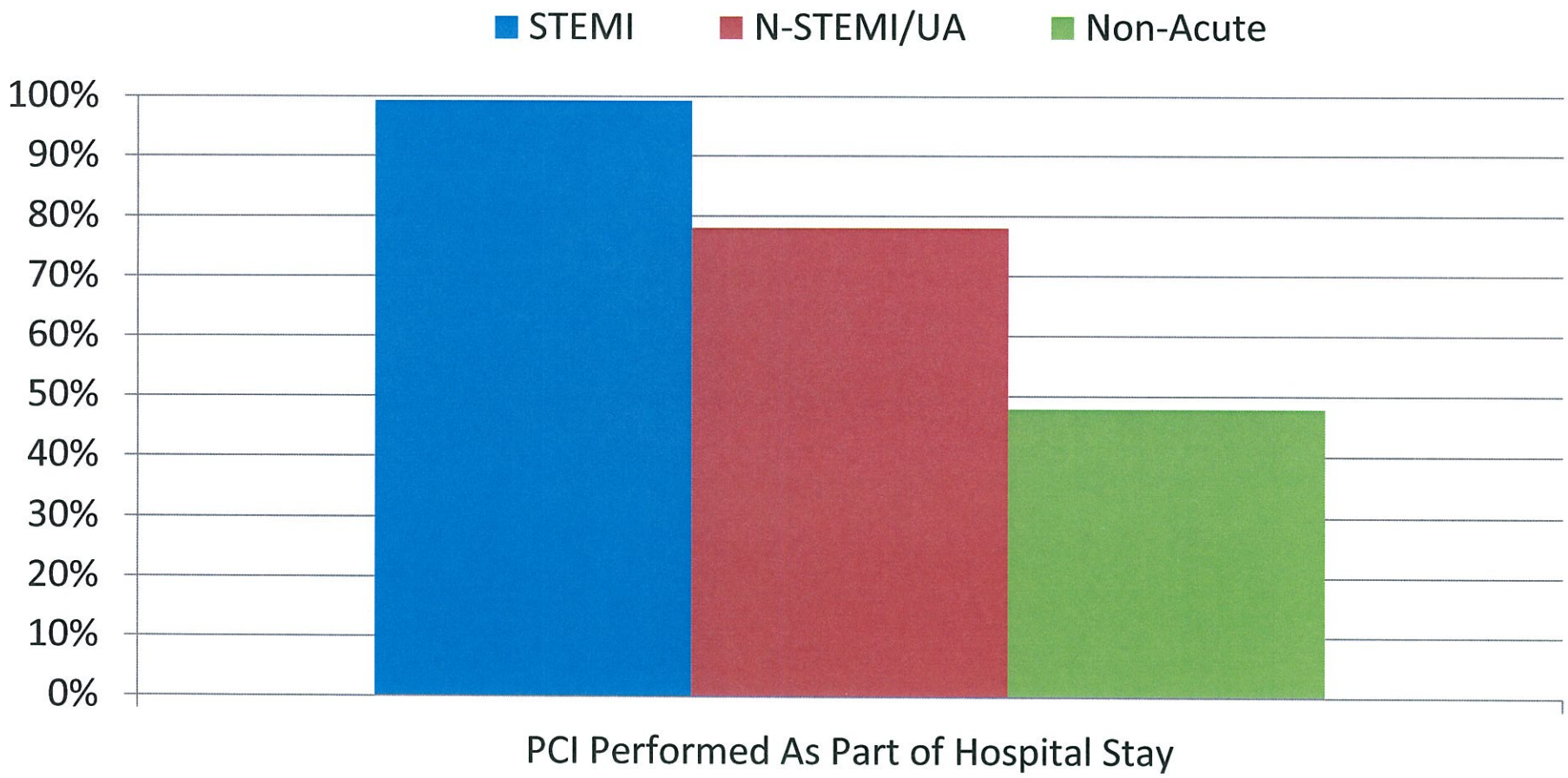
CLINICAL OUTCOMES ASSESSMENT PROGRAM
A PROGRAM OF THE FOUNDATION FOR HEALTH CARE QUALITY



	Outcomes				
Annual PCI volume	Observed mortality	Expected mortality*	CABG	Transfer for CABG	Adverse event**
< 200 (n=1448)	43 (3.0%)	2.6%±8.7%	8 (0.6%)	8 (0.6%)	110 (7.6%)
201-300 (n=1280)	28 (2.2%)	2.6%±9.5%	18(1.4%)	13 (1.0%)	78 (6.1%)
> 300 (n=9240)	196 (2.1%)	2.1%±8.7%	108 (1.2%)	0 (0.0%)	574 (6.2%)
P	0.13	0.060	0.069	<0.0001	0.12

Hospital Status According to PCI Indication

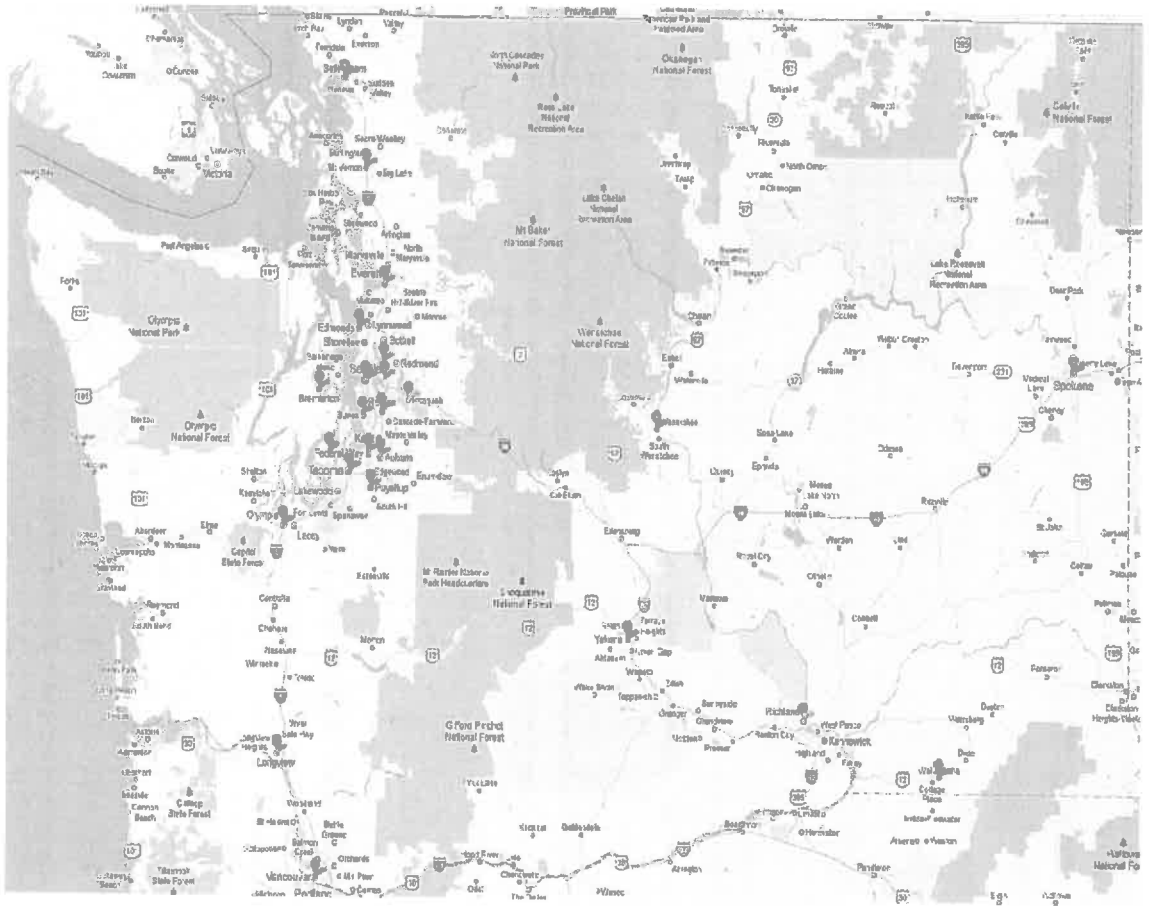
CLINICAL OUTCOMES ASSESSMENT PROGRAM
A PROGRAM OF THE FOUNDATION FOR HEALTH CARE QUALITY



PCI indication	PCI performed as part of hospital stay
STEMI (n=2535)	2516 (99.3%)
NSTEMI/UA (n=6573)	5132 (78.1%)
Non-acute (n=2853)	1269 (47.9%)

Attachment 4
Level I/Level II COAP Criteria

Participating Hospital Locations



Hospital Name	City
Capital Medical Center	Olympia
Central WA Hospital	Wenatchee
Deaconess Medical Center/Rockwood Health	Spokane
Evergreen Medical Center	Kirkland
Harborview Medical Center	Seattle
Harrison Medical Center	Bremerton
Highline Medical Center	Burien
Kadlec Medical Center	Richland
Kennewick General Hospital	Kennewick
Madigan Army Medical Center	JBLM
Multicare Auburn Medical Center	Auburn
Multicare Good Samaritan Hospital	Puyallup
Multicare Tacoma General Hospital	Tacoma
Northwest Hospital & Medical Center	Seattle
Overlake Hospital & Medical Center	Bellevue
PeaceHealth Southwest Medical Center	Vancouver
PeaceHealth St. John Medical Center	Longview
PeaceHealth St. Joseph Medical Center	Bellingham
Providence Regional Medical Center	Everett
Providence Sacred Heart Medical Center	Spokane
Providence St. Peter Medical Center	Olympia
Skagit Valley Hospital	Mt. Vernon
St. Anthony Hospital	Gig Harbor
St. Francis Hospital	Federal Way
St. Joseph Medical Center Tacoma	Tacoma
Swedish Cherry Hill Medical Center	Seattle
Swedish Edmonds Medical Center	Edmonds
Swedish Issaquah Medical Center	Issaquah
University of WA Medical Center	Seattle

2013 Clinical Dashboards - Explanatory Notes

The Clinical Outcomes Assessment Program (COAP) is a Washington State initiative to improve quality of cardiac care and assist in demonstrating accountability in health care by producing timely, credible, comparable clinical information. All 34 hospitals in the state that perform Percutaneous Coronary Interventions (PCI), and all eighteen hospitals that perform Adult Coronary Artery Bypass Graft (CABG) and valve surgeries, participate in COAP. Participating hospitals draw on COAP statewide data and quality improvement support to identify potential opportunities for improvement, develop intervention strategies and track the effectiveness of those interventions. *See the list of participating hospitals preceding these Explanatory Notes.*

Understanding the Clinical Dashboards

Annual risk-adjusted Clinical Dashboards are a key element of COAP's improvement support. The Dashboards present comparable data for each hospital, identify outliers relative to the state average, and track trends at the state level. Individual hospitals demonstrate improvement by responding to and resolving outliers. Most rates are risk-adjusted to reflect the acuity of patients at each hospital. The Technical Notes section at the back of the report details the methods used for risk adjustment. Those outcomes that are not risk-adjusted are shaded in light blue on the data tables.

Quality measures for surgery and PCI are considered outliers if a hospital's performance differs from the state average by more than *two standard deviations*:

If this is a favorable difference, the quality measure is marked in green in the tables
If this is difference is unfavorable, the quality measure is marked in red in the tables

The Dashboards are divided into "Level I", "Level II" and "Level III" indicators.

Level I	Measures were chosen as quality standards because for each indicator, a persistent outlier may signal a serious program deficiency.
Level II	Process and quality measures focus on specific areas of patient management. A pattern of persistent outliers in three or more of these measures may also suggest a serious program deficiency.
Level III	Indicators comprise both new measures that are being tested as well as prior Level II measures that should continue to be encouraged as good practice but which will not be subject to sanctions.

PCI Clinical Dashboard Measures:

PCI data reported to COAP comes from a subset of the NCDR CathPCI v4.3 data base.

Level I	**In-hospital mortality** **Median time to treat for ST-elevated MI**
Level II	**Extended length of stay *** **Adverse post-procedure events ****
Level III	**New post-procedure myocardial infarction** **Appropriate Use Criteria: % not able to be classified; % appropriate, uncertain and inappropriate**

Definitions:

* Extended post-procedure length of stay for STEMI = >5 days; N-STEMI/ACS = >3 days; Non-Acute = >2 days

** Adverse event rates for PCI include: Vascular complications; New renal failure$_1$; Stroke; Arrhythmia requiring treatment; Tamponade; New cardiogenic shock; Occlusion of the treated lesion; Unsuccessful procedure$_2$.

$_1$Renal failure for surgery or PCI: new requirement for dialysis OR creatinine increase to >2.0 AND creatinine increase to twice the baseline level

$_2$Unsuccessful procedure for PCI: post-procedure stenosis > 50% or decrease of < 20% from pre-procedure stenosis

PCI Classification:

The following categorization system will be used to display results and is based on ***Seq#7035 PCI Indication*** **as defined in CathPCI v4.3**

STEMI:

1 (immediate PCI for STEMI), or
2 (PCI for STEMI unstable > 12 hrs from symptom onset), or
3 (PCI for STEMI stable > 12 hrs from symptom onset), or
4 (PCI for STEMI stable after successful full-dose thrombolysis), or
5 (Rescue PCI for STEMI after failed full-does lytics)

NSTEMI ACS:

6 (PCI for high risk Non-STEMI or unstable angina)

NON ACUTE:

7 (Staged PCI), or
8 (Other)

Definitions: PCI Clinical Dashboard Measures

Report Metric	Formula	Denominator
In-Hospital Mortality	dcstatus=2	LatestVisit=1 (the most episode's most recent PCI)
Door to Balloon Time	Median[If (subecgdate & subecgtime NOT missing) THEN (firstdevactidate&time - subecgdate&time) ELSE (firstdevactidate&time - arrivaldate&time)	Admit Source = Emergency Department or Other Non-Transfer *AND* CAD Presentation = ST-Elevation MI (STEMI) or equivalent *AND* PCI Indication = Immediate PCI for STEMI *AND* (PCI Delay Reason = None *OR* D2B<=90) *AND* 0<=D2B<=500
Adverse Events	(postdialysis=1 or (postproccreat>=2*preproccreat AND postproccreat>2)) or (postmi=1) or (postcva=1) or (posthf=1) or (posttamponade=1) or (postbleed=1) or (posttransfusion=1) or (postcardiogenicshock=1) or [(cabgstatus=2,3, or 4) and the PCI procedure is the most recent cath lab visit of the patient-episode) or (postothervascomp=1) or (any postproctimi=1) or (any guidewirelesion=0)	
Extended LOS: STEMI	LOS:Admit-Discharge > 5 (STEMI), >3 (N-STEMI), or >2 (Non-Acute)	
Extended LOS: N-STEMI/ACS		
Extended LOS: Non-Acute		
Post Procedure MI: Non-Acute	**postmi=1**	**priormi=0 or missing**
Appropriate Use	**Clinical Scenarios in Evaluating Appropriate Use:** - **Clinical presentation (e.g. ACS, stable angina)** - **Severity of angina (CCS classification)** - **Extent of ischemia on noninvasive testing and other prognostic factors (e.g. low EF, DM)** - **Extent of anti-anginal therapy** - **Extent of anatomic disease** **Acute = acute myocardial infarction or unstable angina with high-risk features** **Non-acute = stable angina** **Procedures are reported as *Rarely Appropriate* or *Not Classified* (unable to be mapped due to insufficient data) based on national criteria**	

CABG & Valve Clinical Dashboard Measures:

Cardiac Surgery data reported to COAP comes from a subset of the STS data base. Outcomes are reported for the following five categories of procedures: 1) Isolated CABG; 2) Aortic valve replacement; 3) Mitral valve repair or replacement; 4) Aortic valve replacement plus CABG; 5) Mitral valve repair or replacement plus CABG. For each, sites with ≤ 20 procedures are noted.

Level I	In-hospital mortality New requirement for dialysis Renal Insufficiency	Use of arterial grafting Post operative stroke
Level II	Return to operating room (for any reason) Red blood cell transfusion rate Long length of stay (> 14 days)	Return to operating room for bleeding Prolonged intubation (>24 hours) Deep sternal wound infection rate
Level III	Early extubation rate (< 6 hours) Short length of stay (<6 days)	

Definitions: CABG & Valve Clinical Dashboard Measures

Report Metric	Algorithm	Numerator Fields	Denominator Fields
In-Hospital Mortality	Numerator / Denominator	Mort-DC Status = Dead	All Records
Use of Arterial Grafting	Numerator / Denominator	(IMA Artery Used) = (Left IMA) OR (Right IMA) OR (Both IMAs)	(Prev CAB) NOT "Yes" AND (Reason for No IMA) is Missing
Renal Insufficiency	Numerator/Denominator	(Postop-Renal-Renal Failure) = "Yes"	(RF-Renal Fail-Dialysis) NOT "Yes"
New Requirement for Dialysis	Numerator / Denominator	(Comps-Renal-Dialysis) = "Yes"or Post-Procedure creatinine is ≥ 2 times the Pre-Procedure creatinine AND the Post-Procedure Creatinine is >2.	(RF-Dialysis) NOT "Yes"
Post-Operative Stroke	Numerator / Denominator	(Comps-Neuro-Stroke Perm) = "Yes"	All Records
Deep Sternal Infection	Numerator / Denominator	Comps-Infect-Stern Deep = Yes; Comps-Infect-Mediastinitis=Yes	All Records
Any Return to OR	Numerator / Denominator	("Comps-Op-ReOp Bleed/Tamponade" = "Yes") OR ("Comps-Op-ReOp Gft Occl" = "Yes") OR ("Comps-Op-ReOp Other Non Card" = "Yes") OR ("Comps-Op-ReOp Other Card" = "Yes") OR ("Comps-Op-ReOp Vlv Dys" = "Yes")	All Records
Re-Op for Bleeding	Numerator / Denominator	Comps-Op-ReOp Bleed/Tamponade = Yes	All Records
RBC Transfusion Rate	Numerator / Denominator	(Blood Prod - RBC Units > 0) OR (Intraop Blood Products - RBC Units > 0)	All Records
Prolonged Intubation	Numerator / Denominator	Comps-Pulm-Vent Prolonged = Yes	All Records
Long Length of Stay	Numerator / Denominator	LOS-Surgery-Discharge > 14	All Records
Early Extubation	**Numerator / Denominator**	**Postop Vent Hours - Total < 6**	**All Records**
Readmission within 30 Days	**Numerator/Denominator**	**Readm 30 = Yes**	**All Records**
Short Length of Stay	**Numerator / Denominator**	**LOS-Surgery-Discharge < 6**	**All Records**

Role of the Dashboards in Assessing Participation Status

Participation Status denotes whether a hospital has met all of the quality standards set by the COAP community. Participation status is updated twice a year. Participation status is available to the public via the COAP web site at www.coap.org.

Since 2004, hospital performance results have been averaged over three years and have been a criterion for determining participation status.

The Dashboards are the essential tool for demonstrating successful resolution of previous outliers and initiating improvement to address current outliers. Participation status is based on CABG and PCI Level I and II measures. To maintain the status of "participating in full compliance with QI standards," a hospital must meet certain thresholds:

- Any Level I measures that were outliers on the prior dashboard have resolved in the current data year
- Two or fewer of the Level II measures that were outliers in the prior dashboard remain unresolved in the current data year
- No Level I indicator has persisted as an outlier through three 3-year averages
- Two or fewer Level II indicators have persisted as outliers through three 3-year averages

Annual Assessment:

In order to credibly and fairly determine whether prior years' outliers are resolved, the data used to create the Dashboards must meet standards for timeliness and completeness. The Annual assessment considers the following standards:

- Timeliness: submission of a full year's data by February 28th, or the final call for data by COAP, of the following year
- Completeness of critical fields in a given procedure: 90% or greater valid data for all Level I and Level II measures, key risk adjustment fields. The algorithm for creation of the Dashboards provides detailed information on the methods for handling missing data.

Mid-Year Assessment:

The Mid-year assessment evaluates completeness in relation to external data sources, as well as accuracy and engagement in the QI process. The Mid-year assessment considers the following standards:

- Engagement: hospital has submitted a QI plan for any new and persistent outliers
- Accuracy: 90% or better mean score on Inter-Rater Reliability testing or in alternate years, with the COAP audit.
- Completeness as validated against external data sources: 90% or better match rate between procedure volumes submitted to COAP and those found in external data sources such as billing data.

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A hospital meeting ALL of the following standards qualifies for **Full Participation status**. A hospital is at risk for a change to **Partial Participation status** if ANY ONE of the standards is not met:

1. Complete data submitted as of February 28th of the following year;
2. Any Level I measures that were outliers in the prior data year or the prior three-year average do not persist as outliers into the current data year;
3. Two or fewer of the Level II measures that were outliers in the prior data year or the prior three-year average persist as outliers into the current data year;
4. None of the Level I indicators and two or fewer of the Level II indicators from the prior TWO three-year averages persist as outliers in the current three-year average;
5. Hospital has submitted a QI plan to address outliers identified on the Annual Risk-Adjusted Clinical Dashboards;
6. Data collection staff have met the standard on inter-rater reliability test(s)-IRR or audit;
7. Invalid case counts from the prior data year have been resolved;

NOTE: A site may return to participation in full compliance if the next measurement cycle shows that the clinical or data outlier has been resolved, or prior to the next cycle, if the site proposes and successfully completes a Management Committee-approved correction plan.

Attachment 5
AHA/ACC Latest Consensus Document

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CLINICAL COMPETENCE STATEMENT

ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures

A Report of the American College of Cardiology Foundation/American Heart Association/ American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures)

Writing Committee Members

John G. Harold, MD, MACC, FAHA, *Chair**
Theodore A. Bass, MD, FACC, FSCAI, *Vice Chair*†

Thomas M. Bashore, MD, FACC, FAHA, FSCAI
Ralph G. Brindis, MD, MPH, MACC, FSCAI*
John E. Brush, Jr, MD, FACC
James A. Burke, MD, PhD, FACC
Gregory J. Dehmer, MD, FACC, FAHA, FSCAI†
Yuri A. Deychak, MD, FACC
Hani Jneid, MD, FACC, FAHA, FSCAI‡
James G. Jollis, MD, FACC‡
Joel S. Landzberg, MD, FACC
Glenn N. Levine, MD, FACC, FAHA
James B. McClurken, MD, FACC
John C. Messenger, MD, FACC, FSCAI*
Issam D. Moussa, MD, FACC, FAHA, FSCAI†
J. Brent Muhlestein, MD, FACC
Richard M. Pomerantz, MD, FACC, FSCAI
Timothy A. Sanborn, MD, FACC, FAHA
Chittur A. Sivaram, MBBS, FACC
Christopher J. White, MD, FACC, FAHA, FSCAI†
Eric S. Williams, MD, FACC*

*American College of Cardiology Foundation representative; †Society for Cardiovascular Angiography and Interventions representative; ‡American Heart Association representative

ACCF/AHA/ACP Task Force on Clinical Competence and Training Members

Jonathan L. Halperin, MD, FACC, FAHA, *Chair*

Joshua A. Beckman, MD, FACC, FAHA§
Ann Bolger, MD, FACC, FAHA
John G. Byrne, MD, FACC
Steven J. Lester, MD, FACC
Geno J. Merli, MD, FACP
J. Brent Muhlestein, MD, FACC
Ileana L. Pina, MD, FACC, FAHA§
Andrew Wang, MD, FACC
Howard H. Weitz, MBBS, FACC, FACP

§Former Task Force member during the writing effort; Authors with no symbol by their name were included to provide additional content expertise

Author Recusals: Writing committee members are required to recuse themselves from voting on sections to which their specific relationship with industry and other entities may apply; see Appendix 1 for recusal information.

This document was approved by the American College of Cardiology Foundation (ACCF) Board of Trustees, the American Heart Association (AHA) Science Advisory and Coordinating Committee, and the Society for Cardiovascular Angiography and Interventions (SCAI) Board of Trustees in April 2013. For the purpose of complete transparency, disclosure information for the ACCF Board of Trustees, the board of the convening organization of this document, is available at http://www.cardiosource.org/ACC/About-ACC/Who-We-Are/Leadership/Officers-and-Trustees.aspx. ACCF board members with relevant relationships with industry to the document may review and comment on the document but may not vote on approval.

The American College of Cardiology Foundation requests that this document be cited as follows: Harold JG, Bass TA, Bashore TM, Brindis RG, Brush JE Jr., Burke JA, Dehmer GJ, Deychak YA, Jneid H, Jollis JG, Landzberg JS, Levine GN, McClurken JB, Messenger JC, Moussa ID, Muhlestein JB, Pomerantz RM, Sanborn TA, Sivaram CA, White CJ, Williams ES. ACCF/AHA/SCAI 2013 update of the clinical competence statement on coronary artery interventional procedures: a report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). J Am Coll Cardiol 2013;62:357–96. doi: 10.1016/j.jacc.2013.05.002

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Preamble

Granting clinical staff privileges to physicians is the primary mechanism institutions use to uphold quality care. The Joint Commission requires that medical staff privileges be based on professional criteria specified in medical staff bylaws. Physicians themselves are charged with

defining the criteria that constitute professional competence and with evaluating their peers accordingly. The process of evaluating physicians' knowledge and competence has become more complex as various subspecialties have evolved over time.

The American College of Cardiology Foundation (ACCF)/American Heart Association (AHA)/American College of Physicians (ACP) Task Force on Clinical Competence and Training was formed in 1998 to develop recommendations for attaining and maintaining the cognitive and technical skills necessary for the competent performance of a specific cardiovascular service, procedure, or technology. These documents are evidence based, and where evidence is not available, expert opinion is used to formulate recommendations. Indications for and contraindications to specific services or procedures are not included in the scope of these documents. Recommendations are intended to assist those who must judge the competence of cardiovascular healthcare providers entering practice for the first time and/or those in practice undergoing periodic review of their expertise. The assessment of competence is complex and multidimensional; therefore, isolated recommendations contained herein may not necessarily be sufficient or appropriate for judging overall competence. The current document addresses competence in coronary-based cardiovascular interventional procedures and is authored by representatives of the ACCF, the AHA, and the Society for Cardiovascular Angiography and Interventions (SCAI). This document applies to specialists trained in internal medicine and adult cardiology and is not meant to be a clinical competence statement on procedures for congenital heart disease in the child or young adult.

To avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the writing committee, all members of the writing committee, as well as peer reviewers of the document, are asked to disclose all current healthcare-related relationships, including those existing 12 months before initiation of the writing effort. The ACCF/AHA/ACP Task Force on Clinical Competence and Training reviews these disclosures to determine what companies make products (on market or in development) that pertain to the document under development. Based on this information, a writing committee is formed to include a majority of members with no *relevant* relationships with industry or other entity (RWI), led by a chair with *no relevant* RWI. Authors with *relevant* RWI are not permitted to draft or vote on text or recommendations pertaining to their RWI. RWI is reviewed on all conference calls and updated as changes occur. Author and peer reviewer RWI pertinent to this document are disclosed in Appendices 1 and 2, respectively. Additionally, to ensure complete transparency, *authors' comprehensive healthcare-related disclosure information*—including RWI not pertinent to this document—is available online (see Comprehensive RWI Table). Disclosure information for the ACCF/AHA/ACP Task Force on Clinical Competence and Training is also available online at http://www.cardiosource.org/ACC/About-ACC/Who-We-Are/Leadership/Guidelines-and-Documents-Task-Forces.aspx, as well as the ACCF disclosure policy for document development at http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx.

The work of the writing committee was supported exclusively by the ACCF without commercial support. Writing committee members volunteered their time to this effort. Conference calls of the writing committee were confidential and attended only by committee members.

Jonathan L. Halperin, MD, FACC, FAHA
Chair, ACCF/AHA/ACP Task Force on Clinical Competence and Training

1. Introduction

Physician competence is an essential component in the provision of optimal health care. Physicians must have the appropriate training, fund of knowledge, clinical decision making, and technical skills to deliver their services in a competent and caring manner. Healthcare systems and payers also expect optimal care delivered in an efficient and cost-sensitive manner. In formulating conclusions and recommendations, it is important to emphasize that the ultimate goal of setting standards is to facilitate the attainment of optimal patient outcomes. Optimal outcome is most likely when operators select clinically appropriate patients for interventional procedures and perform these procedures at a requisite level of proficiency and competency. Institutional and programmatic quality is ultimately determined by its success in achieving that goal.

This document is an update of the 2007 ACCF/AHA/SCAI Clinical Competence Statement on Cardiac Interventional Procedures (1). The operator and institutional volume discussion, conclusions, and recommendations in this document supersede the recommendations in the 2011 ACCF/AHA/SCAI Guideline on Percutaneous Coronary Intervention (PCI) (2). Although the 2011 PCI guideline includes recommendations regarding operator and institutional volume, it was anticipated that this current writing committee, tasked specifically with examining volume thresholds, would be the primary source and that the PCI guidelines would be subsequently modified.

1.1. Document Development Process

1.1.1. Writing Committee Organization

The writing committee consisted of a broad range of members representing 3 societies, identified on the basis of 1 or more of the following attributes: PCI operators with experience in various clinical settings (e.g., private practice, hospital-based, and academic settings; high-, medium-,

and low-volume operators; small, medium, and large catheterization labs; hybrid labs; and labs with and without surgical backup); physicians experienced in both radial and femoral access; physicians with broad clinical experience who have had considerable previous involvement with PCI; physicians with expertise in systems of care for patients presenting with acute myocardial infarction; a cardiac surgeon; cardiovascular training program directors; catheterization laboratory directors with experience managing a broad cross section of interventional operators; general cardiologists; quality assurance experts; and clinical researchers who have studied PCI outcomes. This writing committee met the College's disclosure requirements for relationships with industry as described in the Preamble.

1.1.2. Document Development and Approval

The writing committee convened by conference call and email to finalize the document outline, develop the initial draft, revise the draft per committee feedback, and ultimately, sign off on the document for external peer review. The ACCF, AHA, and SCAI participated in peer review, resulting in 36 reviewers representing 316 comments. Comments were reviewed and addressed by the writing committee. A member of the ACCF/AHA/ACP Task Force on Clinical Competence and Training served as lead reviewer to ensure that all comments were addressed adequately. Both the writing committee and task force approved the final document to be sent for Board review. The ACCF Board of Trustees, AHA Science Advisory and Coordinating Committee, and the SCAI Board of Trustees reviewed the document, including all peer review comments and writing committee responses, and approved the document in April 2013. This document is considered current until the Task Force on Clinical Competence and Training revises or withdraws it from publication.

1.2. Purpose of This Document

This document was developed to review the currently available scientific data with the following purposes:

1. To characterize the expected success and complication rates for coronary artery interventional procedures when performed by skilled operators.
2. To identify comorbidities and other risk factors that may be used for risk adjustment when assessing procedure-specific expected success and complication rates.
3. To assess the relationship between operator activity level and success rates in PCI procedures as assessed by risk-adjusted outcome statistics.
4. To assess the relationship between institutional activity level and success rates in PCI procedures as assessed by risk-adjusted outcome statistics.
5. To develop recommendations for assessment of operator proficiency and institutional program quality, including data collection to permit monitoring of appropriateness and effectiveness of PCI procedures both at the level of the operator and the institution.
6. To assess the use of coronary procedures in patients with structural disease.

This document addresses coronary-based interventions in the adult and does not address procedures for non–coronary-based interventions involving structural heart disease in the child or adult.

2. Percutaneous Coronary Interventions

2.1. Evolution of Competence and Training Standards

PCI has become a widely practiced and integral component of cardiovascular therapy. The subspecialty has evolved into treating a wide range of both stable and acutely ill patients presenting with a broad spectrum, not only of increasingly complex coronary artery disease, but also of other cardiovascular conditions. The range and complexity of the equipment, adjunctive techniques, and ancillary components used to perform PCI (along with the clinical settings in which it is utilized, e.g., elective and acute coronary disease; native vessel and venous bypass; and lesion location and characteristics) have also evolved dramatically. Coincident with this has been recognition of the specialized knowledge and technical skills required to perform PCI, and the critical roles of formalized training, continuing education, and outcomes monitoring. Formal interventional cardiology training programs were first organized in the 1980s; and in 1999, the American Board of Internal Medicine (ABIM) offered its first examination for added certification in Interventional Cardiology. Currently, eligibility to qualify for this examination requires board certification in general cardiology, and successful completion of a 1-year dedicated interventional cardiology fellowship, in a program accredited by the Accreditation Council of Graduate Medical Education (ACGME). In 2012 to 2013, there were 141 ACGME-accredited programs in Interventional Cardiology, with 319 enrolled fellows. The current ACGME program and educational requirements for interventional cardiology were published in 2007; new/updated requirements became effective in July 2012 (3). The ACCF has further contributed to the definition of training standards and recommendations via its Adult Cardiovascular Medicine Core Cardiology Training (COCATS) documents (4).

During the past several years, there has also been a move toward a more structured definition of competency-based requirements and training. This includes the use of the 6 competency domains promulgated by the ACGME, and adopted and endorsed by the ABIM (medical knowledge; patient care and procedures; practice-based learning; systems-based practice; interpersonal and communication

skills; and professionalism). This format is also increasingly utilized, not only for training programs, but also for demonstration of maintenance of competency for practicing physicians. ACCF has also adopted this format as part of its training and lifelong learning competency documents, and has developed tools and programs to assist physicians in assessing, enhancing, and documenting competency. Section 2.7 of this document depicts core competency components of PCI utilizing this structure. A key characteristic of a competency-based system is the use of outcomes-based evaluations. For training programs, the evaluation tools, for example, include direct observation by instructors, as well as in-training examination, procedure logbooks/portfolios, and simulation. For practicing physicians, the maintenance of the competencies can include, for example, physician-specific data from registries (e.g., ACCF–National Cardiovascular Data Registry [NCDR®]) as well as from hospital databases and quality programs, along with maintenance of certification (MOC) and continuing medical education (CME). The competency framework includes definitions of competency components and potential evaluation tools related to an individual's practice-based learning, as well as skills related to working effectively in healthcare systems, communication with patients and other members of the healthcare team, and professionalism (see Section 2.7).

2.2. Evolution of Coronary Interventional Capabilities

Andreas Gruentzig pioneered the field of coronary intervention with the first coronary balloon angioplasty in 1977 (5,6). During the past 35 years, the field has rapidly expanded. The evolution of the cognitive and technical knowledge base for proficiency in PCI has paralleled the advancements in interventional equipment and the broadening of clinical and angiographic indications for PCI.

Although the basic structure of coronary balloons and atherectomy devices has not changed substantially over the years, the development of the coronary artery stent dramatically altered the practice of coronary intervention. The initial stents available markedly reduced the need for PCI-related emergency coronary bypass surgery (7), and drug-eluting stents have substantially lowered the occurrence of restenosis and the need for repeat revascularization following PCI (8). These technical innovations continue to evolve at a rapid pace, with new devices on the horizon (9,10). These advances come with the responsibility that the interventional cardiologist acquires the technical and cognitive skills necessary to use these emerging devices optimally to provide the best outcomes for their patients.

In tandem with these technical developments, the use of PCI has expanded to more complex lesion subsets such as chronic total occlusions, left main stenosis, and bifurcation lesions (11). These unmet needs spurred industry to produce an expanding selection of specialized devices (e.g., balloons, catheters, wires, and dedicated stents) to facilitate successful procedure completion. Similar to the evolution in the device field, pharmacological advances have continued at a robust pace, contributing to the increased clinical benefit appreciated by patients in recent years (12). These advances most notably involving antithrombotic and antiplatelet agents require the interventional cardiologist to have a solid working knowledge of the pharmacokinetics, indications, contraindications, and optimal timing of long-term monitoring of these drugs (13,14). New oral antithrombin and anti-Xa agents are emerging, which require further understanding of their indications and side effects.

The recognition that coronary angiography provides an imperfect assessment of coronary structure and stenosis severity has led to new imaging modalities such as intravascular ultrasound, optical coherence tomography, and near infrared spectroscopy (15). Assessment of the intermediate-severity stenosis based on the coronary angiogram alone has always been challenging. Following publication of the FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) trial (16), functional testing of angiographic intermediate coronary stenosis with measurement of the fractional flow reserve is now increasingly recommended when noninvasive evidence of ischemia is absent before considering revascularization of such lesions. Furthermore, the FAME 2 trial demonstrated that a fractional flow reserve–guided PCI strategy in patients with stable angina improves outcome beyond that of optimal medical therapy, particularly with regard to reduction of repeat hospitalization for coronary ischemia (17). The correct application of all these new devices requires continued expansion of both cognitive and procedural skill sets by the practicing interventional cardiologist.

Finally, the increasing complexity of PCI in patients with poor cardiac reserve has encouraged the development of several percutaneous left ventricular support devices (18). Insertion and monitoring of these devices necessitates a solid understanding of cardiovascular hemodynamics. In summary, the evolution of the field of interventional cardiovascular medicine has, and will continue, to require an unwavering commitment from the physician community to maintain excellence through lifelong learning.

2.3. Procedural Success and Complications of Coronary Interventional Procedures

2.3.1. PCI Success

PCI success can be defined using angiographic, procedural, and clinical variables. Factors associated with increased success and decreased complication rates include improvements in equipment (e.g., balloon catheters, guide catheters, guidewires), coronary stents (bare-metal stents and drug-eluting stents), embolization protection, aspiration thrombectomy devices, and advances in adjunctive pharmacotherapy (2,19–23).

Historically, angiographic success for balloon angioplasty has been defined as a reduction of minimum percent diameter stenosis to <50% with Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow and without side branch loss, flow-limiting dissection or angiographic thrombus. For coronary stents, a minimum percent diameter stenosis of <20% was the previous angiographic benchmark of an optimal result (24,25). However, with current stents and the recognized importance of adequate stent deployment (26,27), the 2011 ACCF/AHA/SCAI PCI guideline suggests a minimum percent diameter stenosis of <10% (or optimally as close to 0% as possible) as the new angiographic benchmark for stent results (2). In addition, following the conclusion of a successful procedure, there should be TIMI grade 3 flow and no occlusion of a significant side branch, flow-limiting dissection, distal embolization, or angiographic thrombus.

Procedural success is defined as angiographic success without in-hospital major complications such as death, myocardial infarction (MI), stroke, and emergency coronary artery bypass graft (CABG) surgery. The definition of PCI-related MI has evolved over time, and the current definition is provided below in Section 2.3.2 (2,24,25,28–30).

Short-term clinical success includes angiographic and procedural success with the subsequent relief of signs and/or symptoms of myocardial ischemia. Long-term clinical success requires that the relief of myocardial ischemia remain durable, persisting for more than 1 year after the procedure (2). The most common reason for a failure of long-term clinical success has been restenosis. Stent thrombosis is an uncommon, but an important, cause of short- and long-term clinical failure.

2.3.2. PCI Complications

PCI complications were reviewed comprehensively in the 2011 ACCF/AHA/SCAI PCI guideline (2). Major PCI-related complications include death, MI, emergency CABG surgery, and stroke, commonly denoted as MACCE (major adverse cardiovascular and cerebrovascular events). Other important complications include vascular complications (e.g., pseudoaneurysm, arteriovenous fistula, retroperitoneal bleeding, clinically overt atheroembolism), any major bleeding, and contrast nephropathy. The incidence of in-hospital mortality for PCI, determined from the NCDR CathPCI database between 2004 and 2007, was 1.27%, ranging from 0.65% in elective procedures to 4.81% for PCI performed in the setting of ST-elevation myocardial infarction (STEMI) (31). However, an important perspective is provided from a large contemporary single-center series reporting an overall mortality of approximately 1%, but with half of all deaths due to primarily noncardiac causes (32). The incidence of PCI-related MI depends on the criteria used to define MI. The clinical significance of "enzymatically defined" MIs in the absence of clinical or angiographic correlates has been controversial. The third iteration of the ESC/ACCF/AHA/WHF Task Force for the Universal Definition of Myocardial Infarction now requires for the diagnosis of PCI-related MI ("type 4a") both: 1) elevation of troponin (>5 × 99th percentile upper reference limit in patients with normal baseline values or a rise in troponin values >20% if the baseline values are elevated and stable or falling); *and* 2) either symptoms suggestive of myocardial ischemia, or new ischemic echocardiographic (ECG) changes (or new left bundle-branch block), or angiographic evidence of PCI complication, or imaging demonstrating new loss of viable myocardium (30). The need for emergency CABG surgery for a failed PCI has decreased dramatically especially since the introduction of coronary artery stents noting an incidence of 0.4% reported from the NCDR® database from 2004 to 2006 (33). The incidence of PCI-related stroke is also low at 0.22%; however, in-hospital mortality for these patients is quite high, reported to be 25% to 30% (34,35). Finally, it has been recently appreciated that periprocedural bleeding is associated with increased mortality, and accordingly, strategies to avoid bleeding are continuing to be developed (36,37). Factors reported to be associated with an increased risk of bleeding include advanced age, low body mass index, chronic kidney disease, baseline anemia, excessive platelet and/or thrombin inhibition, noncompressible vascular access site, and larger sheath size (2,38,39).

2.4. Patient and Lesion Variables Influencing Success and Complication Rates

Patient characteristics associated with an increased risk of adverse outcome include advanced age, diabetes, chronic kidney disease, heart failure, multivessel disease, clinical presentation with an acute coronary syndrome (non-STEMI or STEMI), and cardiogenic shock (31,40–42). Lesion-related characteristics associated with increased complications and/or lower procedural success include lesion length, thrombus, degenerated saphenous vein grafts, and chronic total occlusions (40,43). With advances in PCI technology, lesion morphology may be currently less predictive of procedural complications compared with the past (44).

The most widely accepted model to predict PCI mortality is the NCDR® CathPCI Risk Score system (Table 1), which utilizes multiple variables to predict inpatient mortality (2,31). This model performs very well (C statistic: approximately 0.90), although the predictive capability decreases in high-risk patients. Consideration of certain general and neurological patient factors in addition to NCDR® variables improves the predictive value of the model (32). Consideration of "compassionate use" features (coma on presentation, active hemodynamic support during PCI, and cardiopulmonary resuscitation at PCI initiation) has

Table 1. The NCDR® CathPCI Risk Score System

Variable	Scoring Response Categories				Total Points	Risk of In-Patient Mortality
Age	<60	≥60, <70	≥70, <80	≥80	0	0.00%
	0	4	8	14	5	0.10%
Cardiogenic shock	No	Yes			10	0.10%
	0	25			15	0.20%
Prior CHF	No	Yes			20	0.30%
	0	5			25	0.60%
Peripheral vascular disease	No	Yes			30	1.10%
	0	5			35	2.00%
Chronic lung disease	No	Yes			40	3.60%
	0	4			45	6.30%
GFR	<30	30–60	60–90	>90	50	10.90%
	18	10	6	0	55	18.30%
NYHA functional class IV	No	Yes			60	29.00%
	0	4			65	42.70%
PCI status (STEMI)	Elective	Urgent	Emergent	Salvage	70	57.60%
	12	15	20	38	75	71.20%
PCI status (no STEMI)	Elective	Urgent	Emergent	Salvage	80	81.00%
	0	8	20	42	85	89.20%
					90	93.80%
					95	96.50%
					100	98.00%

Reprinted with permission from Peterson et al. (31).

CathPCI indicates catheterization percutaneous coronary intervention; CHF, congestive heart failure; GFR, glomerular filtration rate; NCDR®, National Cardiovascular Data Registry; NYHA, New York Heart Association; and STEMI, ST-elevation myocardial infarction.

similarly been shown to increase the predictive ability of the model (45). Models to predict procedural success include the modified ACC/AHA score (40) and the SCAI score (46,47) (Table 2), with good to very good discrimination (C statistic: 0.70 to 0.82). More recently, the SYNTAX (Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) score, which is based on an angiographic calculation, has been shown to have value determining which patients with unprotected left main or multivessel disease undergoing PCI are at greatest risk for long-term major adverse cardiac events (MACE) (48–50). There are similar models available that help predict bleeding in patients with acute coronary syndromes undergoing PCI. Best treatment option proposals are facilitated by the heart team approach endorsed as a Class I recommendation by the ACCF, AHA, Society of Thoracic Surgeons (STS), and American Association for Thoracic Surgery (AATS), particularly when addressing complex patients and/or coronary anatomy. An operator should be familiar with the concepts of anatomical and clinical risk to facilitate optimal clinical decision making when recommending a revascularization strategy for an individual patient.

Table 2. The SCAI Lesion Classification System

Type I lesions (highest success expected, lowest risk)
1. Does not meet criteria for C lesion
2. Patent

Type II lesions
1. Meets any of these criteria for ACC/AHA C lesion
   - Diffuse (>2 cm length)
   - Excessive tortuosity of proximal segment
   - Extremely angulated segments, >90 degrees
   - Inability to protect major side branches
   - Degenerated vein grafts with friable lesions
2. Patent

Type III lesions
1. Does not meet criteria for C lesion
2. Occluded

Type IV lesions
1. Meets any of these criteria for ACC/AHA C lesion
   - Diffuse (>2 cm length)
   - Excessive tortuosity of proximal segment
   - Extremely angulated segments, >90 degrees
   - Inability to protect major side branches
   - Degenerated vein grafts with friable lesions
   - Occluded for >3 months
2. Occluded

Reprinted with permission from Krone et al. (47).

ACC indicates American College of Cardiology; AHA, American Heart Association; CME, continuing medical education; ECG, electrocardiographic; MOC, maintenance of certification; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-elevation myocardial infarction.

2.5. Institutional Characteristics Related to Procedural Success and Complication Rates

2.5.1. Impact of the Facility on Procedural Success

Physical facility requirements. Characteristics of the physical facility in which interventional procedures are performed have important influences on achieving procedural success. The facility must provide the

necessary radiologic, monitoring, and adjunctive patient support equipment to enable operators to perform in the safest and most effective environment. The real-time fluoroscopic and acquired image quality must be optimal to facilitate accurate catheter and device placement and facilitate the correct assessment of procedural results. Physiological monitoring equipment must provide continuous, accurate information about the patient's condition. Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve should be available. Hemodynamic support devices such as intra-aortic balloon pumps and percutaneous ventricular assist devices should be available in institutions routinely performing high-risk PCI. These requisite support equipment must be available and in good operating order to respond to emergency situations (51).

Overall institutional system requirements. The interventional laboratory must have a support system of specifically trained laboratory personnel. Access to (or a detailed plan to access) cardiothoracic surgical, respiratory, and anesthesia services should be available to respond to emergency situations in order to minimize detrimental outcomes (51). The ACCF/AHA/SCAI PCI guideline supports the heart team approach to revascularization for high-risk complex patients (2). The institution should have systems for credentialing, governance, data gathering, and quality assessment. Prospective, unbiased collection of key data elements on all patients and consistent timely feedback of results to providers brings important quality control to the entire interventional program and is critical to assessing and meeting Appropriate Use Criteria for coronary revascularization (52). The 2011 ACCF/AHA/SCAI PCI guideline update (2) recommends that:

- Primary PCI (PPCI) is reasonable in hospitals without onsite cardiac surgery, provided that appropriate planning for program development has been accomplished (Class IIa) (53,54).
- Elective PCI might be considered in hospitals without onsite cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (Class IIb) (54–56).
- Primary or elective PCI should not be performed in hospitals without onsite cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without hemodynamic support capability for transfer (Class III).

2.6. Strategies for Risk Stratification and Operator Evaluation

Large prospective and retrospective databases involving patients undergoing PCI have identified clinical and angiographic characteristics that correlate with procedural success, in-hospital morbidity, and mortality (57–59). These observations have been used to develop multivariate logistic regression models that can stratify patients before the procedure and also predict outcomes based on events during the procedure.

Risk stratification is not perfect and is frequently developed from a large population analysis and must then be validated prospectively in robust clinical data sets. Reliability of the model is best assessed by relative predictive accuracy (C statistic: moderate is >0.80, excellent is >0.90) and scaling accuracy (the Hosmer-Lemeshow statistic). Several models predict periprocedural mortality with C statistic >0.80. Efforts are underway to formulate periprocedural bleeding and postprocedural contrast-induced nephropathy models (60–62).

Model utility also must consider the frequency and clinical importance of the event measured. Very infrequent events, even if severe, may not allow adequate evaluation of operators with low volume. Results of several years of experience must be considered to have a sufficient number of events to support statistical validity without excessively large confidence intervals. Operators and catheterization laboratories should be strongly encouraged to submit information to large and transparent clinical databases that allow for adequate benchmarking and the development of contemporary risk-adjusted outcomes. Comparison of operator outcomes should be only 1 component of a comprehensive continuous quality improvement program at a facility.

2.7. Components of Operator Competence

Table 3 identifies the components of operator competence for PCI utilizing the ACGME core competency structure (see Section 2.1). Included in each of the sections are potential tools for evaluation and outcome assessment.

2.7.1. ABIM Certification

Although ABIM-IC certification and MOC are strongly recommended, it is recognized that for some individuals not eligible for ABIM certification because their training was obtained outside the United States, alternative tools may be acceptable. Interventional cardiologists should also attain at least 30 hours of CME every 2 years.

2.8. Relationships of Institutional and Operator Experience and Activity to Outcomes in Coronary Interventional Procedures

Since the original observation by Luft et al. (63) in 1979 showing fewer deaths among patients undergoing procedures at higher-volume hospitals, the interplay of volume and outcome has been the subject of much investigation. In 1988, the ACC and AHA first adopted

Table 3. Core Competency Components for Percutaneous Coronary Interventions

Medical Knowledge
1. Know normal coronary artery anatomy, its variations and congenital abnormalities, and the physiology of coronary/myocardial blood flow.
2. Know the pathology of atherosclerotic and nonatherosclerotic coronary diseases.
3. Know the causes, pathophysiology, and differential diagnosis of myocardial ischemia and infarction.
4. Know the pathophysiology, clinical characteristics, and management of PCI-related spasm, slow reflow, abrupt closure, and restenosis.
5. Know the structural and polymer characteristics of coronary stents and drugs incorporated into them.
6. Know the coagulation cascade, and the indications, risks, and clinical pharmacology of antiplatelet, anticoagulant, and fibrinolytic drugs used in conjunction with, or in place of, PCI.
7. Know the indications for PCI and the adjunctive and alternative uses of medical therapy and surgery for patients with coronary artery disease.
8. Know the methods to assess functional significance of coronary lesions in the catheterization laboratory.
9. STEMI: know the roles of time of presentation, facility capability, anticipated door-to-device time, presence or absence of ongoing symptoms, and ECG abnormalities on the selection of reperfusion strategy.
10. Know the signs and hemodynamics of cardiac dysfunction, and their impact on reperfusion strategy and PCI decisions.
11. Know the limitations and contraindications of PCI, particularly as these relate to comorbid systemic diseases and special anatomical subsets.
12. Know the specialized equipment, techniques, and devices used to perform PCI, including, but not limited to: • X-ray imaging, radiation safety, and measures to minimize radiation exposure of patients, operators, and staff. • Specialized catheterization recording and safety equipment (physiological data recorders, pressure transducers, blood gas analyzers, defibrillators). • Catheters, guidewires, balloon catheters, stents, atherectomy devices, ultrasound catheters, intra-aortic balloon pumps, puncture site sealing devices, contrast agents, distal protection devices, and thrombus extraction devices.
13. Know the risk factors for, and the signs and management of, major PCI procedural complications and bleeding—including coronary vascular (e.g., dissection, thrombosis, perforation, embolization), and other vascular (e.g., pseudoaneurysm, retroperitoneal hemorrhage, arteriovenous fistula, and stroke) complications.
Know the systemic complications of PCI, including acute pulmonary congestion and contrast-related nephropathy, along with mechanisms to reduce their risk of occurrence.
Evaluation Tools: *ABIM-IC certifying examination; ABIM-IC MOC (see Section 2.7.1); accredited CME.*
Patient Care and Procedures
1. Skill to integrate clinical and laboratory data in selecting appropriate candidates for PCI, incorporating evidence-based guideline and clinical trial information.
2. Skills to perform percutaneous arterial (femoral and brachial/radial) and venous access, including postprocedural management and appropriate use of closure devices.
3. Skills to perform and analyze coronary angiograms, assess functional significance of coronary lesions, and determine risk/benefit of PCI (and the type of PCI) versus alternative revascularization or medical treatments.
4. Skills to effectively and safely operate and manipulate intravascular guidewires, coronary angioplasty balloon catheters, atherectomy devices, and coronary stents.
5. Skill to appropriately select and utilize intracoronary ultrasound, Doppler flow wires, and pressure wires.
6. Achievement of volume and quality outcome benchmarks for PCI—in training and in practice.
7. Skills to promptly detect and treat complications of PCI—both in the laboratory and postprocedure.
8. Skills to promptly recognize, identify cause of, and treat hemodynamic instability, including the appropriate emergent use of pharmacological agents and/or percutaneous mechanical circulatory assist devices.
9. Skills to carry out postprocedural evaluation, establish medical regimen and subsequent outpatient follow-up; including appropriate use of follow-up outpatient testing.
Evaluation Tools: *ABIM-IC certification; direct observation; professional society (ACCF) registries; hospital quality programs; conference participation.*

Continued on the next page

a physician volume standard of about 1 percutaneous transluminal coronary angioplasty (PTCA) case/week to maintain proficiency (64). The first Clinical Competence Statement on PTCA was subsequently published in 1990 by the ACP/ACC/AHA Task Force on Clinical Privileges in Cardiology and advocated a minimum of 75 PTCA procedures/year to maintain continuing competence (65). Since then, the use of PCI volume as a surrogate for quality and the adoption of arbitrarily-defined annual volume standards, despite the lack of

Table 3. Continued

Practice-Based Learning and Improvement
1. Review personal outcomes data via registry and/or hospital quality monitoring programs to identify and carry out areas of focused education or quality initiative.
2. Attend at least 30 hours of PCI CME every 2 years (this may include participation in the hospital's CME-approved multidisciplinary catheterization conference).
3. Participate in PCI quality programs of the hospital, including review of major complications.
4. Carry out structured education regarding new technologies and procedures.
Evaluation Tools: *Professional society registry data; hospital/catheterization lab quality data; catheterization/morbidity and mortality conferences; simulation; ABIM-IC MOC.*
Systems-Based Practice
1. Participate in regular (at least monthly) catheterization laboratory conferences, including participation by clinical cardiologists, interventional operators, and cardiothoracic surgeons.
2. Participate in a hospital-based state, regional, or national database to measure risk-adjusted PCI outcomes of the laboratory and compare them with regional and national benchmarks for improving quality of care.
3. Incorporate risk/benefit and cost awareness factors in clinical decisions and management of patients undergoing PCI.
4. Effectively lead the catheterization laboratory team in the performance of the procedure and care of the patient.
5. In conjunction with the hospital, ensure that the catheterization laboratory meets the following requirements: • Provides safe and quality radiologic, monitoring, and patient support equipment. • Has appropriate and qualified staffing.
Evaluation Tools: *Multisource (360) evaluations, professional society registry outcomes data; hospital/catheterization lab quality data.*
Professionalism
1. Practice evidence-based, guideline-directed, and patient-centered care within the scope of personal technical skills and expertise.
Evaluation Tools: *Multisource evaluations; outcomes and registry data.*
Interpersonal Skills and Communication
1. Communicate effectively and demonstrate sensitivity with patients across a broad socioeconomic, ethnic, and cultural spectrum.
2. Communicate effectively and professionally (and carry out effective transition) with referring physicians and other members of the cardiovascular team.
Evaluation Tools: *Patient satisfaction data; multisource (360) evaluations.*

ABIM-IC indicates American Board of Internal Medicine–Interventional Cardiology; ACCF American College of Cardiology Foundation; CME, continuing medical education; ECG, electrocardiography; MOC, maintenance of certification; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

definitive evidence, have generated much controversy (66,67).

