2013 ACCF/AHA/SCAI 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 and the Society for Cardiovascular Angiography and Interventions

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Writing Committee Representation

PCI Operators experienced in various clinical settings:

- Private practice
- Hospital-based
- Academic settings
- High-, medium-, and low-volume operators
- Small, medium, and large cath labs
- Hybrid labs
- Labs with and without surgical backup

Writing Committee Representation

Physicians with Experience In:

- Radial access
- Femoral access
- Systems of care for patients presenting with AMI
- Quality Assurance
- Clinical Research on PCI Outcomes

Writing Committee Representation

- Broad clinical