2.8.1. Evidence Reviewed

SEARCH STRATEGY

To compile the relevant available scientific evidence relating institutional and operator activity level to outcomes (Online Appendices 1 to 3), we performed a computerized systematic literature search of all publications using Medline (PubMed and Ovid) and Cochrane Databases for studies published since January 1990. We also reviewed abstracts from recent ACCF, AHA, European Society of Cardiology, and Transcatheter Cardiovascular Therapeutics (TCT) proceedings, solicited manuscripts under review for publication from experts in the field, and conducted a manual review of the reference lists from the available studies. Greater weight was given to recent, peer-reviewed publications of high quality. No single work was considered definitive, and the shortcomings of the reviewed studies are discussed at length below.

2.8.1.1. RELATIONSHIP OF INSTITUTIONAL VOLUME TO PROCEDURAL OUTCOME

We identified 17 studies examining the impact of institutional volume to outcomes of PCIs (Online Appendix 1). Of the 8 studies conducted in the PTCA era (46,68–74), all except 1 (68) demonstrated a relationship between hospital volume and outcomes, with lower volume predicting predominantly the need for in-hospital CABG surgery (6 studies) (69–74) or in-hospital mortality (4 studies) (70–73). Of the 9 studies (57,58,75–81) in the stent era, 6 studies demonstrated an inverse relationship between mortality and PCI volume (57,58,75,78–80); 1 study showed a decrease in 30-day and 2-year CABG surgery in high-volume hospitals (77); and another showed a reduction in 30-day and 1-year adjusted rates of death,

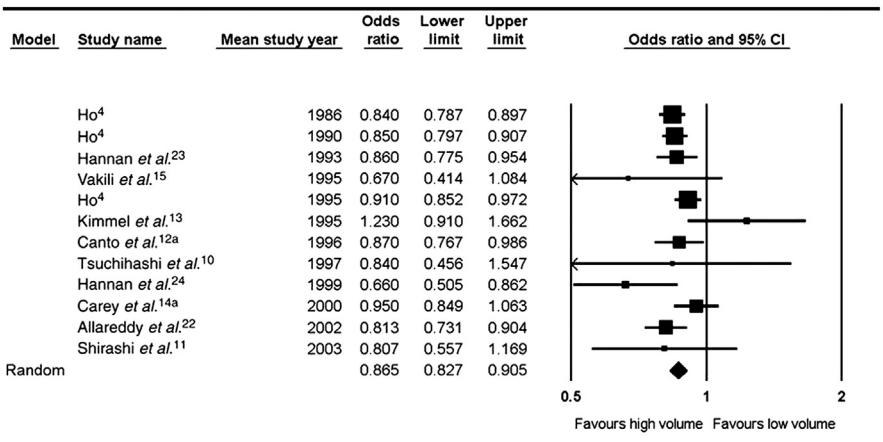
MI, or target-vessel revascularization in high-volume hospitals (81). The relationship between institutional procedural volume and outcome has been confirmed by multiple contemporary large registries, of which 3 included >100,000 patients (58,75,78).

A recent meta-analysis examined the relation between volume and outcome of PCI in 10 reports between 1995 and 2003 from an original pool of 140 papers (82). Of those, 8 studies were conducted in the United States and 7 used high-quality clinical data. The final meta-analysis included 1,322,342 patients from 1,746 hospitals. Patients treated in high-volume hospitals (≥600 PCIs/year) experienced lower in-hospital mortality (odds ratio [OR]: 0.87; 95% confidence interval [CI]: 0.83 to 0.91) compared with patients treated in lower-volume hospitals (400 to 600 PCIs per year) (Figure 1), noting moderate heterogeneity existed. When limiting the analyses to studies using the cutoff point of 400 PCIs/year, heterogeneity was diminished, but the effect estimate remained unchanged (OR: 0.86, 95% CI: 0.82 to 0.90). Interestingly, the more contemporary studies suggested a slightly smaller effect size than earlier studies ($p = 0.06$); however, meta-regression did not show notable changes in the effect size over the years (82).

Overall, the preponderance of data suggests that hospitals in which fewer coronary interventions are performed have a greater incidence of adverse events, notably death and CABG surgery for failed intervention, than hospitals performing more procedures. This relation is supported by earlier studies in the PTCA era (46,69–74), contemporary studies in the stent era (57,58,75–81), and a recent meta-analysis (82). The writing committee recognizes the wide variability of institutional volume thresholds used in the different studies and the complexity and multitude of factors influencing PCI outcomes. However, it is important to note that a signal exists suggesting that an institutional volume threshold <200 PCIs/year appears to be consistently associated with worse outcomes across the various studies (Online Appendix 1) (58,75,80). Full-service (both primary and elective PCI) laboratories performing <200 total cases annually require additional considerations. Many such low-volume laboratories do not have onsite surgery and were developed to provide PPCI services to underserved or geographically isolated populations; a situation that the 2011 PCI guideline acknowledges may be acceptable. Elective PCI is often performed in these facilities to increase the volume of procedures and thus maintain facility and operator proficiency. There are also some laboratories that provide only PPCI service to similar populations. Such facilities must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger-volume facilities. The continued operation of low-volume laboratories that are not serving isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should close. This becomes increasingly relevant in an era of declining procedural volumes and expanded care delivery models for patients with STEMI (83).

2.8.1.2. RELATIONSHIP OF INDIVIDUAL OPERATOR VOLUME TO PROCEDURAL OUTCOME

We identified 9 studies examining the relationship between individual operator caseload and procedural outcomes in the stent era (Online Appendix 2). Of these, 4 studies demonstrated the existence of a relationship between low operator volume and increased adverse outcomes (58,84–86), predominantly CABG, but only 1 showed a modest correlation with in-hospital mortality (86). Notably, the 3 largest reports, each with a study population >100,000 patients, supported the existence of such a relationship (58,84,86).



[a]Unpublished results.

Figure 1. Results of Meta-Analysis of Studies Investigating the Effect of Center Volume on In-Hospital Mortality After PCI

CI indicates confidence interval; and PCI, percutaneous coronary intervention. Reprinted with permission from Post et al. (82).

The largest and most contemporary study involved 3,649 physicians (excluding those performing <10 PCIs/year) from the NCDR® CathPCI Registry and included 345,526 PCI procedures performed in 543 hospitals over 4 consecutive quarters, ending in July 2009. Using hierarchical logistic regression modeling to adjust for patient demographics, comorbidities, cardiac status, and hospital volume, this study compares outcomes including in-hospital mortality of patients treated by operators who performed <75 PCIs/year with those performing ≥75 PCIs/year. Median operator PCI annual volume was 75 PCIs (IQR: 38 to 127) and overall in-hospital mortality was 1.31%. After multivariable adjustment, in-hospital mortality remained significantly higher among physicians performing <75 PCIs/year (OR: 1.14; 95% CI: 1.05 to 1.24), noting that the correlation between in-hospital mortality and operator volume was modest ($R^2 = -0.0057$), and there was no clear inflection point for a minimal volume threshold (Figure 2). The absolute difference in mortality was 0.3% (86). Lower-volume operators had significantly higher rates of other complications, including bleeding, emergency PCI, and the need for postprocedural CABG surgery. A higher mean length of stay was also found in low-volume operator patients. This large NCDR® CathPCI Registry analysis, representing approximately 70% to 80% of all PCIs performed in the United States, has several important limitations including: data are limited to only voluntarily participating hospitals, and long-term outcome data are not available. These findings were reported at the 2011 AHA Scientific Sessions in Orlando, Florida (86), and the final peer-reviewed publication is not yet available.

An earlier report by McGrath et al. (84) analyzed data from the 1997 Medicare national claims database on 167,208 patients undergoing PCI by 6,534 operators. A significant relationship between operator volume and outcome was found, noting a lower risk of post-PCI CABG surgery in patients treated by high-volume operators (>60 PCIs/year); however, there was no observed difference in 30-day mortality (84). Similar findings were obtained by Hannan et al. (58), who analyzed data from 107,713 PCI procedures reported in the New York State Database from 1998 through 2000. Operator volume thresholds were set at 75 PCIs/year on the basis of the ACCF/AHA recommendations, and were compared with higher levels of 100 and 125 procedures/year. There were no differences in risk-adjusted mortality between patients undergoing PCI performed by low- versus high-volume operators for any of the 3 volume thresholds examined (58). However, significant differences for same-day and same-stay CABG surgery were observed for all 3 volume thresholds. For instance, patients undergoing PCI with operators performing <75 PCIs/year had a 65% increase of undergoing same-day CABG surgery and a 55% increase of undergoing same-stay CABG surgery (58). Another study by Moscucci et al. (59) involving 18,504 PCI procedures performed in 14 Michigan hospitals in 2002, demonstrated that patients treated by low-volume operators (<90 PCIs per year) experienced a 63% increase of MACE (a composite of death, MI, stroke or transient ischemic attack, CABG surgery, and repeat PCI) ($p<0.0001$) after multivariable adjustment, but not in-hospital mortality, compared with patients treated by operators in the higher-volume quintile. When using the 75 PCIs/year cutoff, no significant differences in adjusted MACE or mortality rates were observed (85).

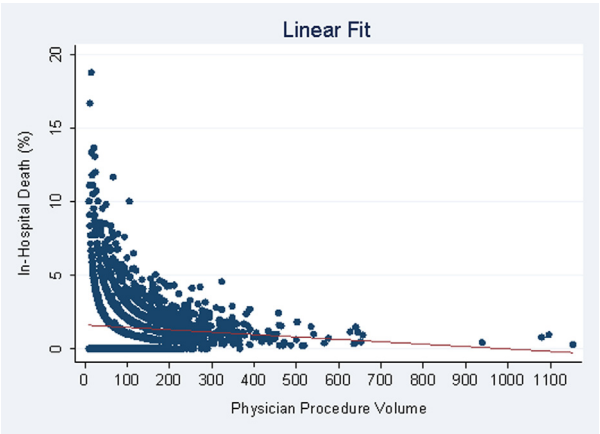


Figure 2. Scatter Plot of PCI Volume Versus In-Hospital Mortality

PCI indicates percutaneous coronary intervention. Reprinted with permission from Minges et al. (86).

The writing committee recognizes that the majority of interventional cardiologists in the United States are not achieving the previously recommended threshold of 75 PCIs annually (87). This may be related to many factors, including but not limited to: (a) the reduction of restenosis related to the widespread use of drug-eluting stents; (b) improved medical therapies and increasing appreciation of the importance of upfront guideline-directed medical management of stable CHD; (c) the presence of more interventional cardiologists and centers in the United States; and (d) the development and implementation and increasing awareness of Appropriate Use Criteria for coronary revascularization (52). We also recognize the increased use of invasive coronary physiological and anatomic assessments (e.g., fractional flow reserve, intravascular ultrasound) by many interventional cardiologists, which are usually not counted as PCI procedures but which, however, may conceivably influence PCI volume. There is also a shift towards the performance of noncoronary-based (structural) cardiac interventions by many experienced high-volume operators.

Overall, it is the opinion of the writing committee that the available evidence does not send a loud signal supporting a consistently strong relationship between operator caseload and mortality (58,84–86). In part, this is a function of the extremely low procedural-related mortality that now exists for PCI. The preponderance of data available is related to

clinical outcomes other than mortality and does suggest a possible relationship between operator volume and emergency CABG surgery and other PCI complications. On the basis of available data and the judgment of the writing committee involving all of these considerations, the writing committee recommends interventional cardiologists perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency. The writing committee acknowledges that this number is established primarily by expert opinion derived from the interpretation of substantial data from multiple sources (each with inherent limitations). Because of the limitations of these data, the writing committee believes operators performing <50 PCIs/year should not be denied privileges or excluded from performing coronary interventions based solely on their procedural volume. The committee acknowledges that there are low-volume operators who provide excellent clinical care and achieve excellent outcomes. In instances where operators are performing <50 PCIs annually, the writing committee strongly encourages both institutions and operators to carefully assess whether their performance is adequate to maintain competence. Other metrics are needed, in addition to volume and risk-adjusted outcomes, which have very wide confidence intervals at low procedure volumes, and thus are difficult to assess accurately. The committee suggests that each facility develop alternative pathways for the evaluation of low-volume operators. These pathways may be established and monitored by an independent institutional committee (consisting of physicians and relevant healthcare personnel) or an external review organization. The writing committee emphasizes that volume is but 1 of several factors that should be considered when assessing an individual operator's competence. Other factors to consider for low-volume operators include (but are not limited to): performance of additional noncoronary cardiovascular interventional procedures, lifetime experience, ABIM certification in interventional cardiology, attendance at educational symposiums, CME credits, and simulation courses.

Although this recommendation focuses on the minimal procedural volume considered acceptable for maintaining competence, the writing committee believes it is important to evaluate the performance of all operators. Separate concerns may exist for very high-volume operators. Compliance with suggested guidelines and appropriateness of procedures are important metrics to consider when evaluating competency of all operators.*

*Although the 2011 ACCF/AHA/SCAI PCI guideline includes recommendations regarding operator and institutional volume, it was anticipated that this current writing group, tasked specifically with examining volume thresholds, would be the primary source and that the 2011 PCI guidelines might be subsequently modified. Therefore, the operator and institutional volume discussion, conclusions, and recommendations in this document supersede the recommendations in the 2011 ACCF/AHA/SCAI Guideline on Percutaneous Coronary Intervention (2).

2.8.1.3. VOLUME AND OUTCOMES RELATIONSHIP FOR PRIMARY PCI IN ACUTE MI

PPCI requires several clinical, cognitive, and procedural skills not necessarily involved with performing elective PCI. Online Appendix 3 summarizes 16 published studies examining the relationship between operator and institutional volume and outcomes in patients undergoing PPCI. Of those studies, 4 showed no relationship between volume and mortality (88–91), although the latter (the only U.S. study of all 4 reports) demonstrated shorter door-to-balloon (DTB) time and greater adherence to evidence-based therapies observed in higher-volume PPCI centers (91). Of the 12 remaining reports, 10 studies (58,92–100) demonstrated a significant inverse relationship between hospital PPCI volume and in-hospital mortality, whereas 2 studies (101,102) showed similar relationships relating hospital total PCI volume to mortality. Only 2 studies (97,99) demonstrated a significant inverse relationship between the operator PPCI volume and in-hospital mortality, whereas 1 report (58) failed to show such a relationship after multivariable adjustment. It is important to note that these relationships were examined nearly exclusively at hospitals with onsite cardiac surgery.

Hannan et al. (58) examined data from the New York State Coronary Angioplasty Reporting System Registry collected between 1998 and 2000, a period when stenting was used in a large majority of STEMI patients. A non-significant trend towards increased in-hospital mortality was observed for low-volume operators when compared with high-volume operators both for volume cutoffs of 8 PPCIs/year (OR: 1.40; 95% CI: 089 to 2.20) and 10 PPCIs/year (OR: 1.27; 95% CI: 0.87 to 1.87). Importantly, a significant increase in the odds of in-hospital mortality was observed with lower institutional volume of PPCI, regardless of whether the threshold was set at 36 PPCIs/year (OR: 2.01; 95% CI: 1.27 to 3.17), 40 PPCIs/year (OR: 1.73; 95% CI: 1.1 to 2.71), or 60 PPCIs/year (OR: 1.45; 95% CI: 1.01 to 2.09). Recently, Srinivas et al. (99) examined the impact of annual hospital and physician volume and their interaction on risk-adjusted mortality in 7,321 patients undergoing PPCI for acute MI from the New York State PCI Registry (2000 to 2002). High-volume operators performing >10 PPCIs/year and those performing >20 PPCIs/year demonstrated a 34% and 37% reduction in risk-adjusted mortality, respectively, compared with their low-volume counterparts ($p < 0.05$). High-volume hospitals (>50 PPCIs/year) also achieved statistically significant reductions in mortality (adjusted OR: 0.58; 95% CI: 0.38 to 0.88). The thresholds at which the benefit was observed were similar to the ACCF/AHA volume recommendations, and as such, the investigators recommended adherence to current guidelines and the monitoring of PPCI performance by low-volume operators (99). A recent analysis (91) explored the relationship between hospital volume (primary and total PCI volumes) and patient outcomes in the AHA's Get With the

Guidelines–Coronary Artery Disease (GWTG–CAD) National Registry (2001 to 2007). Hospitals were divided into tertiles of PPCI volume as low (<36 PPCIs/year), medium (36 to 70 PPCIs/year), and high (>70 PPCIs/year). Total PCI volume was similarly calculated, and hospitals were again divided into tertiles based on the ACCF/AHA recommended thresholds as low (<200 PCIs/year), medium (200 to 400 PCIs/year), and high (>400 PCIs/year). A total of 29,513 patients with STEMI were treated with PPCI at 166 hospitals across the United States. Hospital annual PPCI volume ranged between 9 and 225 patients, with a median of 49 (IQR: 27 to 78) patients. Compared with low- and medium-volume centers, high-volume centers had better median DTB times (98 versus 90 versus 88 minutes, respectively; p for trend <0.001) and were more likely to follow evidence-based guidelines at discharge. The investigators found no significant differences in crude mortality between the PPCI volume groups, even after sequential multivariable adjustment (91). By contrast, patients presenting to low total PCI volume hospitals had a higher crude mortality compared with medium- and high-volume hospitals (3.5% versus 3.3% versus 3.0%, respectively; p for trend = 0.05), which did not remain statistically significant after multivariable adjustment (91). The importance of the GWTG–CAD study (91) stems from its inclusion of a large patient population and representation of real-world contemporary practices from all U.S. census regions. The lack of mortality benefit, although it stands out in contrast to other reports (58,92–100), does not eliminate volume as an important marker of PPCI quality, especially given the differences in secondary outcomes and quality measures (91).

Although a large body of evidence supports the existence of a relationship between hospital volume of PPCI and outcome (Online Appendix 3), only a paucity of studies related total hospital PCI volume to outcome of acute MI (79,102). Spaulding et al. (102) examined the relationship between hospital PCI volume and outcomes after emergency PCI procedures from the CARDIO-ARHIF (Agence Régionale d'Hospitalisation d'Ile de France) Registry, which included a total of 37,848 total PCIs from 44 centers in the greater Paris area (2001 to 2002). Emergency PCI was defined as PCI performed for acute MI, cardiogenic shock, or successfully resuscitated out-of-hospital cardiac arrest. The investigators used a threshold of 400 PCIs/year to define low- (<400) and high-volume (≥400) centers. In this relatively contemporary study in the stent era, the investigators found no relationship between hospital PCI volume and in-hospital mortality for non-emergency procedures. However, a clear inverse relationship existed between hospital volume and mortality for emergency PCIs (8.5% versus 6.8%, p = 0.028), which persisted after multivariable adjustment (102). Complication rates were higher in low-volume centers in patients undergoing both planned and emergency procedures, even after multivariable adjustment (102). In another contemporary study by Zahn et al. (79), a small but significant inverse volume–outcome relationship existed for in-hospital mortality (using total PCI volume threshold of 325 PCIs/year); however, this relationship was only apparent in high-risk subgroups, such as patients presenting with acute MI. Both of these studies have important implications (79,102), because they reinforce the notion that the volume–outcome relationship, if existent in the contemporary era, is likely to be most apparent among high-risk patients undergoing emergency and PPCI procedures.

Based on the available literature, strong evidence exists for an inverse relationship between hospital PPCI volume, in-hospital mortality (with the exception of the GWTG–CAD study) (91) and other major adverse cardiovascular outcomes. No clear signal relating operator PPCI volume and hospital total PCI volume to acute MI outcomes exists. The writing committee endorses the 2011 ACCF/AHA/SCAI PCI guideline recommendation that PPCI for STEMI be performed by experienced operators who perform more than 11 PPCI procedures per year, and ideally, these procedures should be performed at facilities that perform >36 PPCI procedures annually (2). However, the writing committee acknowledges that geographic challenges to timely access for PPCI may exist in some areas. Low-volume centers that only perform PPCI (typically without onsite surgery) and exist to meet critical access needs must demonstrate acceptable outcomes. This can be accomplished through the reliance on stringent systems and process protocols along with close monitoring of clinical outcomes. Such centers enhance their chance of success by an association with larger facilities and the rotation of interventionalists, clinical catheterization lab staff, and hospital support staff at a high-volume PCI center (53).

2.8.1.4. OUTCOMES RELATIONSHIP FOR PCI IN HOSPITALS WITHOUT ONSITE CARDIAC SURGERY

Controversy over the performance of PCI without onsite cardiac surgery has existed for a considerable time in the United States, although it is more widely accepted in many countries abroad (54,103). After publication of the quantitative review by Keeley et al. in 2003, the superiority of PCI over thrombolytic therapy for the treatment of STEMI became widely accepted (104). This acknowledgement encouraged the development of primary PCI programs at hospitals without cardiac surgery in an effort to provide this treatment rapidly to patients with STEMI in their local communities (105). Difficulties sustaining the proficiency of support personnel and operators within a PCI program limited to patients with STEMI were used to support the performance of PCI cases in patients presenting without ST-elevation MI at facilities without onsite cardiac surgery in an attempt to maintain higher PCI volumes and staff expertise (106,107). Despite guideline recommendations in place at the time, the number of PCI facilities without onsite cardiac surgery in

the United States continued to grow (108). In 2007, the SCAI published an expert consensus document, which reviewed the topic of PCI without onsite surgery and provided recommendations to assure appropriate patient care in this setting (54). This document acknowledged the reality that as of 2007, primary and elective PCI without onsite surgery was already being performed in 28 states despite the guideline recommendations current at the time.

2.8.1.4.1. THE SAFETY OF PCI WITHOUT ONSITE CARDIAC SURGERY

As techniques for performing PCI and drug therapies used during PCI continued to improve, the safety of PCI without onsite cardiac surgery has been reevaluated in several recent studies and meta-analyses (33,109–113) (Online Appendix 4). Separate analyses of registry data from Sweden and the United States showed no differences for in-hospital mortality, 30-day mortality, or the need for emergency CABG surgery among hospitals with and without onsite surgery (33,109). Two recent meta-analyses also showed no difference in mortality for primary or non-primary PCI among hospitals with and without onsite surgery and no difference in the need for emergency CABG surgery (110,111). However, in both analyses, heterogeneity was observed in the outcomes for non-primary PCI among sites without onsite surgery, prompting the authors to make strong recommendations about how such sites should function to ensure optimal results. Finally, the Cardiovascular Patient Outcomes Research Team (CPORT) Non-Primary PCI (CPORT-E) trial randomized patients undergoing elective PCI to treatment at hospitals with and without onsite surgery (113). Within the context of this well-controlled study, elective PCI at hospitals without onsite surgery was shown to be not inferior to PCI at hospitals with onsite surgery.

Reflecting the continued accumulation of data on the safety of PCI without onsite surgical backup, the most recent ACCF/AHA/SCAI PCI guideline classified primary PCI without onsite surgery as Class IIa (Level of Evidence: B) and elective PCI as Class IIb (Level of Evidence: B) indications, providing appropriate planning for program development has been accomplished (2). Elective PCI without onsite cardiac surgical backup was considered appropriate only when performed by experienced operators with complication rates and outcomes equivalent or superior to national benchmarks. Accurate assessment of complication rates and patient outcomes via a regional or national data registry, so that outcomes can be compared with established benchmarks, is an important quality control component of any PCI program. Numerous personnel, facility, operator, and structural requirements adapted from the SCAI expert consensus documents were described (2,54).

2.8.1.4.2. EXISTING RECOMMENDATIONS FOR OPERATOR COMPETENCY AT HOSPITALS WITHOUT ONSITE CARDIAC SURGERY

Noting that PCI without onsite surgery is more routinely practiced, it is important to emphasize that almost all safety data come from well-controlled studies or registries at facilities with a strong commitment to quality outcomes. Little has been written concerning operator competency requirements specifically at hospitals without onsite surgery, but it is reasonable to assume that outcomes similar to those reported in the literature would require facilities and operators to adhere to the same requirements outlined in the published studies of PCI without onsite surgery. For example, in CPORT-E, operators were required to meet the requirements for competency set forth in the ACCF/AHA/SCAI guideline existing at the time of the study (minimum 75 PCIs annually), and facilities were required to have an annual PCI volume of 200 cases after the first year of operation. Within these studies, other factors noted as contributing to the favorable outcomes in hospitals without onsite surgery included: a) submitting data to a national repository for benchmarking; b) linkage of such facilities to a tertiary care center for consultation; c) cross-training of personnel; d) similar processes and structures of care for a patient undergoing PCI; e) expeditious transfer for emergency CABG surgery; and f) use of risk-adjustment tools for case selection, outcomes analyses, and comparison of operator performance (33,112,113). It has also been shown that patients admitted to PCI centers without onsite surgery have a higher mortality and are less likely to receive guideline-recommended medications or to receive reperfusion therapy (114). However, when the analysis was restricted to patients who received PPCI, the mortality difference was not significant.

The 2011 ACCF/AHA/SCAI PCI guideline emphasizes that *all* PCI programs need a robust quality improvement program that routinely reviews quality and outcomes for the entire program and for individual operators. Elements of this Class I recommendation include peer review of complicated cases or cases with poor outcome plus random case reviews and participation in a registry so appropriate benchmarks are established and risk adjustment can be performed. Board certification and MOC in interventional cardiology is strongly encouraged (2). Maintenance of certification in interventional cardiology currently requires physicians to document a minimum of 150 interventional cases over the 2 years before expiration of the current certification, completion of self-assessment modules of their medical knowledge, participation in a practice-based quality-improvement activity, and passage of a knowledge-based examination. Operator and hospital volume requirements in the 2011 ACCF/AHA/SCAI PCI guideline were carried forward from the 2005 guideline with the writing committee acknowledging that the volume recommendations were controversial and should have a Level of Evidence C rather than B as in the prior guideline.

The SCAI Expert Consensus Document proposed more rigorous requirements for operators and facilities without onsite surgery to reflect the opinion of the SCAI writing group that a greater experience level is appropriate for PCI

in the absence of onsite surgery (54). They recommended that initial operators at a facility without onsite surgery should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Interventional cardiologists joining those already engaged in PCI without onsite surgery with <500 cases of lifetime experience should be mentored and monitored by qualified physicians until it is determined their skills and judgment are satisfactory and outcomes equivalent or superior to the national benchmarks. Accordingly, this writing committee recommends operators performing PCI without onsite surgery should perform >50 total PCIs per year, including >11 primary PCIs per year. Operators who cannot maintain these case volume recommendations at their primary practice site should maintain privileges and continue to perform PCI procedures at a high-volume institution with onsite surgical backup to meet these annual volume requirements.[†]

2.8.1.4.3. VOLUME–OUTCOME RELATIONSHIP AT FACILITIES WITHOUT ONSITE SURGERY

As noted in an earlier section, the relationship between both operator and hospital volume and outcomes at facilities with onsite cardiac surgery is not straightforward and may be inconsistent across low-volume institutions or operators. This is especially problematic because data from the NCDR® shows a predominance of low-volume hospitals are facilities without onsite surgery (33,83). Several strategies have been suggested to ensure optimal quality and outcomes at low-volume facilities without onsite surgery, including: a) having both operators and support personnel rotate at a high-volume facility to enhance experience; and b) rigorous quality monitoring program with oversight from a high-volume facility or formal evaluation by an external accreditation organization. Performing adequate peer review may be especially difficult at low-volume facilities with only a few operators. It should be emphasized, however, that the strongest rationale for the development of PCI facilities without onsite surgery was the desire to provide rapid PPCI to patients in their communities. Since 2000, there has been a substantial decline in the incidence of STEMI, and there is now greater emphasis on developing systems of care for STEMI patients as promoted in the *Mission Lifeline* initiative (115,116). All of these factors will further challenge smaller facilities wishing to sustain PCI programs, potentially reducing the number of PCIs performed per facility and per operator. Accordingly, the writing committee recommends that an institution without onsite surgery with a volume fewer than 200 procedures annually, unless in a region underserved because of geography, should strongly consider whether or not it should continue to offer this service. This becomes increasingly relevant in an era of declining procedural volumes and expanded institutional capabilities (83).[†]

2.8.1.5. THE INTERPLAY BETWEEN OPERATOR AND INSTITUTIONAL PCI VOLUME AND OUTCOME

It has been widely acknowledged that institutional experience may modify the volume–outcome relationship at the individual operator level. In 1990, Ryan et al. (65, p. 1473) recognized that "operator skill and judgment are greatly influenced by personal experience … and by the environment in which the operator practices."

Hannan et al. (58) demonstrated that, compared with patients undergoing PCI by high-volume operators (≥75/year) in high-volume hospitals (≥400/year), patients undergoing PCI by low-volume operators (<75/year) in low-volume hospitals (<400/year) had significantly higher rates of in-hospital mortality (OR: 5.92; 95% CI: 3.25 to 10.97), same-day CABG (OR: 4.02; 95% CI: 1.04 to 15.57), and same-stay CABG (OR: 3.19; 95% CI: 1.51 to 6.77). A comparison of the size of the effect estimates showed that the increase in adverse outcomes became additive when PCIs are performed by low-volume operators in low-volume hospitals (58). A similar institutional–operator volume relationship (117) to outcomes was reported in 452,404 patients undergoing PCI in Florida and New York between 1996 and 2001. Operators performing ≥75 PCIs at hospitals performing >400 PCIs had the lowest occurrence of the overall composite outcome (in-hospital mortality and emergency CABG surgery) in each year (117). Srinivas et al. (99) demonstrated a significant interaction between hospital and physician volume with respect to adjusted mortality (p=0.02) among acute MI patients undergoing PPCI from the New York State PCI Registry (2000 to 2002). PPCI by high-volume physicians (>10 PPCIs/year) in high-volume hospitals (>50 PPCIs/year) was associated with the lowest risk-adjusted mortality, followed by high-volume physicians in low-volume hospitals, low-volume physicians in high-volume hospitals, and finally, low-volume physicians in low-volume hospitals.

2.8.1.6. LIMITATIONS OF THE EXISTING EVIDENCE

The majority of evidence related to volume–outcome relationship is derived from retrospective administrative data, observational studies, or large registry data; all of which have shortcomings (Online Appendices 1–3). Many of these studies used administrative data to analyze volume–outcome relations. Incomplete reporting of comorbidities is an important limitation of administrative data (73,76). A comparison of administrative versus clinical data in patients found that the former failed to identify more than half of patients with a prognostically important condition

[†]Although the 2011 ACCF/AHA/SCAI PCI guideline includes recommendations regarding operator and institutional volume, it was anticipated that this current writing group, tasked specifically with examining volume thresholds, would be the primary source and that the 2011 PCI guidelines might be subsequently modified. Therefore, the operator and institutional volume discussion, conclusions, and recommendations in this document supersede the recommendations in the 2011 ACCF/AHA/SCAI Guideline on Percutaneous Coronary Intervention (2).

identified by the clinical information system (118). Administrative data may also be confounded by miscoding, including increased coding of comorbidities to raise reimbursement (118). Additional recognized limitations of specific databases exist. When using the Medicare data, for example, one needs to extrapolate the total number of procedures from the number of Medicare procedures (68,70,71,84). By contrast, the GWTG initiative is a quality improvement registry and not meant to examine the volume–outcome relationships (91). Data are submitted voluntarily to the GWTG–CAD database by participating hospitals and collected by medical chart review, and are thus dependent on the accuracy and completeness of abstraction (91). The New York Registry (58,97,99,101,117) is characterized by mandatory participation and a comprehensive auditing process, which ensures accuracy and minimizes self-reporting bias. However, because of New York's certificate of need system, the number of low-volume hospitals in the registry is limited, so it is more difficult to study their performance. Data on timeliness of reperfusion are also lacking, and the generalizability of data from a single state registry remains questionable. The latter is not an issue for the Nationwide Inpatient Sample database, which represents a 20% stratified sample of community hospitals in the United States. However, the Nationwide Inpatient Sample database does not capture long-term mortality and clinical outcomes, and has no information on the severity of the primary diagnosis or comorbid conditions, which precludes robust risk-adjustment analyses (78).

Overall, data from these studies should be viewed in the context of their retrospective observational nature. They identify only associations rather than causality. In addition, despite the use of intricate multivariable analyses in the various studies, no amount of adjustment in regression models can completely separate the greater illness severity from worse outcomes, and some portion of the relationship may still be due to selection bias. Referral bias is also an important confounder, with low-volume hospitals having disproportionately more patients with acute coronary syndrome and a lower percentage of stable coronary artery disease patients. The National Surgical Quality Improvement Program studies underscored the limitations of claims data and administrative databases in the provision of adequate risk-adjustment models that are crucial for volume–outcome studies (67).

2.8.2. Volume as a Surrogate for Quality

2.8.2.1. PLAUSIBLE EXPLANATIONS FOR THE VOLUME–OUTCOME RELATIONSHIP

Various factors can explain the relationship between PCI volume and outcome. It is possible that PCI volume is correlated with enhanced care processes, including the implementation of specific clinical practice guidelines for patients undergoing PCI or familiarity with treating its complications and emergencies. The influence of the learning effect among operators (high-volume operators developing more experience) is also important. High-volume hospitals are likely to have high-volume operators and, consequently, experience better outcomes. High-volume hospitals may also be accepting higher-risk patients with more complex anatomy that may adversely affect outcomes.

2.8.2.2. LIFETIME PCI EXPERIENCE RELATIONSHIP TO QUALITY

Historically, volume has been used as a surrogate for quality because it was most easily measureable. However, we feel it is important to note that volume is only 1 of many factors affecting the outcome and quality of PCI. Many studies have emphasized that the quality of systems of care are more important than volume in determining the overall quality of procedural care at an institution. Volume should not be substituted for prospectively monitored and properly risk-adjusted outcomes (67); however, evaluating competency is only feasible when an operator or an institution performs an adequate number of cases to assess risk-adjusted outcomes. The 2011 ACCF/AHA/SCAI PCI guideline emphasized that risk-adjusted outcomes remain preferable to institutional and individual operator volumes as quality measures (2), outlining the importance to shift the paradigm from examining volume (a surrogate of outcome) to direct outcome assessment. Lifetime operator experience and appropriateness of procedure are also important metrics. One small study from Japan (7 operators performing PCI on 121 STEMI patients) demonstrated that junior cardiologists who performed >50 elective PCIs can perform PPCI with similar outcomes to experienced operators (>5 years of experience and board certified). However, the impact of lifetime operator experience needs to be explored in larger studies, especially in our current environment when many experienced operators are increasingly performing structural interventions at the expense of lower coronary interventional volume, and older experienced operators often are required to take less on-call time than younger members of their group. Periodic case review to ascertain appropriateness and quality of PCI procedures is also important (refer to section 2.10.5.1). Low-risk PCIs performed for the wrong indication are likely to have favorable outcomes but still reflect poor PCI quality because of inappropriateness of selection. Variables affecting PCI outcome are summarized in Table 4 (119).

Table 4. Possible Predictors of Clinical Outcomes Following PCI

Case selection
Patient-specific risk factors
Institutional volume: sharing of techniques, more experience in high-risk cases
Operator volume: annual, lifetime
Appropriateness criteria and indication level
High-risk case selection may be related to higher case volume
Location of hospital: rural/suburban, community, academic teaching
Board certification: cognitive learning, evidence-based practice

Reprinted with permission from Klein et al. (128).
PCI indicates percutaneous coronary intervention.

2.8.2.3. CAUTION AGAINST PREOCCUPATION WITH SPECIFIC VOLUME RECOMMENDATIONS

The 2011 ACCF/AHA/SCAI PCI guideline recommended that PCI should be performed by operators with an acceptable annual volume (>75 procedures) at high-volume centers (>400 procedures) with onsite cardiac surgery (2). These volume recommendations were carried over from the 2005 ACCF/AHA/SCAI PCI guideline (25) but downgraded to a Level of Evidence C, recognizing that they represent expert opinion and lack strong and consistent evidence from the literature. The 2011 PCI guidelines also encouraged the ACCF/AHA/SCAI Clinical Competence Statement on Cardiac Interventional Procedures writing committee to review this issue (2).

It is the opinion of our writing committee that the public, policymakers, and payers should not overemphasize specific volume recommendations recognizing that this is just 1 of many factors that may be related to clinical outcomes. Notably, 1 report found that <1/3 of physicians performed >10 PPCIs/year (99), whereas another showed that >1/3 of U.S. hospitals did not achieve the 36 PPCIs/year threshold (91). The Leapfrog Group initially focused on minimum volume standards to measure quality and encouraged their members to contract with hospitals that meet minimum volume thresholds (120). However, in 2003, they expanded their measures to include documented adherence to certain clinical care processes and direct outcomes measurement (i.e., risk-adjusted mortality) (121). Of note, the 2010 European Society of Cardiology Guidelines on Myocardial Revascularization avoided giving specific recommendations on operator or hospital minimum volumes (122).

The relative benefit of more favorable outcomes at facilities with higher volumes must be weighed against the potential decline in access resulting from minimum volume standards or regionalization of care. Although regionalization of care may ensure better outcomes (especially in the early stages of a medical intervention), it may also limit healthcare access and may therefore have negative consequences for patients in less populated areas requiring emergency PCI. After reviewing the preponderance of evidence, the writing committee could not identify definite cutoffs for procedural volume above or below which operators perform well or poorly. We recognize that advancements in technology and periprocedural care may result in progressive improvement in PCI outcomes and may at least partially offset the adverse institution volume–outcome relationship. A study evaluating temporal trends in the volume–outcome relationship in California found that over time, the disparity in outcomes between low- and high-volume hospitals had narrowed (73). These findings were, however, disputed by others who found no evidence of attenuation over time of the volume–outcome relationship (82).

Our writing committee recognizes that there are institutions with low volumes that appear to achieve very acceptable results just as there are low-volume operators with better than expected outcomes and a few high-volume operators with worse outcomes (85). Because of the likelihood of statistical imprecision when examining outcomes of low-volume operators, other metrics are needed in addition to volume and risk-adjusted outcomes. It is also important to account for operators' lifetime experiences: many experienced operators are currently performing low-volume coronary interventional work and shifting to structural work or a larger portion of administrative duties, and these should be distinguished from *"inexperienced"* low-volume operators. Institutions are encouraged to perform periodic peer review of random interventional cases for all operators. Importantly, low-volume operators should undergo more scrutinized case review. Participation in regional and national registries such as the NCDR® CathPCI Registry is strongly recommended. Such registries should provide timely data that are risk-adjusted, robust, audited, and benchmarked so that clinicians, hospitals, regulatory bodies and other stakeholders can accurately assess the quality of care delivered. Additional emphasis on educational symposia, CME credits, and simulation courses may provide other venues to enhance quality for all operators. Currently, several simulation companies have products designed to present coronary, peripheral, carotid, and structural cardiac cases that can be used for teaching or evaluation of cognitive and procedural skills. The use of these simulators has mostly been in the area of fellow education or MOC modules, or industry has used them to train practitioners to use new or less frequently used devices. Supported by accumulating evidence, many educators advocate the use of simulator-based training as a means to complement conventional training in interventional cardiology (123–126). There are emerging data suggesting that simulators might serve to identify low-ability operators; however, the writing committee acknowledges current technological and access limitations currently exist, presenting challenges to the widespread use of simulation (127).

2.8.3. Conclusions

In the current era, volume–outcome relationships are not as robust as those that were shown when balloon angioplasty was the only treatment modality. More recent data support a modest volume–outcome relationship for variables other than mortality, but these data have limitations and are not consistent across all studies. An institutional volume threshold <200 PCIs/annually appears to be consistently associated with worse outcomes, but above this level, there was no relationship between even higher annual volumes and improved outcomes. Accordingly, the writing committee recommends a minimum institutional volume threshold of 200 PCIs per year. There is less evidence to support a threshold for individual operator volume for both elective and primary PCI. It is the writing committee's recommendation that interventional cardiologists perform a minimum of 50 PCI procedures per year (averaged over

a 2-year period) to maintain competency. The writing committee cautions against focusing on specific volume recommendations, and emphasizes that procedural volume is 1 of several variables to consider when determining operator competency. Volume is not a surrogate for quality and should not be substituted for risk-adjusted outcomes and other measures of quality. Periodic case review and ascertainment of the appropriateness of procedures should be performed for all operators and at all institutions. Our writing committee strongly encourages the participation in a local or national registry, such as the NCDR® CathPCI Registry, which can help measure performance, assess appropriateness of procedures, and promote continuous quality improvement.

2.9. Radial Access

Radial coronary angiography was first introduced by Lucian Campeau in 1989 (129), followed by radial PCI first performed by Ferdinand Kiemeneij in 1992 (130). Over the last 2 decades, the use of radial coronary angiography and intervention has steadily increased across Europe, Asia, and Canada (131–133). The penetration of the radial approach into the United States, however, has been slow and was estimated at 2% in 2008 (134) but continues to rise (135). The slow adoption of this technique in the United States has been due to a prior lack of formal training during fellowships as well as the lack of well-defined training pathways for physicians in practice.

Use of the radial artery for diagnostic and interventional coronary procedures has been compared with the femoral approach in both observational studies and randomized trials and has demonstrated significant reductions in bleeding and access site complications (131–134,136,137). The most compelling evidence supporting the advantages of radial access comes from the RIVAL (Radial versus Femoral Access for Coronary Angiography and Intervention in Patients with Acute Coronary Syndromes) trial (136), which compared outcomes in 7,021 patients randomized to either radial (n = 3,507) or femoral access (n = 3,514). Although the primary endpoint (e.g., death, MI, bleeding, access site complications) was negative, this trial demonstrated that in certain situations (e.g., patients presenting with STEMI) a radial approach may be associated with significant reduction in access site complications and mortality versus a femoral access approach (Figure 3). Furthermore, this study supports prior observations (137,138) reporting a patient preference for the radial approach noting less discomfort and greater postprocedural mobility.

The use of a transradial approach, however, is associated with a steeper learning curve (139), and potential increased radiation exposure and radial artery occlusion that can be as high as 30% if best practices are not followed (140). Patient selection and preprocedural evaluation are critical components of assuring a successful transradial procedure. The ideal patient characteristics include: 1) hemodynamic stability; 2) age <70 years; 3) no history of prior ipsilateral brachial or transradial procedure; and 4) a palpable radial artery with a strong pulse and presence of a normal Barbeau test (141). Relative contraindications to the radial approach include an absent radial pulse, an abnormal Barbeau test, severe vasospastic conditions, planned or existing arteriovenous shunt for dialysis, and the potential use of the radial artery as a conduit for aortocoronary bypass.

The Barbeau test evaluates the patency of the ulnopalmar arterial arches by recording both pulse oximetry and plethysmography during radial artery compression. An oximetric probe is placed on the first finger or thumb of the hand where access is to be obtained. When the radial and ulnar arteries are occluded, the waveform should be dampened, and no oxygen saturation number can be recorded. The Barbeau test is more sensitive than the Allen's or modified Allen's tests, and classifies patients into 4 groups. If the waveform remains dampened after release of the compressed ulnar artery, the test is considered abnormal (type D), and the radial artery should not be punctured. Type D pattern usually occurs in only 1.5% of patients.

2.9.1. Training

Current interventional cardiology training program guidelines provide no specific recommendations regarding training for the transradial approach. The ACCF Core Cardiology Training Symposium (COCATS) guidelines state that one needs the ability to "perform vascular access from the femoral, radial, or brachial route" (142). Also, the current ACGME Program Requirements for Graduate Medical Education in Interventional Cardiology states that "Fellows must have formal instruction, clinical experience, and must demonstrate competence in the performance of coronary interventions [via] femoral and brachial/radial cannulation of normal and abnormally-located coronary ostia" (3, p. 10).

Ideally, interventional fellows would graduate with competency in radial and femoral procedures, and practicing physicians would have a well-defined pathway to gain these skills. However, this has not come to fruition in the United States due to the small number of radial procedures and the limited number of interventional cardiologists skilled in this technique. Training in radial coronary angiography and interventions should include acquisition of knowledge and competence in the following:

1. Anatomy of the upper extremity vasculature
2. Patient evaluation and selection for transradial approach
3. Selection of right or left transradial approach
4. Patient preparation and room set-up
5. Radial artery access
6. Arterial vasodilators and antithrombotic pharmacology
7. Catheter selection and manipulation for diagnostic and interventional procedures
8. Troubleshooting during transradial approach

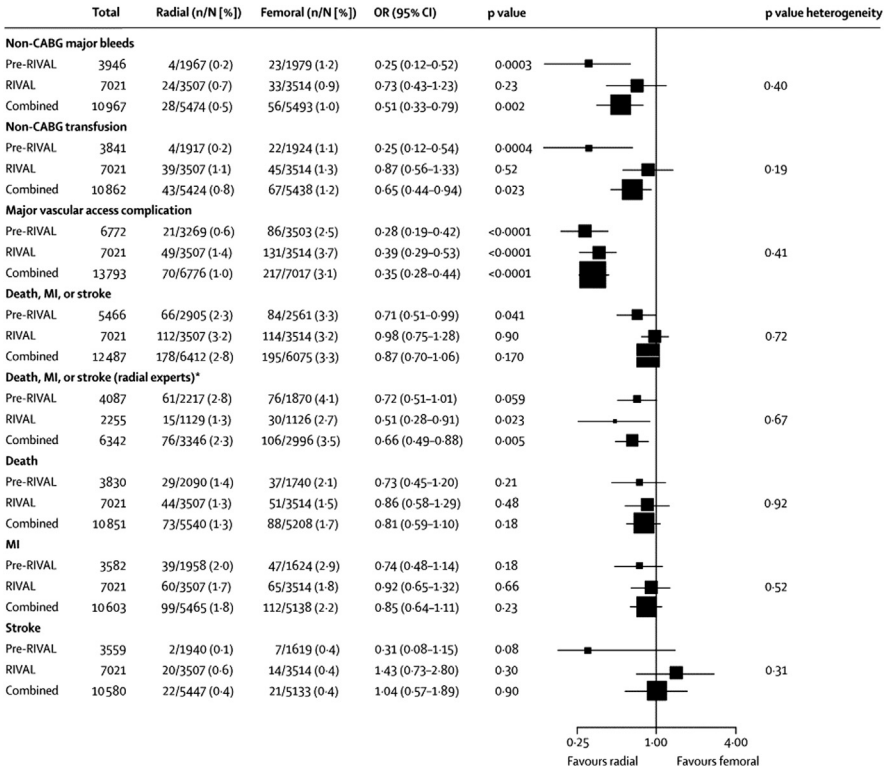


Figure 3. Forest Plot of the Updated Meta-Analysis (RIVAL Trial)

*Defined as centers with radial as the preferred route or known expert centers for pre-RIVAL, and centers with the highest tertile radial intervention center volume for RIVAL. CABG indicates coronary artery bypass graft surgery; CI, confidence interval; MI, myocardial infarction; OR, odds ratio; and RIVAL, Radial vs. Femoral Access for Coronary Angiography and Intervention in Patients with Acute Coronary Syndromes trial. Reprinted with permission from Jolly et al. (136).

9. Prevention, recognition, and management of complications
10. Sheath removal and access site management

For physicians in practice, the number of cases required for competency will be based on the expertise of the operator. The learning curve for any new procedure partially depends on the cumulative experience of the operator in catheter-based interventions. Fellows in training will need prospectively defined curricula that cover the spectrum of cognitive and technical skills required to master this approach.

2.9.2. Competency

Currently, there are no standard guidelines that define competency in radial angiography and interventions. The SCAI subcommittee for transradial angiography and intervention proposed the following criteria (141):

- Level 1 competency: able to perform simple diagnostic cases on patients with favorable upper limb anatomy (large men)
- Level 2 competency: Able to perform simple diagnostic and interventional procedures on patients with more challenging upper limb anatomy (elective single vessel PCI; bypass grafts, small women, radial and subclavian loops)
- Level 3 competency: Able to perform complex interventional procedures even with challenging limb anatomy (chronic total occlusions, multivessel, acute MI)

At the present time, as such pathways develop, the outcomes of PCI procedures via the radial approach should be assessed in a similar manner to that of other PCI procedures, with attention to bleeding, access site complications, and overall outcomes. These procedures should be included in the overall volume statistics for the operator, and institutions or operators may wish to separately evaluate operator or laboratory performance based upon route of access. Further expansion of specialized training courses for interventional cardiologists already in practice wanting to acquire competencies in radial coronary angiography and PCI should be provided to meet current needs.

2.10. Quality Assurance

2.10.1. Definition of Quality in PCI

Quality in PCI includes selecting appropriate patients for the procedure, achieving risk-adjusted outcomes that are comparable to national benchmark standards (in terms of procedural success and adverse event rates), using reasonable resources, achieving quality procedure execution

(including the use of evidence-based medical therapies) and providing an acceptable patient experience (143). To achieve optimal quality and outcomes in PCI, including acceptable angiographic, procedural, and clinical success rates, it is necessary that operators and the supporting institution be appropriately skilled and experienced, collect data to allow quality analysis, and have established appropriate systems of care.

2.10.2. Institutional Requirement for a Quality Assurance Program

In the United States, responsibility for quality assurance is vested in the healthcare institution that is responsible to the public to ensure that patient care conducted under its jurisdiction is of acceptable quality. Quality assurance should include continuous quality assessment and improvement (QI) processes, and should be conducted at the levels of the entire program and the individual operator.

The writing committee supports the recommendation of the 2011 ACCF/AHA/SCAI PCI guideline that every PCI program should operate a quality improvement program that routinely: 1) reviews quality and outcomes of the entire program; 2) reviews results of individual operators; 3) includes risk adjustment; 4) provides peer review of difficult or complicated cases; and 5) performs random case reviews (2). Each institution that provides PCI services must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. The program should provide an opportunity for interventional cardiologists and all involved physicians, including members of an integrated heart team, to review its overall results on a regular basis and receive periodic feedback to enhance deficiencies in PCI care. The review process should tabulate the outcomes achieved both by individual operators and the overall program, and compare them with national benchmark standards with appropriate risk adjustment. The review process should also assess the appropriateness of the interventional procedures, and examine other procedural variables pertinent to quality execution of the procedure, periprocedural management, and resource utilization. Valid quality assessment requires that the institution maintain meticulous and confidential records that include patients' demographics and clinical characteristics necessary to assess these measures and conduct risk adjustment in a transparent manner.

An independent and dedicated committee should be established and ideally include both physicians and relevant healthcare personnel in a cooperative effort minimizing any conflict of interest. Interventional cardiologists are best suited to perform the primary role in evaluating PCI quality and leading the quality assurance program. The process should be instituted with the support of hospital administrators who can help provide resources for registry participation, conduct analyses, and support other aspects of the QI process. The hospital risk management department, responsible for investigating reported events and government-mandated quality indicators, should work in cooperation with the physician-led quality assurance program. Use of the data for non-QI purposes (e.g., marketing strategies, improving referral) should be strongly discouraged. Programmatic deficiencies, in particular, should be identified with the involvement of hospital risk management, when appropriate.

The institution should also ensure that all operators are properly trained and certified (including MOC) and possess the cognitive knowledge and technical skills required to perform PCI (144).

2.10.3. Complexity of Determination of PCI Quality

2.10.3.1. IDENTIFICATION OF PCI QUALITY INDICATORS

Components of an optimal quality assurance program require that several outcome and process measures are routinely and timely collected and analyzed. A dedicated database must be established with hospital support and should include explicitly defined quality indicators that reflect patient outcomes and processes of care. Table 5 provides an example of core PCI outcomes and measures that every quality assurance program is encouraged to

Table 5. PCI Outcomes and Adverse Events

- Major outcomes
  - Mortality (in-hospital, 30 day)
  - Unplanned CABG surgery (same day, same stay: urgent vs. elective)
  - Stroke, TIA, or other neurological events
  - Myocardial infarction* or ischemia
  - Arrhythmias requiring treatment
  - Cardiac arrest in the cardiac catheterization laboratory
  - Hemodynamic instability requiring therapy
  - Major contrast reaction
- Procedural adverse events
  - Coronary
    - Abrupt closure requiring specific therapy
    - Distal embolization/no reflow
    - Coronary perforation
    - Cardiac tamponade
    - Stent thrombosis
    - Other AEs (e.g., stent loss, retained foreign body, guidewire fracture)
  - Systemic/Peripheral
    - Contrast-induced nephropathy/new requirement for dialysis
    - Excess radiation dose (fluoroscopy time/dose)
    - Intracranial hemorrhage
    - Vascular site complications
      - Major drop in hemoglobin (>3.0 g/L) or requirement for blood transfusion
      - Major bleeding
      - Access site vascular injury
      - Retroperitoneal hemorrhage
      - Arterial access vessel occlusion or dissection
      - Access site infection
      - DVT/pulmonary embolism
    - Other AEs (e.g., stent loss—peripheral)
- Additional measures
  - Door-to-balloon time in STEMI
- Wrong patient or procedure

*Universal Definition of Myocardial Infarction should be employed. Adapted with permission from Klein et al. (128).

AEs indicates adverse events; CABG, coronary artery bypass graft surgery; DVT, deep vein thrombosis; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; and TIA, transient ischemic attack.

record and submit to national or regional databases. The QI process can be best implemented by incorporating clinical practice guidelines and appropriateness criteria for coronary revascularization (2,52), as they have been shown to improve clinical outcomes (59,145,146).

2.10.3.2. ROLE OF RISK ADJUSTMENT IN ASSESSING QUALITY

An adverse event rate that is not appropriately risk-adjusted has limited value. Data compiled from large registries of PCI procedures have generated multivariable risk adjustment models for mortality and other adverse events. Most of these models are based on logistic regression analyses of in-hospital events (predominantly mortality) using a large number of prospectively-collected variables. Notably, many of these models were derived from earlier patients' cohorts, and are outdated in the current era of rapidly evolving technology and medical therapy. Contemporary PCI risk scores and predictive models are summarized in Online Appendix 5 (31, 147–153). Sufficient resources must be available to adequately measure baseline patient risk permitting valid risk adjustment of outcomes and determining appropriateness of the intervention.

2.10.3.3. NATIONAL BENCHMARKING

National benchmarking is a means to compare a physician's clinical practice and patient outcomes against his/her peers, and is a valuable means to understand high variances in low incidence adverse events (154). Benchmarking requires standardized collection of clinical and procedural data for PCI using identical elements that are entered into a single electronic repository. This allows regular comparison of risk-adjusted outcomes and complications with national standards. A complete and accurate comprehension of clinical results requires benchmarking of risk-adjusted outcomes to account for differences in patient characteristics and avoid self-reporting bias (155). Appropriate short-term follow-up should also be arranged prior to discharge, because 30-day outcomes have become increasingly required for reimbursement purposes.

The writing committee of the current Clinical Competence Statement echoes the 2011 ACCF/AHA/SCAI PCI guideline in encouraging the participation in a recognized national quality database. Registries such as the ACCF NCDR® CathPCI Registry (156,157), which began in 1998, are designed to standardize reporting of catheterization laboratory outcomes. These types of clinical registries offer the opportunity to have a comprehensive national reporting system that fulfills the goals of assessing and benchmarking quality and outcomes. They can also be utilized to measure performance and utilization rates, promote continuous quality improvement, conduct post-market drug and device surveillance, assess appropriateness of procedures, and track patient safety (154). We look forward to the expansion of currently available databases to better capture important safety, longer-term outcome, quality of life, and resource utilization measurements.

2.10.3.4. OTHER CHALLENGES IN DETERMINING QUALITY

Given the complexity of case selection and procedure conduct, quality is difficult to measure in PCI and is not determined solely by adverse event rates even when properly risk-adjusted. Notably, procedural volume is a weak and inconsistent measure of quality, and it should not be used alone as a quality indicator. In addition, only short-term outcomes (such as in-hospital mortality) are usually used as the benchmark for risk-adjusted outcomes, and long-term outcomes (including repeat revascularization, recurrent MI, death, and re-hospitalization rates) are often underutilized. Accurate assessment of quality is more problematic for low-volume operators and institutions because of small expected absolute event rates and issues of statistical imprecision. Thus, particularly in low-volume circumstances, quality may be better assessed by an intensive case-review process. Case review also has merits in very high-volume situations as it can identify subtleties of case selection and procedure conduct that may not be reflected in pooled statistical data. It is the opinion of the writing committee that all operators should undergo periodic peer review, with more intensive review process for low-volume operators. Although performance of very high-volume operators is more easily monitored using risk-adjusted outcomes models with comparison to national benchmarks, these operators should also be reviewed for the appropriateness of procedures and indications criteria to assure the clinical necessity of these procedures. Finally, the possibility of conflicts of interest among competing physicians exists. It is therefore strongly advised that a formal method of oversight for perceived conflicts of interest among peer reviewers be used and carefully scrutinized.

2.10.4. Requirement for Institutional Resources and Support

A high-quality PCI program requires appropriately trained, experienced, and skilled operators. However, the operator does not work in a vacuum, but rather needs a well-maintained high-quality cardiac catheterization facility to practice effectively. In addition, the operator depends on a multidisciplinary institutional infrastructure for support and response to emergencies, including adequate cardiothoracic surgical support (onsite or with a pre-defined strategy for offsite surgical back-up). System "stress test" drills to assess logistics flow capabilities of both the referring and receiving centers can help refine a well-coordinated emergent transfer. Therefore, to provide quality PCI services, the institution must ensure that its catheterization facility is properly equipped and managed, and that all of its necessary support services, including data collection, are of high quality and are readily available.

Educational activities such as cardiac catheterization and quality improvement conferences should be encouraged by the institution and should be held routinely. Presentation of clinical and technically challenging cases, including those with complications and unexpected developments

during the conduct of a PCI, along with appropriateness reviews, is important. Advances in current communication technologies, such as video conferencing or simulcast case reviews, can facilitate this process. It is important to appreciate that the separation of peer review from more traditional teaching activities is most appropriate for optimal quality assurance.

2.10.5. Quality Assessment and Implementation Processes

Quality assessment is a complex process that includes more than a mere tabulation of success and complication rates. The PCI quality assurance program should be comprehensive and evaluate multiple patient subsets so as to promote both individual physician and system-wide quality improvement.

The core of most PCI quality assurance programs should include: a) the collection of clinically relevant data, which contain variables that allow assessment of clinical processes, performance, and outcomes; b) feedback of this performance and outcomes data to clinicians, ideally with risk-adjustment and benchmarking of the data; and c) implementation of appropriate interventions to promote reduction in inefficient variation in care while simultaneously improving performance (158). PCI quality assurance must include an ongoing, peer review assessment of the clinical proficiency of each operator including random case review, realistic identification of programmatic and individual operator strengths and weaknesses, and comparison of individual and aggregate outcomes against national standards and benchmark databases. Components of quality in coronary interventional procedures include: a) appropriateness of case selection; b) quality of procedural execution; c) proper response to intra-procedural problems; d) accurate assessment of procedural outcome both short- and long-term; and e) appropriateness of periprocedural management. SCAI recently published a report to establish the standard by which interventional program quality should be measured (128). Quality includes the ability of an interventional cardiologist to provide safe and efficient care to appropriately selected patients, and the expertise to treat a wide range of coronary pathology in these patients.

2.10.5.1. THE PEER REVIEW PROCESS

The quality assessment process should also conduct random and detailed reviews of both cases that have adverse outcomes, to determine the causes of the adverse events, and of uncomplicated cases, in order to judge case selection appropriateness and procedural execution quality. These reviews should be conducted by recognized, experienced, unbiased interventional cardiologists, drawn either from within the institution or externally. Noninvasive cardiologists may also participate in the review committees, especially when it comes to assessing procedural appropriateness. A timely and periodically conducted review process is essential as the reviewers should provide continuous feedback to the institutions and operators to enhance the care process. Review of cineangiography films should be undertaken to address technical issues. External review represents a second layer of unbiased review of the interventional program. The Accreditation for Cardiovascular Excellence (ACE), initially created by the SCAI in 2010 and cosponsored by the ACCF, is 1 example of an external peer review body, which offers formal, objective, and independent evaluation and monitoring to PCI facilities to ensure that they meet the highest possible standards for patient care and safety. Other forms of external review options exist and individual institutions will need to determine the appropriate external review option for its particular clinical needs, should that be desired. Confidential and constructive feedback of performance and outcomes data should be given to clinicians to promote changes in practice and improve performance (158).

2.10.5.2. METHODS OF REMEDIATION

When the continuous quality improvement process identifies a systemic problem that requires remediation, the quality assurance committee must investigate the root cause and devise a solution. A formalized plan and implementation strategy (including continued reassessment) should be proposed, and ongoing modification may be required to reach the target result. Recommendations should be based on a comprehensive knowledge of the issue and input from all appropriate stakeholders. When concerns with operator performance arise, remediation should be implemented in a stepwise fashion. Remediation methods may start with an initial discussion with the operator, followed by a nonpunitive action plan with appropriate and constructive feedback, such as proctoring a number of cases by the lab director or an experienced operator, as well as additional CME requirements. If this is unsuccessful or the operator is uncooperative with the plan of remediation, then the next steps may include referral to an external agency or internal hospital committee which may result in penalties or sanctions for the operator, and possibly revocation of the operator's privileges.

2.10.5.3. CONFIDENTIALITY

The Federal Health Care Improvement Act of 1986 recognized the importance of quality assurance programs and the importance of protecting participants and their deliberations. Protecting patient safety is most important in the quality assurance process. The committee must behave equitably and transparently to ensure fairness to the operator, quality for the patient, and credibility for the committee. Outcomes must be presented while maintaining absolute confidentiality of the operators. Use of confidential information to target an individual physician should not be allowed.

2.10.6. Conclusions

The cornerstone of quality assurance monitoring is the transparent reporting and continued assessment of procedural outcome data including adverse events. Equally important components include establishing criteria for assessing procedure appropriateness and applying proper risk adjustment to interpret adverse event rates. A quality interventional program performs appropriately selected procedures while achieving risk-adjusted outcomes that are favorably comparable to national benchmark standards. There has been considerable controversy surrounding the efforts to define standards and methodologies for conducting quality assurance. An objective, physician-led process that includes appropriate evaluation and corrective action plans and is organized to assure a fair and impartial review of performance, provides a reasonable level of assurance that quality is being accurately assessed and promoted. An effective process should also include random case review, develop critical pathways, and accomplish and document positive changes in practice.

2.11. Summary of Key Recommendations for PCI

Physical Facility and Institutional Requirements (*see Section 2.5.1*)

***Physical Facility Requirements*:**

- The facility must provide the necessary radiological, monitoring, and adjunctive patient support equipment to enable operators to perform in the safest and most effective environment.
- The real-time fluoroscopic and acquired image quality must be optimal to facilitate accurate catheter and device placement and facilitate the correct assessment of procedural results.
- Physiological monitoring equipment must provide continuous, accurate information about the patient's condition.
- Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve should be available.
- Hemodynamic support devices such as intra-aortic balloon pumps and percutaneous ventricular assist devices should be available in institutions routinely performing high-risk PCI.
- These requisite support equipment must be available and in good operating order to respond to emergency situations.

***Institutional Requirements*:**

- The interventional laboratory must have an extensive support system of specifically trained laboratory personnel. Cardiothoracic surgical, respiratory, and anesthesia services should be available to respond to emergency situations in order to minimize detrimental outcomes.
- The institution should have systems for credentialing, governance, data gathering, and quality assessment. Prospective, unbiased collection of key data elements on all patients and consistent timely feedback of results to providers brings important quality control to the entire interventional program and is critical to assessing and meeting appropriate use criteria for coronary revascularization.
- The writing committee endorses the ACCF/AHA/SCAI PCI guideline (2) recommendations that:
  - Primary PCI is reasonable in hospitals without onsite cardiac surgery, provided that appropriate planning for program development has been accomplished (Class IIa).
  - Elective PCI might be considered in hospitals without onsite cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (Class IIb).
  - Primary or elective PCI should not be performed in hospitals without onsite cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without hemodynamic support capability for transfer (Class III).
- System "stress test" drills to assess logistics flow capabilities of both the referring and receiving centers can help refine a well-coordinated emergent transfer.

Components of Operator Competence (*see Section 2.7*)

- See Table 3 for the components of operator competence for PCI utilizing the ACGME core competency structure pertaining to medical knowledge; patient care and procedures; practice-based learning; systems-based practice; interpersonal and communication skills; and professionalism.

Maintenance of Quality

***Institutional* (*see Section 2.8.1.1*)**

- Full-service laboratories (both primary and elective PCI, with and without onsite cardiac surgery) performing <200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger-volume facilities. The continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should close.

***Individual Operator* (*see Section 2.8.1.2*)**

- The individual operator level volume is 1 of several factors that should be considered in assessing operator

competence, including lifetime experience, institutional volume, individual operator's other cardiovascular interventions, and quality assessment of the operator's ongoing performance.
- Interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year (averaged over a 2-year period) to maintain competency.
- Facilities should develop internal review processes to assess operators <50 PCIs annually.
- Additional emphasis on educational symposiums, CME credits, and simulation courses may provide other venues to enhance quality for all operators.
- These recommendations supplant the recommendations in the 2011 ACCF/AHA/SCAI Guidelines on PCI.
- Operators should have ABIM board certification in interventional cardiology and maintain certification, with the exception of operators who have gone through equivalent training outside the United States and are ineligible to take the ABIM certification and recertification exams.

***Primary PCI* (*see Section 2.8.1.3*)**

- Primary PCI for STEMI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.
- These recommendations supplant the recommendations in the 2011 ACCF/AHA/SCAI Guidelines on PCI.

Quality Assurance

***Institutional Requirements* (*see Section 2.10.2*)**

- Each institution that provides PCI services must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes.
- To reach these goals, every PCI program should operate a quality improvement program that routinely: 1) reviews quality and outcomes of the entire program; 2) reviews results of individual operators; 3) includes risk adjustment; 4) provides peer review of difficult or complicated cases; and 5) performs random case reviews.
- The review process should assess the appropriateness of the interventional procedures. Evaluation should include both the clinical criteria for the procedure and the quality and interpretation of the angiograms.
- Valid quality assessment requires that the institution maintain meticulous and confidential records that include patients' demographics and clinical characteristics necessary to assess these measures and conduct risk adjustment in a transparent manner.
- An independent and dedicated committee should be established and ideally include both physicians and relevant healthcare personnel in a cooperative effort minimizing any conflicts of interest. Interventional cardiologists are best suited to perform the primary role in evaluating PCI quality and leading the quality assurance program.
- The process should be instituted with the support of hospital administrators, who can help provide resources for registry participation, conduct analyses, and support other aspects of the QI process.

***Institutional Resources and Support* (*see Section 2.10.4*)**

- The institution must ensure that its catheterization facility is properly equipped and managed, and that all of its necessary support services, including data collection, are of high quality and are readily available.
- Educational activities such as cardiac catheterization and quality improvement conferences should be encouraged by the institution and should be held routinely. Presentation of clinical and technically-challenging cases, including those with complications and unexpected developments during the conduct of a PCI along with appropriateness reviews, is important.

***National Benchmarking* (*see Sections 2.8.2.3 and 2.10.3.3*)**

- Participation in regional and national registries such as the NCDR® CathPCI Registry is strongly encouraged. Such registries should provide timely data that are risk-adjusted, robust, audited, and benchmarked so that clinicians, hospitals, regulatory bodies, and other stakeholders can accurately assess the quality of care delivered.

***Quality Assessment and Implementation Process* (*see Sections 2.10.3.3, 2.10.3.4, 2.10.5, and 2.10.5.1*)**

- PCI quality assurance must include an ongoing, peer review assessment of the clinical proficiency of each operator including random case review, realistic identification of programmatic and individual operator strengths and weaknesses, and comparison of individual and aggregate outcomes against national standards and benchmark databases.
- Performance of all operators should be monitored using risk-adjusted outcome models with comparison to national benchmarks, and operators should be reviewed for the appropriateness of procedures and indications criteria to ensure the clinical necessity of the procedures.
- All operators should undergo periodic peer review, with more intensive review process for low-volume operators.
- In instances where operators are performing less than the suggested range, both institutions and operators are strongly encouraged to carefully assess whether their performance is adequate to maintain their competence and whether they should continue performing coronary interventions.

- A formal method of oversight for perceived conflicts of interest among peer reviewers should be used and carefully scrutinized.
- The quality assessment process should conduct random and detailed reviews of both cases that have adverse outcomes, to determine the causes of the adverse events, and of uncomplicated cases, in order to judge case selection appropriateness and procedural execution quality. These reviews should be conducted by recognized, experienced, unbiased interventional cardiologists drawn either from within the institution or externally. Noninvasive cardiologists may also participate in the review committees, especially when it comes to assessing procedural appropriateness.
- A timely and periodically conducted review process is essential as the reviewers should provide continuous feedback to the institutions and operators to enhance the care process.
- Review of cineangiography films should be undertaken to address technical issues.
- Confidential and constructive feedback of performance and outcomes data should be given to clinicians to promote changes in practice and improve performance.
- Addressing limitations of currently available databases to include other important quality metrics such as longer term efficacy and safety endpoints, quality of life, and resource utilization would be helpful in determining quality performance.

3. Other Coronary Interventions

Coronary interventions are occasionally required to provide an invasive therapeutic approach to hypertrophic cardiomyopathy, ventricular tachycardia (VT), and coronary fistulae. These are rare clinical situations that pose a unique problem for the establishment of operator and staff competency. These procedures should only be performed in major centers where there is a particular interest in the disease processes and adequate clinical volume to provide experience in the appropriate interventional techniques. A dedicated multidisciplinary team should be in place. These procedures require such a multidisciplinary team approach that involves cardiologists, surgeons, technicians, and nurses all working together to achieve optimal results.

3.1. Alcohol Septal Ablation for Hypertrophic Obstructive Cardiomyopathy

3.1.1. Background

The first description of the use of alcohol septal ablation for hypertrophic obstructive cardiomyopathy (HOCM) appeared in 1995 (159) and the 10-year follow-up of that first group of 12 patients was recently reported (160). Although most studies have reported single-institutional data, the multicenter North American Registry data (161) reviewed 874 patients who had undergone the procedure. A mortality rate of 0.7% from the procedure was reported. This latter group outlined the major complications associated with the contemporary use of the procedure and the clinical variables that predicted death during follow-up. A recent single-institution nonrandomized report of 177 patients who had alcohol ablation for HOCM revealed a survival rate similar to both the general population and to an age- and gender-matched surgical myomectomy cohort at 5.7 years of follow-up (162).

The principle of alcohol ablation depends on the localized injection of alcohol into a septal perforator artery that supplies the basal interventricular septum to create a controlled MI that will eventually lead to septal scarring and thinning. Localization requires identifying of the myocardium subtended by the coronary perforator. To properly perform the procedure requires a thorough knowledge of the geometric substrate. Usually, left ventricular outflow track (LVOT) obstruction is caused by asymmetrical septal hypertrophy and anterior displacement of the papillary muscle resulting in contact of the septum and anterior mitral leaflet during systole. However, LVOT gradients may also result from an abnormal mitral valve with redundant leaflets or accessory chordae. In addition, changes in aortoventricular alignment may also create obstruction with normal or only mild septal hypertrophy—a feature of LVOT obstruction in the elderly. Finally, gradients at the midventricular level or toward the left ventricular apex may not have the appropriate septal perforator supply and would not be appropriate for the use of alcohol ablation techniques. A thorough knowledge of catheterization anatomy and coronary interventional techniques, as well as echocardiographic and (even magnetic resonance imaging) imaging of the left ventricular and mitral apparatus anatomy, is therefore critical in some cases of HOCM. These skills are a prerequisite for selection of the appropriate patients and for the successful performance of these studies.

The 2011 ACCF/AHA Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy (163) outlines a suggested treatment algorithm for the appropriate use of alcohol septal ablation in the treatment of symptomatic patients with HOCM. It is important that these procedures be performed only at specialized centers dedicated to the comprehensive and multidisciplinary treatment of these patients.

3.1.2. Criteria for Competency

3.1.2.1. OPERATOR COMPETENCY

Using the ACGME core competencies to define the issues, it is the recommendation of this writing committee that the following be considered:

Patient Care: The operator should have a thorough knowledge of the impact HOCM physiology plays in the patient's symptom complex. Many of the symptoms

attributed to HOCM overlap with other disease states, particularly if there is concurrent lung disease, coronary disease, anemia, etc., so optimal patient care requires the operator to differentiate symptoms related to HOCM from these other issues. Medical therapy should be appropriate and considered to have been a failure before the procedure is attempted. At least 1 dedicated surgeon with a working knowledge of myectomy and valve repair should be part of the overall program, and there should be regular case reviews. For complex cases, surgical consultation should be sought, and the multidisciplinary team should agree that the interventional procedure is warranted. Nursing staff should be trained to recognize complications, both early and late, following the procedure.

Medical Knowledge and Procedural Volume: To gain the appropriate skill set for the performance of alcohol ablation requires the knowledge base related to the disease process (as described above) and the technical skills to safely perform the procedure. Medical knowledge regarding the procedure can be gained at courses at major meetings, participation in clinical trials or by working with colleagues at one's own institution or at another facility.

To gain the particular skill of alcohol ablation for HOCM patients, the committee suggests that *initially* each operator perform the first *5 studies in a proctored situation* assisting a skilled operator. These procedures could be done at the operator's own facility or at the skilled operator's facility. The ACCF/AHA HOCM guideline suggests that an *experienced operator* should not be defined until one has performed *>20 procedures* or the procedures have all been performed at a *facility* that has a cumulative volume of *50 procedures*. If the procedures are performed at a facility with a cumulative experience of <50 cases, it is recommended that the catheterization laboratory quality assurance committee (or one appointed by the institution) be responsible for reviewing all of the first 20 cases performed. For maintenance of skills, it is recommended that each *individual principal operator* perform at *least 10 procedures per year*. This latter number has also been suggested in a report from the SCAI training program directors (164) as being the minimal number for certification of cardiovascular trainees within the structural heart disease program who desire alcohol ablation skills as part of their interventional training.

The minimal number of procedures, however, does not correlate with either operator skill or patient outcomes. The committee feels strongly that alcohol ablation for HOCM should be performed only with a multidisciplinary team, and that volume is just 1 of many factors that should be considered in assessing operator competency. After each operator has developed the needed skillset in a proctored environment, then, given the rarity of the procedure, 5 alcohol ablations for HOCM per year should be considered a reasonable volume to maintain that skillset. The bottom line remains that the onus is on the local credentialing process and the quality assurance committee to ensure an operator is qualified and his/her procedural outcomes are of the highest possible quality.

Practice-Based Learning: The facility should provide a regular forum for the presentation of individual cases and provide the operators with feedback on the techniques and results obtained. These reviews should stress the use of evidence-based therapy and discuss best practices. As the field develops, these regular conferences should stress ways to improve the procedure and both institutional and individual outcomes. Literature reviews should be incorporated and verification confirmed that the practices being used conform to the established guidelines.

Interpersonal and Communication Skill: At the recommended periodic review sessions, any communication or conflicts regarding the appropriateness of the procedures or the technical issues should be directly discussed. Patient satisfaction should be addressed and criticisms acted upon. Feedback from staff and nursing should also be provided to ensure optimal patient care is being performed and that staff members are receiving the appropriate training.

Professionalism: Any criticism of the handling of the patient's care at any stage should be addressed. This includes ensuring the patient and his family understand the procedure, are treated respectfully and honestly, the consent process is clear, the referring physician is kept well informed, and all of the team members are acknowledged for their contributions.

Systems-Based Practice: The facility should have a formal commitment to the structural heart disease program and be supportive of establishing and maintaining the highest quality. Because care of the patient requires careful follow-up, it is important that the practitioners in the entire health system be aware of the potential complications from the procedure, and that a system is in place that allows for potential issues to be addressed should an untoward event occur after the procedure. Because many patients will receive the bulk of their care locally and not at the referral center, a systems-wide educational effort should be made to inform the healthcare professionals of the indications and contraindications of the procedure and the expected outcomes. A clear mechanism should be in place that allows ready access to a member of the procedural team should questions arise.

3.1.2.2. STAFF COMPETENCY

Many of the core competencies that apply to the operator are transferrable to staff involved as well. There should be a dedicated staff that has an interest in the procedure. It is particularly important that the cardiac catheterization team and the echocardiographic team work together, and they are considered a vital part of the procedural effort. The staff should be trained to anticipate all aspects of the procedure. Not only should initial training be formalized, but also continuing education should be considered a key element in the program design and maintenance.

3.2. Alcohol Ablation for Ventricular Arrhythmias

3.2.1. Background

When catheter-based ablation techniques to control VT using endocardial and epicardial techniques fail to resolve an intractable VT focus, a controlled infarction of the VT circuit may be feasible with alcohol injection into an epicardial coronary branch that supplies the region of interest on electrophysiological mapping (165). Once a potential branch is identified, the injection of iced saline or transient balloon occlusion of the vessel is performed to observe whether the arrhythmia terminates. Multiple branches may be tested before VT termination is achieved. If such a vessel is identified, alcohol injection then is used to produce a controlled infarction within the VT circuit. In 1 series, the method was reported successful in 56% of the patients attempted (166). The need for this approach has been estimated to be very low at about 1% to 2% of VT ablation cases (167).

3.2.2. Criteria for Competency

Given the highly specialized setting where this procedure is being attempted, only those in a tertiary center with experience in both coronary intervention and electrophysiology studies should consider performing these procedures. There are no established guidelines, and only case reports and very small series have been reported. Operators must meet established criteria for routine competency in this infrequently performed procedure, and should be knowledgeable and capable of describing the risks and benefits of this procedure versus other clinical choices. Alcohol ablation for VT should always be performed in the presence of the electrophysiologist who performed the mapping and the electrophysiology ablation procedure. The alcohol ablation procedure should be performed under continuous direct electrophysiological guidance. Prospective and retrospective catheterization laboratory review of such cases should be routinely undertaken, and at times, institutional review board approval should be sought for unusual situations. Although the committee acknowledges these procedures are being occasionally done in very controlled settings, monitoring these "orphan" procedures necessarily requires a robust quality assurance program to ensure patient safety and to approve operator competence. Institutional board review approval is a requisite.

3.3. Coronary Artery Fistula Closure

3.3.1. Background

The vast majority of coronary fistulae are congenital in nature, though iatrogenic fistulae have been reported after PCI for total occlusions, after septal myectomy for HOCM and following right heart biopsies of the interventricular septum. Congenital fistulae can arise from either coronary and generally (but not always) drain into right heart structures. Large fistulae carry a risk for coronary steal and myocardial ischemia and/or infarction. Rarely dissection, rupture, and endarteritis have been reported. Small fistulae may increase in size over time. Most coronary fistulae are detected as incidental findings during coronary angiography and are of no consequence. Auscultation of large fistulae reveals a continuous murmur. Closure of large fistulae has been achieved most often with coils, though vascular plugs and covered stents may be used when appropriate and feasible. The 2008 ACC/AHA Guidelines for Adults with Congenital Heart Disease (168) recommend that all symptomatic coronary fistulae should be intervened upon, but only large, audible fistula should be occluded if no symptoms. It is recognized that there are no clear definitions of symptoms related to these fistulae, unless there is evidence for a volume overload or demonstrable myocardial ischemia.

3.3.2. Criteria for Competency

3.3.2.1. OPERATOR COMPETENCY

Patient Care: As most patients do not need intervention for incidental coronary fistulae, optimal patient care requires the operator be able to identify those that require closure and understand how to best assess whether the lesion has significance. Surgical consultation should be included in the evaluation to ensure the appropriate approach is being considered. If a vascular interventional radiologist has experience in vascular occlusion, consultation with him/her should be part of good patient care.

Medical Knowledge and Procedural Volume: The operator should have a thorough understanding of the cause and anatomic features of any coronary fistula of concern. Delineation of the course of the fistula is critical to deciding if any percutaneous approach is feasible. The operator must be comfortable with coronary intervention and understand how to use vascular coils, plugs, and covered stents, depending on what is required. The procedures should only be done in centers that have a particular interest in such interventions. Because of the rarity of these procedures, a team approach with interventional radiology and surgery should be considered optimal when the operator is gaining experience. Although the SCAI training director's survey suggested a competency threshold of 10 procedures for cardiovascular fellows (164), this procedure is so uncommon and sporadic that it would be unlikely that such a threshold is achievable even in large programs. The onus once again falls on the credentialing and quality assurance oversight committees to review all of these procedures done at any institution.

Practice-Based Learning: The need for input from physicians outside the interventional cardiac catheterization laboratory mandates that patients proposed for this procedure be presented at a forum where the pros and cons of catheter-based and surgical-based options are presented. Various approaches should be discussed in the context of the group experience and the available literature. Attendance at national or regional meetings to improve the skill set need should be encouraged.

Interpersonal and Communication Skills: Patients and staff should have a thorough understanding of the procedure. Communication with patients' families and referring physicians is vital in case an adverse outcome should result. Operators must be able to work with consultants to arrive at the appropriate decision making.

Professionalism: Operators should be able to accept the advice of colleagues from surgery and radiology regarding the best approach for coronary fistula closure. Team members should be respected for their contributions.

Systems-Based Practice: As with other structural heart disease conditions, there must be a strong commitment from the facility administration to encourage and support a program that provides unique care offered at few other places. Communication of the ability to perform these procedures should be known throughout the respective health system. An effort should be made by the principle faculty and operators in the structural heart disease program to educate physicians in the hospital network as to when the procedure is required. Outcome data should be presented periodically so that physicians and other healthcare providers understand the risks and anticipated results from the procedure.

3.3.2.2. STAFF COMPETENCY

As with all coronary procedures the vital core competencies described must be an integral part of the expectation from staff as well as operators in the cardiac catheterization laboratory. Staff should be informed of procedural requirements and educated about the use of each of the interventional devices that is anticipated to be required. They should be an integral part of the process. They should be educated as to the complications that might occur, so as to best alert the operator at the earliest time when a potential untoward event appears imminent.

3.4. Summary of Key Recommendations Regarding "Other Coronary Interventions"

Multidisciplinary Approach

- Given that coronary interventions in patients with hypertrophic cardiomyopathy, ventricular tachycardia and coronary fistulae are rare, a team approach including coronary interventionalists, cardiothoracic surgeons, and cardiothoracic anesthesiologists is important for optimal results. Dedicated personnel should be identified, and a regular review of program activity and results documented.

Institutional Requirements

- These procedures should only be done in institutions with a strong commitment to provide all of the necessary equipment and staff support required to ensure these rare and complex procedures can be done safely and with a high degree of success.

Operator Competence

- The ACGME Core Competency Structure pertaining to medical knowledge; patient care and procedures; practice-based learning; systems-based practice; interpersonal and communication skills; and professionalism are outlined above for each procedure. Although there are no established minimal volume numbers for these procedures, it is suggested for HOCM alcohol ablation that the first 5 procedures be proctored and that maintenance of skills generally requires the performance of at least 5 procedures per year.

The Critical Importance of the Quality Assurance Program

- All of the issues outlined in regard to the quality assurance (QA) program for routine PCI procedures apply to the performance of these procedures. In addition, however, given the rarity of the procedures, it is recommended that all coronary interventions for HOCM, coronary fistula, and VT be reviewed by the multidisciplinary team and the institutional QA process. These processes must be functioning and active to provide appropriate oversight if operators are to perform these uncommon coronary procedures in a safe and monitored environment.

President and Staff

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APPENDIX 1. 2013 ACCF/AHA/SCAI CLINICAL COMPETENCE STATEMENT ON CORONARY ARTERY INTERVENTIONAL PROCEDURES (REVISION OF 2007 STATEMENT)—AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Thomas M. Bashore	Duke University Medical Center—Professor of Medicine; Clinical Chief, Division of Cardiology	None	None	None	None	None	None
Theodore A. Bass	University of Florida Shands Jacksonville Cardiovascular Center—Professor of Medicine; Chief Cardiology Division	• Daiichi Sankyo-Lilly†	None	None	None	None	None
Ralph G. Brindis	University of California, San Francisco—Clinical Professor of Medicine	None	None	None	None	None	None
John E. Brush, Jr.	Eastern Virginia Medical School; Sentara Cardiology Specialists, Sentara Healthcare—Professor of Medicine	• United Healthcare Scientific Advisory Board	None	None	None	None	None
James A. Burke	Lehigh Valley Heart Network—Associate Chief of Cardiology	None	None	None	None	None	None
Gregory J. Dehmer	Texas A&M College of Medicine, Scott & White Clinic Cardiology Division—Professor of Medicine; Director of Cardiology	None	None	None	• Direct Flow Medical	None	None
Yuri A. Deychak	Johns Hopkins Community Physicians Heartcare—Cardiologist	None	None	None	None	None	None
John G. Harold	Cedars-Sinai Heart Institute—Attending Physician; Cedars-Sinai Medical Center and David Geffen School of Medicine at UCLA—Clinical Professor of Medicine	None	None	None	None	None	None
Hani Jneid	Baylor College of Medicine and the MEDVAMC—Associate Professor of Medicine	None	None	None	None	None	None
James G. Jollis	Duke University Medical Center—Associate Professor of Medicine	None	None	None	• Medtronic Foundation† • Sanofi-Aventis†	None	None
Joel S. Landzberg	Hackensack University Medical Center—Clinical Associate Professor of Medicine	None	None	None	• Boehringer Ingelheim, RELY, RELYABLE studies—PI • Roche, dal-OUTCOMES studies—PI	None	None
Glenn N. Levine	Baylor College of Medicine—Professor of Medicine	None	None	None	None	None	None
James B. McClurken	Temple University Hospital Department of Cardiothoracic Surgery—	None	None	None	None	None	None
John C. Messenger	University of Colorado— Director, Cardiac Cath Lab; Associate Professor of Medicine	None	None	None	• Medtronic*	None	None
Issam D. Moussa	Mayo Clinic, Florida—Professor and Chair, Division of Cardiovascular Diseases	None	None	None	None	None	None
J. Brent Muhlestein	Intermountain Medical Center—Professor of Medicine	None	• Bristol-Myers Squibb • Daiichi-Sankyo • Forest • Gilead • Lilly • Merck • Sanofi-Aventis	None	• Glaxo	None	None
Richard M. Pomerantz	St. Agnes Hospital—Chairman, Department of Medicine	None	None	None	None	None	None

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APPENDIX 1. CONTINUED

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
Timothy A. Sanborn	Northshore University Healthsystem—Head, Division of Cardiology	None	None	None	None	None	None
Chittur A. Sivaram	University of Oklahoma—Professor of Medicine and Associate Dean	• Medtronic	None	None	None	None	None
Christopher J. White	Ochsner Clinic Foundation—Chairman, Department of Cardiology	• Baxter	None	None	• Boston Scientific* • Neovasc* • St. Jude	None	None
Eric S. Williams	Indiana University School of Medicine Krannert Institute of Cardiology—Professor of Medicine and Associate Dean	None	None	None	None	None	None

This table represents the relationships of committee members with industry and other entities that were determined to be relevant to this document. These relationships were reviewed and updated in conjunction with all meetings and/or conference calls of the writing committee during the document development process. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of 5% or more of the voting stock or share of the business entity, or ownership of ≥$10 000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx for definitions of disclosure categories or additional information about the ACCF Disclosure Policy for Writing Committees. *No financial benefit. †Significant relationship.

PI indicates principal investigator.

APPENDIX 2. 2013 ACC/AHA/SCAI CLINICAL COMPETENCE STATEMENT ON CORONARY ARTERY INTERVENTIONAL PROCEDURES (REVISION OF 2007 STATEMENT)—REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)

Peer Reviewer	Representation	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Lyndon C. Box	Official Reviewer—Society for Cardiovascular Angiography and Interventions	University of Florida Division of Cardiology—Assistant Professor	None	None	None	None	None	None
George D. Dangas	Official Reviewer—ACCF Board of Trustees	Mount Sinai Medical Center—Program Director, Interventional Cardiology	• Astra-Zeneca • Johnson & Johnson • Merck • Regado • Sanofi-Aventis	None	None	• Abbott* • Bristol Myers Squibb* • Daiichi-Sankyo* • Eli Lilly* • The Medicines Company* • Medtronic* • Sanofi-Aventis*	• Abbott Vascular* • Accumetrics* • Cordis* • EV3* • Gilead* • Infraredx* • Lutonix* • Medtronic* • PLC* • The Medicines Company* • Tryton* • Volcano* • W.L. Gore*	None
David P. Faxon	Official Reviewer—American Heart Association	Brigham and Women's Hospital—Professor of Medicine	• Boston Scientific Corporation	None	• REVA Medical	• Sanofi-Aventis	• Circulation: Cardiovascular Interventions—Editor†	None
Daniel Kolansky	Official Reviewer—American Heart Association	Hospital of the University of Pennsylvania—Director, Cardiac Care Unit	• Up To Date	None	None	None	• Conor MedSystems	• Defendant, cardiology care and cardiac catheterization, 2009 & 2010
John P. Reilly	Official Reviewer—Society for Cardiovascular Angiography and Interventions	Ochsner Clinic Foundation—Director, Cardiovascular CT	None	• Daiichi-Sankyo-Lilly†	• Johnson & Johnson† • Medtronic† • Pfizer	None	None	None

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APPENDIX 2. CONTINUED

Peer Reviewer	Representation	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Jean-Francois Tanguay	Official Reviewer—ACCF Board of Governors	Institut de Cardiologie de Montreal—Director, Coronary Unit	None	None	None	None	• Abbott Vascular† • Astra Zeneca† • Eli Lilly† • Merck Canada† • Servier†	None
Andrew Wang	Official Reviewer—ACCF Task Force on Clinical Competence and Training Statements	Duke University Medical Center Division of Cardiovascular Medicine—Associate Professor of Medicine	None	None	None	• Abbott Vascular† • Edwards Lifesciences† • Gilead Sciences†	None	None
H. Vernon Anderson	Content Reviewer—ACCF Interventional Scientific Council	University of Texas Cardiology Division—Professor of Medicine	• Symbios Clinical Research	None	None	None	• Eli Lilly	None
Eric R. Bates	Content Reviewer—ACCF/AHA/SCAI PCI Guideline	University of Michigan Hospitals and Health Centers—Professor of Medicine	• AstraZeneca • Bristol-Myers Squibb • Daiichi-Sankyo • Eli Lilly • Merck • Sanofi-Aventis	None	None	None	None	None
James C. Blankenship	Content Reviewer—ACCF/AHA/SCAI PCI Guideline	Geisinger Medical Center—Director, Cardiac Catheterization Lab	None	None	None	• Abiomed* • AstraZeneca* • Boston Scientific* • Kai Pharmaceutical* • Novartis* • Schering-Plough* • The Medicines Company* • Volcano Corporation*	None	None
Emmanouil S. Brilakis	Content Reviewer—ACCF Interventional Scientific Council	University of Texas Southwestern Medical School—Director, Cardiac Catheterization Lab, VA North Texas Healthcare System	• Bridgepoint Medical • HMP Communications • St. Jude† • Terumo	None	None	None	Medtronic†	• Defendant, review of case of left main disease, 2011
John G. Byrne	Content Reviewer—ACCF Surgeon Scientific Council	Vanderbilt University Medical Center—Chair, Department of Cardiac Surgery	None	None	None	None	None	• Defendant, cardiac surgery, 2010
T. Bruce Ferguson, Jr.	Content Reviewer—ACCF Surgeon Scientific Council	East Carolina Heart Institute Brody School of Medicine—Professor of Surgery and Physiology	None	None	None	• Novadaq Technologies, Inc.†	• Edwards Laboratories	None
Kirk N. Garratt	Content Reviewer—ACCF NCDR CathPCI Research and Publications Subcommittee	Lenox Hill Hospital—Associate Professor of Medicine	• Abbott Vascular • Boston Scientific • Daiichi-Sankyo-Lilly† • The Medicines Company	• Abbott Vascular • Boston Scientific • Medtronic • The Medicines Company	None	None	None	• Defendant, blood pressure management and elective angiography, 2008 • Defendant, radial access for angioplasty, 2006 • Defendant, indication for bypass surgery, 2005
Lloyd W. Klein	Content Reviewer—ACCF Interventional Scientific Council	Rush University Medical Center—Professor of Medicine	None	None	None	None	None	None

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APPENDIX 2. CONTINUED

Peer Reviewer	Representation	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Austin H. Kutscher, Jr.	Content Reviewer—ACCF Board of Governors	Hunterdon Cardiovascular Associates	• Medtronic	• Boehringer • Forest Laboratories	None	•Boehringer	• Boehringer, Pradaxa GI study—PI	None
Steven J. Lester	Content—ACCF Task Force on Clinical Competence and Training Statements	Mayo Clinic—Associate Professor of Medicine, Department of Cardiovascular Diseases	None	None	None	None	None	None
Thomas Lewandowski	Content Reviewer—ACCF Board of Governors	Appleton Cardiology Associates—Cardiologist	None	None	None	None	None	None
Sandra Lewis	Official Reviewer—ACCF Board of Governors	NW Cardiovascular Institute—Clinical Associate Professor	None	None	None	Roche	• Medtronic* • Regence BlueCross BlueShield	None
Scott M. Lilly	Official Reviewer—ACCF Board of Governors	University of Pennsylvania—Fellow, Interventional Cardiology	None	None	None	None	None	None
Ehtisham Mahmud	Content Reviewer—ACCF Interventional Scientific Council	University of California, San Diego—Chief of Cardiovascular Medicine; Co-Director, Sulpizio Cardiovascular Center; Director, Interventional Cardiology & Cardiovascular Catheterization Labs	• Eli Lilly† • Gilead • Medtronic	• Eli Lilly† • Medtronic	None	• Abbott Vascular† • Accumetrics† • Boston Scientific† • Gilead† • Merck Schering Plough • Sanofi-Aventis • Eli Lilly† • The Medicines Company†	•St. Jude's	None
Debabrata Mukherjee	Content Reviewer—ACCF Interventional Scientific Council	Texas Tech University Health Sciences Center—Chief, Cardiovascular Medicine	None	None	None	None	None	None
Srinivas Murali	Official Reviewer—ACCF Board of Governors	Allegheny General Hospital—Director, Division of Cardiovascular Medicine	• Gilead • Bayer	None	None	None	None	None
Srihari Naidu	Content Reviewer—ACCF Interventional Scientific Council	Winthrop University Hospital—Director, Cardiac Catheterization Lab	None	None	None	None	None	None
Rick Nishimura	Content Reviewer—ACCF/AHA Ventricular Heart Disease Guideline	Mayo Clinic, Division of Cardiovascular Services—Judd and Mary Morris Leighton Professor of Medicine	None	None	None	None	None	None
Patrick O'Gara	Content Reviewer—ACCF/AHA ST Elevation Myocardial Infarction Guideline	Harvard Medical School; Brigham and Women's Hospital—Professor of Medicine; Director, Clinical Cardiology	None	None	None	• Lantheus Medical Imaging (DSMB)	None	None
Sunil V. Rao	Content Reviewer—ACCF Interventional Scientific Council	Duke University Medical Center—Associate Professor of Medicine	• AstraZeneca • Daiichi Sankyo-Lilly • Terumo Medical • The Medicines Company	None	None	None	None	• Defendant, catheterization related complications, 2011
Michael E. Ring	Official Reviewer—ACCF Board of Governors	Providence Sacred Heart Medical Center and Children's Hospital	• Boston Scientific • Medtronic	None	None	None		• Defendant, certificate of need for PCI, 2012

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APPENDIX 2. CONTINUED

Peer Reviewer	Representation	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
John F. Robb	Official Reviewer—ACCF Board of Governors	Dartmouth-Hitchcock Medical Center—Director, Interventional Cardiology	None	None	None	• Edwards LifeSciences, Partner 2—PI*		None
Robert A. Shor	Official Reviewer—ACCF Board of Governors	The Cardiovascular Group, PC—Cardiologist	None	None	None	None	None	None
John W. Shuck	Official Reviewer—ACCF Board of Governors	Cardiology Consultants—Cardiologist	None	None	None	None	None	None
George L. Smith	Official Reviewer—ACCF Board of Governors	Northern California Medical Associates—Cardiologist	None	None	None	None	None	None
Carl L. Tommaso	Content Reviewer—ACCF/AHA PCI Performance Measures	Northshore Medical System	None	None	None	None	None	• Defendant, retained wire, 2006
E. Murat Tuzcu	Content Reviewer—ACCF Interventional Scientific Council	Cleveland Clinic Foundation—Professor of Medicine	None	None	None	• Edwards Lifesciences*	None	None
Robert C. Welsh	Official Reviewer—ACCF Board of Governors	University of Alberta and Mazankowski Alberta Heart Institute—Associate Professor; Director, Adult Cardiac Catheterization and Interventional Cardiology	• AstraZeneca • Bayer • Boehringer Ingelheim • Edwards Lifesciences • Eli Lilly • Medtronic • Servier	None	None	• Abiomed	None	None

This table represents the relationships of reviewers with industry and other entities that were disclosed at the time of peer review and determined to be relevant. It does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. A relationship is considered to be modest if it is less than significant under the preceding definition. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Names are listed in alphabetical order within each category of review. According to the ACCF/AHA, a person has a ***relevant*** relationship IF: a) The ***relationship or interest*** relates to the same or similar subject matter, intellectual property or asset, topic, or issue addressed in the ***document***; or b) **The *company/entity* (with whom the relationship exists)** makes a drug, drug class, or device addressed in the *document*, or makes a competing drug or device addressed in the ***document***; or c) The ***person or a member of the person's household***, has a reasonable potential for financial, professional or other personal gain or loss as a result of the issues/content addressed in the ***document***. *No financial benefit. †Indicates significant relationship.

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; NCDR, National Cardiovascular Data Registry; PCI, Percutaneous Coronary Intervention; SCAI, Society for Cardiovascular Angiography and Interventions.

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APPENDIX 3. ACRONYMS AND ABBREVIATIONS LIST

Acronyms and Abbreviations	
ABIM	American Board of Internal Medicine
ACCF	American College of Cardiology Foundation
ACP	American College of Physicians
AHA	American Heart Association
CABG	coronary artery bypass graft
CME	continuing medical education
COCATS	Core Cardiology Training
DTB	door-to-balloon
ECG	electrocardiogram
HOCM	hypertrophic obstructive cardiomyopathy
LVOT	left ventricular outflow track
MACCE	major adverse cardiovascular and cerebrovascular events
MACE	major adverse cardiac events
MI	myocardial infarction
MOC	maintenance of competence
NCDR	National Cardiovascular Data Registry
PCI	percutaneous coronary intervention
PPCI	primary percutaneous coronary intervention
PTCA	percutaneous transluminal coronary angioplasty
QI	quality improvement
SCAI	Society for Cardiovascular Angiography and Interventions
STEMI	ST-elevation myocardial infarction
VT	ventricular tachycardia

Attachment 6
SCAI Latest Consensus Document

Catheterization and Cardiovascular Interventions 00:00–00 (2014)

Clinical Decision Making

SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

Gregory J. Dehmer,[1*] MD, James C. Blankenship,[2] MD, Mehmet Cilingiroglu,[3] MD, James G. Dwyer,[4] MD, Dmitriy N. Feldman,[5] MD, Timothy J. Gardner,[6] MD, Cindy L. Grines,[7] MD, and Mandeep Singh,[8] MD, MPH

Key words: angioplasty; coronary artery bypass surgery; consensus

INTRODUCTION

In 2007, the Society for Cardiovascular Angiography and Interventions (SCAI) published an Expert Consensus Document titled "The Current Status and Future Direction of Percutaneous Coronary Intervention without On-Site Surgical Backup" [1]. This document summarized the available data on the performance of percutaneous coronary intervention (PCI) without on-site surgery in the United States (US), reviewed the existing literature, examined the recommendations for the performance of PCI in this setting from several professional organizations abroad and from experienced programs in the US, defined the best practices for facilities engaged in PCI without on-site surgery and made recommendations for the future role of PCI without on-site surgery.

Since publication of that document, new studies, meta-analyses, and randomized trials have been published comparing PCI with and without on-site surgery. In addition, the total number of PCIs performed annually has decreased, reports about the overuse of PCI have emerged, and appropriate use criteria for coronary revascularization have been published. A noteworthy change occurred in the 2011 PCI guideline in which elective PCI was upgraded to Class IIb and primary PCI was upgraded to Class IIa at facilities without on-site surgery [2]. Several tables on the structure and operation of programs without on-site surgery from the 2007 SCAI Expert Consensus Document were used in the 2011 PCI guideline recommendations. Finally, new updates of the ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards and the ACCF/AHA/SCAI Clinical Competence in

[1]Baylor Scott & White Health, Central Texas, Temple, TX. SCAI Writing Committee Member and Chair
[2]Geisinger Health System, Danville, PA. SCAI Writing Committee Member
[3]Arkansas Heart Hospital, Little Rock, AR. SCAI Writing Committee Member
[4]Heart and Vascular Center of Northern Arizona, Flagstaff, AZ. SCAI Writing Committee Member
[5]New York Presbyterian Hospital, New York, NY. SCAI Writing Committee Member
[6]Christiana Care Health System, Newark, DE. AHA Writing Committee Member
[7]Detroit Medical Center, Detroit, MI. SCAI Writing Committee Member
[8]Mayo Clinic, Rochester MN. ACC Writing Committee Member

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Conflict of interest: See Appendix 1.

*Correspondence to: Gregory J. Dehmer, Cardiology Division, [MS 33 ST156], BaylorScott & White Health, Central Texas 2401 South 31st Street, Temple, TX 76513. E-mail: gdehmer@sw.org

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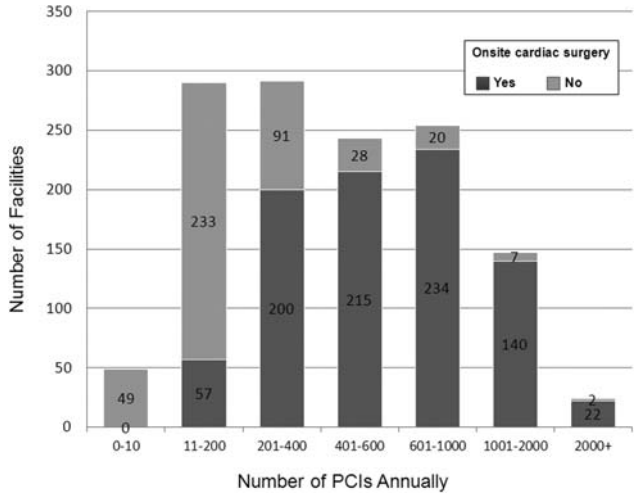

Fig. 1. PCI volume at facilities with and without cardiac surgery. (Reproduced from Ref [8] with permission. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

Coronary Artery Interventional Procedures have been published [3,4].

Although many of the concerns about the safety of PCI without on-site surgery have been resolved, there are new issues to consider as the delivery of PCI continues to evolve in the US. Accordingly, the SCAI, ACCF, and AHA have engaged in this effort to reevaluate the current status of PCI without on-site surgery in the US. The specific goals of this effort were to:

1. Determine current trends in the prevalence of PCI without on-site surgery in the US;
2. Summarize new literature related to the performance of PCI without on-site surgery;
3. Review existing guidelines, expert consensus documents, competency statements and other documents related to PCI without on-site surgery and summarize all relevant information into a single resource document;
4. Outline the current best practice methods and requirements for facilities engaged in performing PCI without on-site surgery; and
5. Evaluate the role of PCI without on-site surgery within the current US healthcare system.

Trends in the Performance of PCI

Although the use of PCI in the US had grown considerably since the early 1980s, data from the Nationwide Inpatient Sample cited by the Agency for Healthcare Research and Quality shows that the annual volume of PCI procedures peaked in 2006 and has since declined by over 30% [5]. Numerous factors have contributed to this decline, including a reduction in restenosis by drug-eluting stents, a greater emphasis on medical therapy for the treatment of stable coronary artery disease, enhanced primary and secondary prevention efforts, a reduction in the incidence of ST-segment elevation myocardial infarction (STEMI), the increasing use of techniques such as fractional flow reserve to better evaluate lesion severity and the development and application of appropriate use criteria [5,6]. As a result of these factors, many operators and hospitals now have low-volume practices. Using data from 2008, Maroney et al. estimated that 61% of interventional cardiologists performed 40 or fewer Medicare fee-for-service PCIs annually [7]. Clinical data from 1298 facilities reporting to the National Cardiovascular Data Registry (NCDR) show that 49% of facilities performed $\leq$400 PCIs and 26% performed $\leq$200 PCIs annually (Fig. 1) [8]. Approximately 33% of facilities had no on-site surgery, and among these, 65% (282 facilities) had an annual case volume of $\leq$200 PCI procedures. F1

Across the US, PCI without on-site surgery has increased since 2007. The writing committee assessed the current use of PCI without on-site surgery from a survey of ACC Governors for each state, data from industry sources and direct contact with physicians in various states (Fig. 2). Currently, 45 states allow both primary and elective PCI without on-site surgery, 4 states allow only primary PCI without on-site surgery, and 1 state prohibits PCI without on-site surgery. PCI without on-site surgery is regulated by the State Department of Health in 34 states but is unregulated in the remaining 16 states. Elective PCI without on-site surgery was allowed at selected facilities in 9 states but only as part of statewide demonstration projects or to allow participation in the Cardiovascular Patient Outcomes Research Team (CPORT) Nonprimary PCI (CPORT-E) trial [9]. Since the conclusion of CPORT-E, the use of PCI without on-site surgery is being revaluated in several of these states. PCI without on-site surgery is currently performed in 19 of the 65 cardiac catheterization laboratories within the Veterans Health Administration [10]. F2

Recent Literature on PCI Without On-site Surgery

Since 2006, 11 original studies and 3 meta-analyses on the topic of PCI without on-site surgery have been identified by a computerized systematic literature search using Medline (PubMed and Ovid) and Cochrane Databases [9,11–23].

Primary PCI without on-site surgery. Seven studies and 2 meta-analyses of primary PCI showed no

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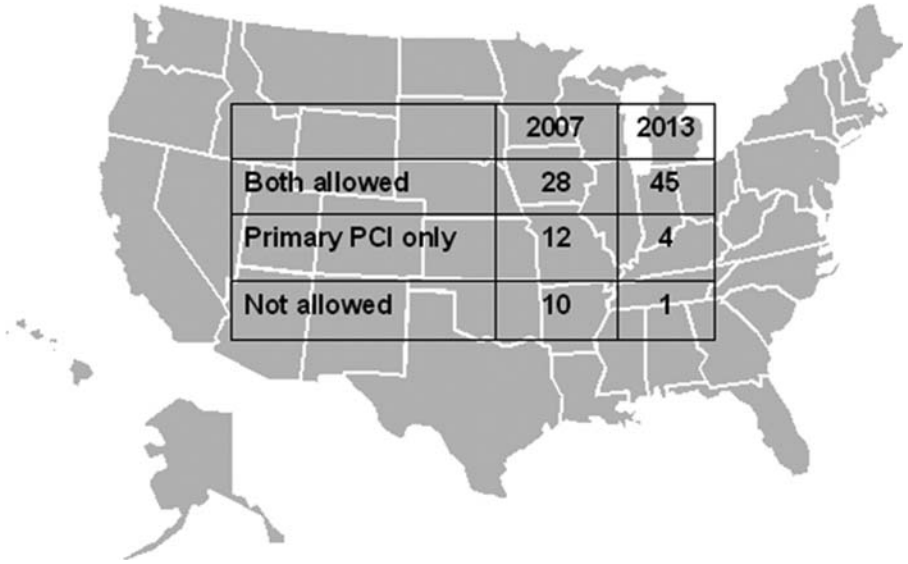

Fig. 2. Change in the availability of PCI without on-site surgery from 2007 to 2013. The numbers shown indicate the number of states where primary and nonprimary PCI without on-site surgery are allowed.

difference for in-hospital or 30-day mortality between sites with and without on-site surgery (Table I). None of the individual studies examining the occurrence of emergency CABG surgery after primary PCI showed a difference between sites with and without on-site surgery. However, 1 meta-analysis showed that sites without on-site surgery had a lower occurrence of emergency CABG surgery after primary PCI (odds ratio, 0.53; 95% confidence interval 0.35–0.79) [20].

PCI without on-site surgery for conditions other than STEMI. Eight studies examined nonprimary PCI at sites with and without on-site surgery (Table II). The majority of studies and meta-analyses showed no difference in mortality or a need for emergency CABG at sites without on-site surgery. One study at a high-volume facility performing only elective PCIs and staffed by high-volume interventionalists showed a lower mortality at the facility without on-site surgery (OR, 0.11; 95% CI 0.01–0.79) [21]. However, the baseline clinical and angiographic characteristics of the study groups with and without on-site surgery were sufficiently different that a meaningful adjusted analysis could not be performed, and there is therefore the possibility of a case selection bias.

Two randomized trials of nonprimary PCI have now been published. The CPORT-E trial randomized over 18,000 patients in a 1 : 3 ratio to undergo PCI at hospitals with and without on-site cardiac surgery, respectively [9]. High-risk patients were excluded, as was the use of atherectomy devices. The trial had 2 primary endpoints: 6-week mortality and 9-month incidence of major adverse cardiac events (composite of death, Q-wave myocardial infarction, or target-vessel revascularization). The 6-week mortality rate was 0.9% at hospitals without on-site surgery compared with 1.0% at those with on-site surgery ($P = 0.004$ for noninferiority). The 9-month rates of major adverse cardiac events were 11.2% and 12.1% at hospitals with and without on-site surgery, respectively ($P = 0.05$ for noninferiority). A similar, but smaller randomized study of nonemergency PCI was performed in Massachusetts hospitals [11]. The rates of major adverse cardiac events were 9.5% in hospitals without on-site cardiac surgery and 9.4% in hospitals with on-site cardiac surgery at 30 days (relative risk, 1.00; 95% one-sided upper confidence limit, 1.22; $P < 0.001$ for noninferiority) and 17.3% and 17.8%, respectively, at 12 months (relative risk, 0.98; 95% one-sided upper confidence limit, 1.13; $P < 0.001$ for noninferiority). The individual rates of death, myocardial infarction, repeat revascularization and stroke did not differ significantly between the groups at either time point.

Three meta-analyses conducted primarily with registry data have examined the use of nonprimary PCI at facilities with and without on-site surgery [19,20,23]. Overall, the mortality rate and need for emergency CABG surgery did not differ between hospitals with and without on-site surgery. In 1 meta-analysis, after adjusting for publication bias, the mortality rate for nonprimary PCI was 25% higher at centers without on-site surgery compared with centers that had on-site surgery (OR, 1.25; 95% CI, 1.01–1.53; $P = 0.04$) [20]. However, it is important to note that these meta-analyses preceded the publication of the 2 randomized trials [9,11]. Therefore, based on these

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TABLE I. Studies on Primary PCI Without On-site Surgery Published Since 2006

Author (Year)	Sites	On-site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007) [12]	Multicenter SCAAR Registry	No	857	7.0	1.05 (0.79–1.40)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
		Yes	4,595	6.7		0.2		
Peels (2007) [13]	Single center	No	336	2.1	2.17 (0.26–17.8)	0	0.10 (0.00–2.51)	
		Yes	103	0.97		1.0		
Pereira (2008) [14]	Multicenter Portuguese Registry	No	1214	5.0	0.79 (0.55–1.14)	1.8	1.52 (0.90–2.56)	Cardiogenic shock mortality was 53.4% with on-site surgery and 50.9% without (NS)
		Yes	1470	4.0		2.7		
Kutcher (2009) [15]	Multicenter NCDR Registry	No	1,934	5.1	0.97 (0.79–1.20)	0.7	0.60 (0.35–1.03)	In-hospital mortality reported. Only 42% of sites without on-site surgery performed ≥36 primary PCIs annually compared with 80% of sites with on-site surgery
		Yes	31,099	5.2		1.2		
Pride (2009) [16]	Multicenter NRMI Database	No	1,795	3.3	0.86 (0.61–1.23)			Propensity matched patient cohort. In-hospital mortality reported and only for patients undergoing primary PCI. Incidence of emergency CABG not reported
		Yes	1,795	3.8				
Hannan (2009) [17]	Multicenter New York State Database	No	1,729	2.3	1.22 (0.76–1.94)	0.06	0.17 (0.02–1.38)	Propensity matched patient cohort. In-hospital/30-day mortality reported
		Yes	1,729	1.9		0.35		
Singh (2009) [18]	3 sites Mayo Clinic experience	No	667	2.5	0.80 (0.42–1.54)	0.7	1.25 (0.33–4.68)	Propensity matched patient cohort of nonelective PCI defined as acute MI within 24 h or cardiogenic shock.
		Yes	667	3.1		0.6		
Meta-analyses								
Zia [2011] [19]		No	8703	6.1	0.93 (0.83–1.05)	3.0	0.87 (0.68–1.11)	9 studies included in the analysis
		Yes	97386	7.6		3.4		
Singh M [2011] [20]		No	16489	4.6	0.96 (0.88–1.05)	0.22	0.53 (0.35–0.79)	11 studies included in the analysis
		Yes	107585	7.2		1.03		

CABG, coronary artery bypass graft surgery; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; OR, odds ratio; PCI, percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry.

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TABLE II. Studies on Nonprimary PCI Without On-site Surgery Published Since 2006

Author (Year)	Sites	On-site Surgery	No. of Patients in Arm	Mortality		Emergency CABG		Comments
				Incidence %	OR (95% CI)	Incidence %	OR (95% CI)	
Carlsson (2007) [12]	Multicenter SCAAR	No	7,981	0.81	1.23 (0.91–1.65)	0.1		30-day mortality is reported; Incidence of emergency CABG is for all patients (primary and nonprimary PCI)
	Registry	Yes	20,930	0.66		0.2		
Frutkin (2008) [21]	2 sites	No	1,090	0.09	0.11 (0.01–0.79)	0.2	6.10 (0.55–67.3)	Nonrandomized comparison of 2 sites. Stable and unstable angina plus NSTEMI included. In-hospital mortality shown
		Yes	3,317	0.8		0.03		
Pereira (2008) [14]	Multicenter Portuguese	No	4831	0.5	1.43 (0.85–2.41)	0.7	3.14 (2.13–4.63)	
	Registry	Yes	5584	0.7		2.1		
Kutcher (2009) [15]	Multicenter NCDR	No	6,802	0.8	0.99 (0.76–1.30)	0.2	0.69 (0.40–1.16)	72% of sites without on-site surgery performed <200 PCIs annually compared with 6% among sites with on-site surgery
	Registry	Yes	268,312	0.8		0.3		
Pride (2009) [22]	Multicenter NRMI	No	1,282	1.0	0.76 (0.37–1.58)			Only patients with NSTEMI included in study cohort
	Registry	Yes	1,282	1.3				
Singh (2009) [18]	3 sites Mayo clinic	No	1,842	0.2	0.57 (0.17–1.95)	0	1.00 (0.02–50.4)	Propensity matched patient cohort
	Experience	Yes	1,842	0.4		0.2		
Aversano (2012) [9]	Multicenter Randomized Trial	No	14,149	0.9		0.1		Mortality reported after 6 weeks and incidence of emergency CABG shown.
		Yes	4,718	1.0		0.2		
Jacobs (2013) [11]	Multicenter Randomized Trial	No	2774	0.7	1.96 (0.58–6.64)	0.3	2.30 (0.3–18.6)	All-cause and cardiac mortality at 30 days were no different. PCI without on-site surgery was not inferior
		Yes	917	0.3		0.1		
Meta-analyses								
Zia (2011) [19]		No	28552	1.6	1.03 (0.64–1.66)	1.0	1.38 (0.65–2.95)	6 studies included in the analysis
		Yes	881261	2.1		0.9		
Singh M (2011) [20]		No	30423	0.9	1.15 (0.93–1.41)	0.17	1.21 (0.52–2.85)	9 studies included in the analysis
		Yes	883865	0.8		0.29		
Singh PP (2011) [23]		No	1812	0.17	2.3 (0.60–12.97)	0.11	0.47 (0.07–3.19)	4 studies included in the analysis but only 2 with data on mortality and CABG; Risk ratios rather than OR are reported in this analysis
		Yes	4039	0.72		0.02		

CABG, coronary artery bypass graft surgery; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction Infarction; OR, odds ratio; PCI, percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry.

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recent studies, there is no indication of increased mortality or a greater need for emergency CABG for either primary or nonprimary PCI at sites without on-site cardiac surgery.

Guidelines, Competency Documents, Policy Statements, and Other Programs

Since 2007, there have been several new documents published that provide guidance for the performance of PCI without on-site surgery. Each new document builds incrementally upon the recommendations from prior documents with slight modifications based on new information. The recommendations for PCI programs without on-site surgery are maturing and becoming uniform over time through the vetting of these recommendations by numerous separate writing committees and undergoing extensive external reviews during document development. Key recommendations for PCI without on-site surgery from those documents are briefly summarized below and have been combined to develop the unified recommendations in this document.

2009 Focused Guideline Update on the Management of Patients with STEMI and Guideline Update on PCI

The 2009 focused update of the ACC/AHA guidelines for the management of patients with STEMI and the ACC/AHA/SCAI guidelines on PCI has been superseded by newer separate guidelines for STEMI and PCI [2,24,25]. However, a number of the recommendations from the 2009 document regarding triage and transfer of patients and the development of local STEMI systems have been incorporated into the current document.

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Compared with prior guidelines, the 2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention stipulated new classification ratings for both primary and elective PCI at hospitals without on-site cardiac surgery [2]. Primary PCI was assigned a class IIa recommendation (*Level of Evidence: B*) stating that primary PCI is "reasonable," provided appropriate planning for program development has been accomplished. Previously, this was assigned a class IIb recommendation. Elective PCI, previously assigned a class III recommendation, was given a class IIb recommendation (*Level of Evidence: B*) stating it "might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection". Elective PCI without on-site cardiac surgical backup was considered appropriate only when performed by experienced operators, with complication rates and outcomes equivalent or superior to national benchmarks. Importantly, the ACCF/AHA/SCAI PCI guidelines state, "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery." The guideline assigns a class III recommendation (*Level of Evidence: C*) to performing primary or elective PCI in hospitals without on-site cardiac surgery without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital and without appropriate hemodynamic support capability for transfers. The 2011 PCI guideline document adapted personnel, facility, operator and structural requirements for PCI without on-site surgery from the 2007 SCAI Expert Consensus document [1]. New facility and operator volume requirements were not addressed in the 2011 PCI guidelines but deferred to the 2013 PCI Clinical Competency document [4]. In 2011, ACCF/AHA also published a Guideline for Coronary Artery Bypass Surgery that did not discuss the performance of PCI without on-site surgery [26].

2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

Similar to the 2011 PCI guidelines, this document presented requirements for PCI at facilities without on-site cardiac surgery that were derived from the 2007 SCAI expert consensus document with some modifications [3]. This document also presented criteria for excluding patients, based on risk and lesion characteristics, from PCI at facilities without on-site cardiac surgery. The document prescribed the quality assurance/quality improvement (QA/QI) program necessary for all cardiac catheterization laboratories with specific recommendations for structure, process, and outcome variables appropriate for monitoring. Moreover, it recommended that all major complications be reviewed by the QA/QI committee at least every 6 months and that any individual operator with complication rates above benchmarks for 2 consecutive 6-month intervals should have the issue directly addressed by the QA director with a written plan for remediation. The document also recommended that a random sample of cases from all operators should be reviewed at least annually.

2013 ACCF/AHA/SCAI Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures

In addition to defining numerous requirements for operator competency, new operator, and facility PCI

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volume requirements were established [4]. Reflecting the overall decline in PCI volumes, this document recommended that laboratories performing both primary and elective PCI, with and without on-site cardiac surgery, should perform a minimum of 200 PCIs annually. Laboratories performing <200 cases annually must have stringent systems and process protocols in place with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. The existence of laboratories performing <200 PCIs annually that are not serving isolated or underserved populations should be questioned, and any laboratory that cannot maintain satisfactory outcomes should be closed. This recommendation was based on an extensive review of studies that identified a signal suggesting worse outcomes in laboratories performing <200 PCIs annually. The writing committee recommended that operators perform a minimum of 50 PCIs annually [averaged over 2 years], including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200 total and >36 primary PCI procedures annually. However, it was emphasized that individual operator volume is but one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, the operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance. Operators who cannot maintain these case volume recommendations at their primary practice site should maintain privileges and continue to perform PCI procedures at a high-volume institution with on-site surgical backup to meet annual volume requirements. It was also recommended that operators should be board certified in interventional cardiology and maintain certification, with the exception of operators who have received equivalent training outside the US and are ineligible for board certification in the US.

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction

This document did not specifically comment on PCI without on-site cardiac surgery but supported the 2011 ACCF/AHA/SCAI PCI guidelines recommendations [25]. It recommended that primary PCI be performed in high-volume, well-equipped centers with experienced interventional cardiologists, and skilled support staff.

2010 European Society of Cardiology and European Association for Cardio-Thoracic Surgery Guidelines

In contrast to the 2011 ACC/AHA/SCAI PCI guidelines, the 2010 European Society of Cardiology and the European Association for Cardio-Thoracic Surgery guidelines on myocardial revascularization do not comment on PCI without on-site surgery or issues related to institutional or operator competency [27]. However, the European guidelines continue to stress the importance of full disclosure regarding the lack of availability of on-site cardiac surgery and the inadvisability of performing PCI for high-risk patients/lesions at facilities that do not have on-site surgical backup.

The European guidelines for STEMI do not provide specific recommendations regarding PCI at centers without on-site surgery [28]. Rather, emphasis is placed on the development of networks between hospitals with differing levels of technology, connected by an efficient emergency transport system. To maximize staff experience, the guidelines recommend that primary PCI centers perform procedures 24 h a day, 7 days a week for all STEMI patients.

Other models mentioned in the European guidelines, although not ideal, include weekly or daily rotation of primary PCI centers or multiple primary PCI centers in the same region. Hospitals that cannot offer a 24/7 service for primary PCI should be allowed to perform primary PCI in patients already admitted for another reason and who develop STEMI during their hospital stay. These hospitals should, however, be discouraged from initiating a service limited to daytime or within-hours primary PCI, because this generates confusion with Emergency Medical Services (EMS) operators and is unlikely to match the door-to-balloon time and quality of intervention of focused 24/7 primary PCI centers. In a survey of European countries, the mean population served by a single primary PCI center varied between 0.3 and 7.4 million inhabitants. In countries offering primary PCI services to the majority of their STEMI patients, this population varied between 0.3 and 1.1 million per center [29]. In small service areas, experience can be suboptimal due to an insufficient number of STEMI patients, but the optimal size of a catchment area could not be clearly defined. For geographical areas where the expected transfer time to a primary PCI center makes it impossible to achieve satisfactory reperfusion times, thrombolysis with subsequent immediate transfer to a primary PCI center has been endorsed. Although there is a risk of intracranial bleeding, a potential role for this strategy in selected circumstances has been emphasized [30].

Other Guidelines and Recommendations

The 2007 SCAI Expert Consensus Document summarized the recommendations from the British Cardiac Society and British Cardiovascular Intervention Society, the Cardiac Society of Australia and New Zealand

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(CSANZ), the Spanish Society of Cardiology, the Brazilian Society of Hemodynamics and Interventional Cardiology (*Sociedade Brasileira de Hemodinamica e Cardiologia Intervencionista*) and from several other countries [31–39]. Since 2007, only the guidelines from CSANZ have been updated, most recently in 2011 [32]. CSANZ guidelines state that primary PCI without on-site surgery should be performed: (a) by operators and institutions meeting the overall requirements and standards of primary PCI centers; (b) by institutions with a proven plan for rapid transport to a cardiac surgical center; (c) in a timely fashion (<90 min); and (d) using rigorous case selection criteria. The CSANZ guidelines acknowledged that rural patients might have limited access to diagnostic angiography and PCI, and providing these services at institutions without on-site surgery by appropriately trained individuals facilitates equity of access, which should result in improved quality of care. However, the CSANZ guidelines also specifically state that rural and regional centers should not perform elective, high-risk PCI procedures if they are located more than 1 hour travel time from cardiac surgery centers.

AHA Policy Statement on PCI Without Surgical Backup

In March 2012, the AHA issued a policy statement on PCI without surgical backup defining two major reasons for providing PCI without on-site surgery [40]. First, PCI without on-site surgery is considered reasonable if the intent is to provide high quality timely primary PCI for patients with STEMI. The statement recommended that each community and facility in the community have an agreed-upon plan for how STEMI patients are to be treated. The plan should indicate hospitals that should receive STEMI patients from EMS units capable of obtaining diagnostic electrocardiograms, the management at the initial receiving hospital and written criteria and agreements for the expeditious transfer of patients from nonPCI-capable to PCI-capable facilities. Second, PCI without on-site surgery is a reasonable consideration for providing local care to patients and families who do not want to travel significant distances or who have certain preferred local physicians. This is an important consideration, but the policy statement emphasized that evolving evidence suggests that such centers should have mechanisms in place to ensure high quality care. In addition to emphasizing the current guideline classifications for PCI without on-site surgery, the AHA policy statement provided recommendations for states wishing to address the issue of PCI without on-site surgery through the regulation of legislation.

Mission Lifeline

The Mission Lifeline program developed in 2006 from a series of conferences sponsored by the AHA and has continued to mature [41–43]. The goal of Mission Lifeline is to improve the quality of care and outcomes for patients with STEMI and to improve healthcare system readiness and response to STEMI. An important focus of Mission Lifeline is to increase the number of patients with timely access to primary PCI. Criteria for the structure and operation of a STEMI referral and STEMI-receiving hospitals are part of the Mission Lifeline initiative and apply to facilities without on-site surgery.

Door-to-Balloon Alliance

The Door-to-Balloon [D2B^{TM}] effort began in January 2006 when the ACC recognized the need to reduce D2B times for patients with STEMI. This led to the development of a national initiative to achieve D2B times $\leq$90 min for at least 75% of nontransfer primary PCI patients with STEMI in participating hospitals performing primary PCI. This alliance consists of a nationwide network of hospitals, physician champions and strategic partners committed to improving D2B times. Participation in the Alliance provides the necessary tools; information and support for helping hospitals achieve the D2B treatment goals and encourages the use of real-time performance feedback on D2B times to drive the quality improvement effort [44]. The D2B program has been highly successful, having achieved its initial goals [45].

Access to Primary PCI in the United States

Data from the American Hospital Association and the 2000 US Census were used to estimate the proportion of the adult population ($\geq$18 years of age) who lived within 60 min of a PCI hospital [46]. An estimated 79.0% lived within a 1 hour drive of a PCI hospital, with a median driving time of 11.3 min. Even among those living closer to non-PCI hospitals, 74% would experience <30 min of additional delay with a direct referral to a PCI hospital. Approximately 5 years later, Concannon et al., using similar data sources and methodology, showed that despite a 44% relative increase in the number of facilities capable of performing PCI, the number of adults within a 1 hour drive of a PCI facility increased to only 79.9%, with the median driving time reduced by <1 min to 10.5 min [47]. Access in rural areas remained far less than in urban areas, with driving times reduced for only 9% of the population compared with the earlier survey. These findings mirrored a smaller experience in Michigan

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where expansion of primary PCI to 12 hospitals without on-site surgery increased access for only 4.8% of the population [48]. Finally, Horwitz et al. showed that hospitals are more likely to introduce new invasive cardiac services when neighboring hospitals already offer such services and confirmed that the increase in the number of hospitals offering invasive cardiac services has not led to a corresponding increase in geographic access [49]. In total, these data support the argument that the addition of more PCI centers has not substantially improved access to PCI services for most patients.

Financial Considerations for Facilities Providing PCI Without On-site Surgery

Medicare payments to hospitals for invasive cardiac procedures have generally remained favorable, although physician reimbursement has decreased. Per-case revenue margins for PCI are typically higher than the overall hospital operating margins, and PCI improves the hospital case mix index. PCI programs bring prestige to an institution, and STEMI is one of the most prestigious diseases for treatment [50,51]. The push to develop rapid STEMI care has led many to currently advocate for EMS bypassing non-PCI hospitals; there is even consideration being given to triaging patients based on D2B metrics. Exclusion from providing STEMI care might be a lesser financial concern than the loss of downstream revenue from additional testing in patients suspected of having an acute coronary syndrome. This includes not only testing performed to exclude CAD as the cause of chest pain but also testing to evaluate noncardiac causes of chest pain. This can be an additional financial motivator for developing PCI facilities [52]. How the further bundling of payments and reimbursements on a global or capitated basis by accountable care organizations (ACO) will affect PCI programs is unclear at this time, but given the concerns about the cost of healthcare, increases in payments are unlikely [53,54]. However, even in an ACO environment, hospitals might benefit from keeping cardiovascular procedures in-house where they have the ability to control costs rather than transfering patients to tertiary hospitals.

The Volume-Outcome Relationship for PCI and the Certificate of Need

There are 26 states with Certificate of Need (CON) regulations for the development of cardiac catheterization laboratories, but the effect of such regulations is uncertain. Ho et al. found that the removal of state cardiac CON regulations was associated with an increase in the number of hospitals performing CABG and PCI, but the statewide number of procedures was unchanged. The average procedure volume per hospital for both CABG and PCI therefore declined [55]. Despite this, they found no evidence that CON regulations lowered procedural mortality rates for CABG or PCI. In other studies, CON regulation of cardiac catheterization was associated with care that was judged more appropriate, whereas the removal of CON regulation of cardiac surgery has been associated with an increase in low-volume cardiac surgical centers and increased mortality [56,57]. Concerns have been raised that the proliferation of small centers performing complex procedures that have a small but definite risk of important complications might dilute the ability to provide efficient high quality service [52,58]. Reduced mortality has been associated with an increased volume of primary PCI procedures in centers, higher volume operators, total volume of PCIs in centers, and the commitment of a center to provide PCI rather than fibrinolytic therapy [59–63]. Lieu et al. reported that redundant or low-volume primary PCI programs were cost ineffective [64]. Elective PCI at centers without on-site surgery was more expensive than PCI at centers with on-site surgery in one case-matched study [65]. In addition, the high fixed costs of a cardiac surgery program in the face of decreasing surgical volumes is leading to the consolidation of numerous smaller surgery programs, depriving some PCI programs of surgical backup.

The issue of a PCI volume-outcome relationship was extensively reviewed in the 2013 PCI Competency document for centers with and without on-site surgery and for primary and elective PCI [4]. The document concluded that in the current era, volume-outcome relationships are not as robust as in the past when balloon angioplasty was the only treatment modality. However, an institutional volume threshold of <200 PCIs annually appeared to be consistently associated with worse outcomes. Primary PCI volume $\leq$ the guideline-recommended minimum of 36 annually was associated with worse in-hospital mortality in a recent series of over 86,000 patients in the NCDR [66]. The cutoff points of <200 total PCIs annually and ≤ 36 primary PCIs annually has important implications because 26% of the PCI facilities submitting data to the NCDR performed ≤ 200 total PCIs annually and 38% performed ≤ 36 primary PCIs annually [8,66]. Recent data suggested a modest volume-outcome relationship for variables other than mortality, but these data have limitations and are not consistent across all studies [4]. Although there was an association between annual PCI volumes <200 and worse outcomes, there was no association between higher annual hospital volumes and improved outcomes at higher volume PCI centers. There was less evidence to support a threshold for individual operator volume for both elective and primary PCI.

TABLE III. Facility Requirements for PCI Programs Without On-Site Surgery

General Recommendations	Source
Requisite support equipment must be available and in good working order to respond to emergency situations.	PCI-GL PCI-CS ML
Should demonstrate appropriate planning for program development and should complete both a primary PCI development program and an elective PCI development program. Program developments to include routine care process and case selection review.	AHA D2B
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services such as intensive care, advanced imaging (CT, MR and other vascular imaging), respiratory care, blood bank and nephrology consultation with access to dialysis.	PCI-GL, PCI-CS ECD
The institution should have systems for credentialing and governing the PCI program. On-site data collection, quality assessment, quality improvement and error management are essential. Each institution must establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes. A quality improvement program should routinely 1) review quality and outcomes of the entire program; 2) review results of individual operators; 3) include risk adjustment; 4) provide peer review of difficult or complicated cases; and 5) perform random case reviews. The review process should assess the appropriateness of the interventional procedures. Evaluation should include the clinical indications for the procedure, technical performance and the quality and interpretation of the coronary angiograms.	PCI-CS, AHA, PCI-GL ECD
Written agreements for emergency transfer of patients to a facility with cardiac surgery must exist. Transport protocols should be tested a minimum of 2 times per year involving both the referring and receiving facility. Develop agreements with a ground or air ambulance service capable of advanced life support and IABP transfer that guarantees a transport vehicle will be on-site to begin transport in $\leq$30 min *and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery*. Tertiary facility must agree to accept emergent and nonemergent transfers for additional medical care, cardiac surgery or intervention. *Tertiary centers should be able to establish cardiopulmonary bypass on emergency transfer patients within <120 min of an urgent referral*.	PCI-GL, AHA PCI-CS ECD *New*
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability. The capability for real-time transfer of images and hemodynamic data [via T-1 transmission line] as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is highly recommended.	PCI-GL PCI-CS ML
Appropriate inventory of interventional equipment, including guide catheters, balloons and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. *Access to other diagnostic modalities such as intravascular ultrasound and fractional flow reserve is required*. Rotational or other atherectomy devices and the treatment of CTOs should not be performed in facilities without on-site surgery.	PCI-GL, PCI-CS *New*
Meticulous clinical and angiographic selection criteria for PCI (Table V).	PCI-GL, AHA
Participation in a national data registry, such as the ACC NCDR in the United States is required. This allows benchmarking, risk adjustment and facilitates outcomes analysis of local data.	PCI-GL ECD AHA
A program should be in place to track and ensure treatments with ACC/AHA guideline-based Class I therapies, both acutely and at discharge.	PCI-CS, ML
Full service laboratories [both primary and elective PCI, with and without on-site cardiac surgery] performing <200 cases annually must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and catheterization laboratory staff experience through collaborative relationships with larger volume facilities. Both physicians and staff should have the opportunity to work at a high volume center to enhance their skills. The continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory outcomes should be closed.	PCI-CS
Geographic isolation exists if the emergency transport time to another facility for a STEMI patient is >30 min.	*New*
Satisfactory outcomes should be defined by each local facility as part of their quality review process and should be based on national or regional benchmarks. Programs that fail to meet their established criteria for satisfactory performance for 2 consecutive quarters must undertake efforts to improve engaging outside experts if necessary. Failure to improve quality metrics should also be grounds for program closure regardless of the location.	ML PCI-CS D2B
As part of the local continuous quality improvement program, there should be a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of improvement opportunities.	PCI-GL

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TABLE III. *Continued*

General Recommendations	Source
STEMI Treatment Recommendations	
Each community should develop a STEMI system of care that follows standards at least as strong as those developed for Mission Lifeline, including:	2009 PCI-GL
• Performance of primary PCI as the first-choice treatment for STEMI to ensure streamlined care paths and increased case volumes.	2011 PCI-GL
• A process for prehospital identification and activation.	
• Protocols for triage, diagnosis and cardiac catheterization laboratory activation should be established within the primary PCI hospital/STEMI-Receiving Center.	ML D2B
• A single activation phone call should alert the STEMI team. Criteria for EMS activation of the cardiac catheterization laboratory should be established in conjunction with EMS providers.	
• Transfer protocols for patients who arrive at STEMI referral centers who are in cardiogenic shock and/or are primary PCI candidates ineligible for fibrinolytic drugs.	
STEMI receiving centers should be available and on-call 24 hours/7 days a week (no diversion) to perform primary PCI. Primary PCI should not be performed at facilities unless it is provided on a 24/7 schedule.[a] The cardiac catheterization laboratory staff and interventional cardiologist should arrive within 30 min of a STEMI activation call. Facilities should have a plan for triage and treatment of simultaneous presentation of STEMI patients.	PCI-GL, AHA ML
STEMI receiving centers should perform a minimum of 36 primary PCI procedures annually, and these procedures should ideally be performed at facilities that perform a minimum of 200 total PCI procedures annually.	PCI-GL PCI-CS ML
Facilities performing only primary PCI should perform a minimum of 36 primary PCIs annually and work in collaboration with a high volume PCI facility to ensure good outcomes	PCI-GL PCI-CS
There should be a recognized STEMI-Receiving Center liaison/system coordinator to the system and a recognized physician champion.	ML
The STEMI-Receiving Centers should participate in the Mission Lifeline-approved data collection tool, ACTION Registry-Get with the Guidelines™.	ML D2B
They should also participate in the regional Mission Lifeline Stakeholder group (if available) to contribute to the development of a regional STEMI System of Care Plan	ML
Monthly multidisciplinary team meetings to evaluate outcomes and quality improvement data. Operational issues should be reviewed, problems identified, and solutions implemented. The following measurements should be evaluated on an ongoing basis:	ML
a. Door-to-first device time, nontransfer patients	
b. STEMI Referral Hospital ED door-to-balloon [first device used] time	
c. First medical contact to balloon inflation [first device used] time, nontransfer patients	
d. First medical contact to balloon inflation [first device used] time, transfer patients	
e. Proportion of eligible patients receiving reperfusion therapy	
f. Proportion of eligible patients administered guideline-based class I therapies	
g. Proportion of patients with field diagnosis of STEMI and activation of the Cardiac Catheterization Laboratory for intended primary PCI who	
i. do not undergo acute catheterization because of misdiagnosis	
ii. undergo acute catheterization and found to have no elevation in cardiac biomarkers and no revascularization in the first 24 h	
h. In-hospital mortality	

[a]Required for U.S. facilities but might not be possible for all facilities worldwide.

ACC, American College of Cardiology; AHA, American Heart Association policy statement; CT, computed tomography; CTO, chronic total occlusion; D2B, Door-to-Balloon Alliance; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; EMS, emergency medical systems; GL, Guidelines; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; ML, Mission Lifeline; MR, magnetic resonance; New, New recommendation in this document; NCDR, National Cardiovascular Data Registry; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-segment elevation myocardial infarction.

Italics font: New or modified recommendation in the document.

Recommendations

We have provided recommendations for PCI without on-site surgery that are a composite of recommendations from the 2007 SCAI Expert Consensus Statement, the 2011 PCI guidelines, the 2012 Expert Consensus Document on Cardiac Catheterization Laboratory Standards, the 2013 PCI Competency statement and recommendations from the policy statement of the American Heart Association and requirements for the Mission Lifeline program and D2B Alliance [1–4,40,43,44]. Redundant recommendations from these documents were consolidated, and the writing committee included several new recommendations consistent with evolving practice standards.

TABLE IV. Personnel Requirements for PCI Programs Without On-Site Surgery

Personnel Recommendations	Source
Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.	PCI GL PCI-CS
Coronary care unit nursing staff must be experienced and comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, management of IABP, *management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia and access site complications*.	PCI-GL PCI-CS *New*
Personnel should be capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.	PCI-GL
Operators should have ABIM board certification in interventional cardiology and maintain certification, with the exception of operators who have gone through equivalent training outside the United States and are ineligible for ABIM certification and recertification exams.	PCI-CS,
Interventional cardiologists should perform a minimum of 50 coronary interventional procedures per year [averaged over a 2-year period] to maintain competency.	PCI-CS
Primary PCI should be performed by experienced operators who perform a minimum of 50 elective PCI procedures per year and, ideally, at least 11 primary PCI procedures per year. Ideally, these procedures should be performed in institutions that perform more than 200 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.	PCI-CS ML
Facilities should develop internal review processes to assess operators performing <50 PCIs annually. Individual operator level volume is one of several factors that should be considered in assessing operator competence, which include lifetime experience, institutional volume, individual operator's other cardiovascular interventions and quality assessment of the operator's ongoing performance.	PCI-CS
It is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by existing physicians until it is determined their skills, judgment and outcomes are acceptable.	*New*

ABIM, American Board of Internal Medicine; ML, Mission Lifeline; PCI-CS, 2013 PCI Competency Statement; PCI-GL, 2011 ACCF/AHA/SCAI PCI guidelines; IABP, intra-aortic balloon pump; New, new recommendation in this document; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

Italics font: New or modified recommendation in the document.

Facility Requirements for PCI Programs Without On-Site Surgery

Facility requirements are similar to those presented in past documents but now include a greater emphasis on the presence of quality review programs for facilities and operators, as described in the 2013 PCI competency document (4) (Table III). Diagnostic modalities such as IVUS and especially fractional flow reserve previously considered desirable for facilities without on-site surgery have now increased in importance and are necessary for all PCI centers.

The 2013 PCI Competency Document identified a signal suggesting that an institutional volume threshold of <200 PCIs/year was associated with worse outcomes. Therefore, the 2013 Competency Document recommended that the continued operation of laboratories performing <200 procedures annually that are not serving isolated or underserved populations be questioned and that any laboratory that cannot maintain satisfactory outcomes should be closed. Past documents have not specified any criteria for geographic isolation. The writing committee suggests it be defined not by distance but by the time required for emergency transport of a STEMI patient to another facility. Hospitals justify the creation of new PCI centers without on-site surgery by stating that they improve access for geographically under-served populations and allow patients to be cared for in close geographic proximity to their own families and physicians. However, multiple low-volume and partial-service PCI centers within a geographic area diffuse PCI expertise, increase costs for the overall health system and have not been shown to improve access [46–49]. If the transfer time is ≤30 min, it is reasonable to assume that transfer to the nearest PCI center will provide reperfusion as rapidly as if it were available at the first hospital. For transport times longer than 30 min, performing PCI on-site is likely to be quicker than a transfer. The development of PCI facilities within a 30-min emergency transfer time to an established facility is therefore strongly discouraged.

What constitutes a reasonable transport time for a patient requiring emergency surgery has not been consistently addressed in prior documents. Both CPORT-E and MASS-COMM studies provide guidance contained in their on-line supplementary materials [9,11]. Both require a transport vehicle to be available to begin transport within 30 min and arrival at the surgical hospital within 60 min of the decision to declare the need for emergency surgery. MASS-COMM further recommends that surgical intervention begin within 120 min. Given the existing data on the distribution of PCI facilities in the US, the performance of elective PCI at facilities that cannot meet these transfer times is discouraged [46,47].

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TABLE V. Recommendations for Off-Site Surgical Backup and Case Selection

Recommendations–Cardiologist–Cardiac Surgeon Interactions	Source
Interventional cardiologists must establish a working relationship with cardiac surgeons at the receiving facility.	PCI-GL ECD
Cardiac surgeons should have privileges at the referring facility to allow review of treatment options as time allows.	PCI-GL ECD
Ideally, face-to-face meetings between cardiothoracic surgeons and cardiologists involved should occur on a regular basis *(Heart Team approach) especially for the discussion of management of patients undergoing nonprimary PCI who have left main, three-vessel CAD or two-vessel CAD with involvement of the LAD or comorbidities such as diabetes, depressed LV function or complex anatomy.*	PCI-GL ECD *New*
Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.	PCI-GL ECD
Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at that time.	PCI-GL ECD
Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.	PCI-GL ECD
Interventional cardiologist should be familiar with and have immediate access to appropriate life support devices, such an intraaortic balloon pumps, and should be qualified for handling emergencies such as pericardial tamponade and embolization.	PCI-GL ECD
Hospital administrations from both facilities endorse the transfer agreement.	PCI-GL ECD
Transferring physicians obtain consent for surgery from patients or appropriate surrogates.	PCI-GL ECD
Initial informed consent for PCI discloses that the procedure is being performed without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery and state that a written plan for transfer exists. *Consent for PCI should be obtained before the procedure and before any sedatives are given. Consent for PCI obtained while the patient is on the table is not informed consent and is unacceptable in non-emergency situations.*	PCI-GL ECD *New*
Recommendations - Case Selection and Management	
Avoid intervention in patients with: • >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired. • Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography. • Lesions in areas other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms). • Lesions with TIMI flow grade 3 in patients with left main or three-vessel disease where bypass surgery is likely a superior revascularization strategy compared with PCI. • Culprit lesions in more distal branches that jeopardize only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention. • *Chronic total occlusion.*	PCI-GL ECD *New*
The management of patients with STEMI resuscitated from sudden cardiac death is complex, and decisions about the need for immediate PCI with or without therapeutic hypothermia or possible transfer to a tertiary facility for treatment should be individualized.	
Emergency transfer for coronary bypass surgery patients with • High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support. • Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer.	PCI-GL ECD

CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; IABP, intraaortic balloon pump; LV, left ventricle; New, new recommendation in this document; PCI, percutaneous coronary intervention; TIMI, thrombolysis in myocardial Infarction.
Italics font: New or modified recommendation in the document

The 2013 PCI competency document also states that any laboratory that cannot maintain satisfactory outcomes should be closed; however, there is currently no national definition for "satisfactory outcomes". The writing committee recommends that these be defined by each PCI center, including those with on-site surgery, as part of their quality review process, using national benchmark data. Programs failing to meet established criteria for satisfactory performance for two consecutive quarters must undertake efforts to improve their

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TABLE VI. Patient and Lesion Characteristics That Could be Unsuitable for Nonemergency Procedures at Facilities Without On-Site Cardiac Surgery

High-risk patients	Source
• Decompensated congestive heart failure [Killip Class ≥3] without evidence for active ischemia.	PCI-GL
• Recent [<8 weeks] cerebrovascular accident.	AHA
• Advanced malignancy.	ECD
• Known clotting disorders.	
• LVEF ≤30%.	
• Chronic kidney disease [creatinine >2.0 mg/dl or creatinine clearance <60mL/min].	
• Serious ongoing ventricular arrhythmias.	
• Patients with left main stenosis [>50% diameter] or three-vessel disease unprotected by prior bypass surgery [>70% stenoses in the proximal or mid segments of all major epicardial coronary arteries], treatment of any or all stenoses. Scoring systems, such as SYNTAX may be useful in defining the extent of disease and type of revascularization procedure.	
• Patients with a single-target lesion that jeopardizes an extensive amount of myocardium.	
• Patients undergoing intervention on the last remaining conduit to the heart.	
High-risk lesions	
• Unprotected left main stenosis.	PCI-GL
• Diffuse disease [>20 mm in length].	ECD
• Extremely angulated segment [>90%] or excessive proximal or in-lesion tortuosity.	*New*
• More than moderate calcification of a stenosis or proximal segment	
• Inability to protect major side branches.	
• Degenerated older vein grafts with friable lesions.	
• Substantial thrombus in the vessel or at the lesion site.	
• Any other feature that could, in the operator's judgment, impede successful stent deployment.	
• Anticipated need for rotational or other atherectomy device, cutting balloon or laser.	
The characteristics listed above identify high-risk patient and lesion features but are not absolute contraindications to performing PCI at a facility without on-site surgery. For example, an elevated creatinine levels increases the procedure risk for the patient, but this is not unique to facilities without on-site surgery and treatments to mitigate this complication can be used at all facilities. Ultimately, the operator should consider all factors and make a decision about the suitability of the patient for PCI at the facility.	*New*
Strategy for surgical backup based on lesion and patient risk	
• High-risk patients with high-risk lesions should not undergo nonemergency PCI at a facility without on-site surgery.	PCI-GL
• High-risk patients with nonhigh-risk lesions: Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.	
• Non-high-risk patients with high-risk lesions require no additional precautions.	
• Non-high-risk patients with nonhigh-risk lesions require no additional precautions. Best scenario for PCI without on-site surgery.	

CTO, chronic total occlusion; ECD, 2012 Expert Consensus Document on Cardiac Catheterization Standards; PCI-GL, 2011 ACCF/AHA/SCAI PCI Guidelines; LVEF, left ventricular ejection fraction; New, new recommendation; PCI,percutaneous coronary intervention; SYNTAX, Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery.
Italics font: New or modified recommendation in the document.

performance, engaging outside experts if necessary. Failure to improve quality metrics should lead to program closure regardless of the location. To ensure proper assessment and monitoring, laboratories are required to submit data to a national data registry, have regular meetings to discuss key performance metrics and develop plans for the correction of any deficiencies. Especially with facility PCI volumes decreasing, it becomes increasingly difficult to determine whether there are significant differences in the data reports from year to year. For example, to detect (with statistically certainty) a doubling of in-hospital mortality from 1% to 2% at a hospital with an annual case volume of 200 PCIs, nearly 4 years of continuous data collection would be required. This does not negate the importance of data submission to a national registry that can help identify trends, but it emphasizes why these same data must be carefully evaluated and adjudicated at the local facility. The importance of unbiased local or external peer review cannot be overemphasized [67,68]. Implementation of the SCAI Quality Toolkit and certification by Accreditation for Cardiovascular Excellence [ACE] are recommended as resources for improving quality [69,70].

Personnel Requirements for PCI Programs Without On-Site Surgery

Recognizing the potential for isolation and the advantage of clinical experience, the 2007 SCAI Expert Consensus Document included a recommendation that operators at PCI programs without on-site

surgery perform at least 100 total and 18 primary PCIs annually, a recommendation that might not be achievable in the current environment. The 2013 PCI Competency Document moves away from strict volume requirements to focus more on achieving quality metrics for facilities and individual operators. As noted earlier, the 2013 Competency document recommended that operators perform a minimum of 50 PCIs annually (averaged over 2 years), including no less than 11 primary PCIs annually. Ideally, these procedures should be performed in institutions performing >200 total and
T4 >36 primary PCI procedures annually (Table IV). Again acknowledging the importance of experience, the 2007 SCAI Expert Consensus Document suggested that initial operators at a new program without on-site surgery should have a lifetime experience of >500 PCIs as primary operator after completing a fellowship. In the current environment of decreasing PCI volumes and in view of the recommendations of the 2013 PCI competence document, this number would be difficult to achieve. Nevertheless, it is unwise for a newly trained interventional cardiologist to start a new PCI program. Newly trained interventional cardiologists joining an established PCI program should be mentored by more experienced physicians until it is determined that the skills, judgment and outcomes of these new cardiologists are acceptable.

Requirements for Off-Site Surgical Backup

Recommendations for the interactions between cardi-
T5 ologists and cardiac surgeons are listed in Table V. A limitation of programs performing PCI without on-site surgery is the lack of on-site access to a cardiac surgeon for consultation about revascularization options. This makes the concept of a Heart Team consultation more difficult to achieve and could necessitate performing only diagnostic catheterization until a case review with a cardiac surgeon can be performed. The application of telemedicine consultations with a heart surgeon could facilitate these interactions. In reality, many of the nonemergency patients who merit discussion by a Heart Team are not optimal candidates for PCI at facilities without on-site cardiac surgery. It is important to emphasize that the role of the cardiac surgeon is not confined to the treatment of PCI complications but includes the participation in decisions about revascularization options. Recommendations for case selection at facilities without on-site surgery are shown in Table V, and criteria for identifying high-risk lesions
T6 and patients are contained in Table VI. There are statistical models for identifying PCI patients at higher risk for mortality or emergency CABG that could be helpful for identifying patients who should not undergo PCI at facilities without on-site surgery [18,71]. However, these models have not been tested or applied on a large scale to determine the advisability of performing a PCI at facilities without on-site surgery.

The Delivery of PCI Services in the Future

As a result of the additional randomized studies on PCI without on-site surgery and the recent change in guideline recommendations, the performance of PCI without on-site surgery in the US has gained greater acceptance, and questions about its safety in the presence of a proven, well defined, and protocol driven approach have diminished. PCI programs should be evaluated based on their ability to: (a) sustain adequate quality metrics, (b) provide access to elective and emergency PCI procedures that would otherwise be unavailable in their service area, and (c) maintain the operator and institutional volumes recommended in the 2013 PCI Competency Document. For the future, the focus must now shift to developing a rational plan for the distribution of PCI services. Small PCI programs with large fixed costs are inefficient and unnecessary if they do not improve access in areas of need. However, it is unlikely that issues of system-wide efficiency will be addressed without central planning on the state or federal level. This writing group reaffirms the statement from the 2011 ACCF/AHA/SCAI PCI Guidelines that "desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery" and suggests that new programs offering PCI without on-site surgery are inappropriate unless they clearly serve geographically isolated populations. The writing group recognizes the need for ongoing study and surveillance of all PCI programs through participation in national databases encourages public reporting of their results and acknowledges that further declines in PCI volumes might necessitate the closure of PCI programs in the future.

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APPENDIX 1. SCAI/ACCF/AHA Expert Consensus Document Update on Percutaneous Coronary Intervention without On-Site Surgical Backup—Author Relationships with Industry and Other Entities (Relevant)

Committee Member	Employment	Consultant	Speaker's Bureau	Ownership/ Partnership/Principal	Personal Research	Institutional, Organizational or Other Financial Benefit	Expert Witness
James C. Blankenship	Geisinger Medical Center—Director, Cardiac Catheterization Laboratory	None	None	None	• Abiomed* • Astra-Zeneca* • Boston Scientific* • Kai Pharmaceutical* • Novartis • Schering Plough • The Medicines Company* • Volcano	• SCAI—Vice President*	None
Mehmet Cilingiroglu	Arkansas Heart Hospital	None	None	None	None	None	None
Greg J. Dehmer (Chair)	Texas A&M College of Medicine, Scott & White Clinic Cardiology Division—Professor of Medicine; Director of Cardiology	None	None	None	None	None	None
James G. Dwyer	Heart and Vascular Center of Northern Arizona	None	None	None	None	None	None
Dmitriy N. Feldman	New York Presbyterian Hospital/Cornell	• Gilead • Maquet	• Abbott Vascular • Bristol Myers Squibb* • Daiichi-Sankyo • Eli Lilly • Pfizer • The Medicines Company*	None	None	None	None
Timothy J. Gardner	Christiana Care Health System—Medical Director	None	None	None	None	None	None
Cindy L. Grines	Harper University Hospital—Vice President	• Abbott Vascular • Bristol Meyers Squibb • Lilly USA • Merck • The Medicines Company • Volcano*	None	None	None	• Journal of Interventional Cardiology†	None
Mandeep Singh	Mayo Clinic	None	None	None	None	None	None

This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors, including those not deemed to be relevant to this document, at the time this document was under development. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10 000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx for definitions of disclosure categories or additional information about the ACCF Disclosure Policy for Writing Committees.

*No financial benefit.

†Significant relationship.

ACC indicates American College of Cardiology; AMA, American Medical Association; FDA, Food and Drug Administration; NHLBI, National Heart Lung and Blood Institute; SCAI, Society for Cardiovascular Angiography and Intervention.

Attachment 7
COAP Letter

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

DATE: January 23, 2015

TO: Department of Health

RE: Nomination to Remove Elective PCI from the Listing of Tertiary Services

The Clinical Outcomes Assessment Program (COAP), a program of the Foundation for Health Care Quality, has been collecting data and providing a collaborative environment within which the safety and quality of cardiac revascularization procedures can be ensured across the entire State of Washington for almost 20 years.

Participation in COAP, while currently voluntary, has maintained membership from all hospitals that provide revascularization services. This 100% participation is a critical element which allows for continuous monitoring and immediately identifies differences in process and outcome metrics among institutions. Through its rigorous quality improvement reporting and standards, COAP is able to provide a service that is unparalleled in the country. The ability to analyze the data to examine facility and provider level variations in care puts us in a unique position to be the mechanism on which the state can rely for monitoring of PCI and cardiac surgery quality.

We welcome the opportunity to discuss how this process might be structured to best meet the goals of the Department of Health in ensuring that both elective and non-elective procedures are maintained at the highest standard of care.

Sincerely,

Shilpen Patel, MD
COAP Medical Director
shilpenp@uw.edu

Kristin Sitcov
COAP Program Director
ksitcov@qualityhealth.org

Terry Rogers, MD
CEO Foundation for Health Care Quality
trogers@qualityhealth.org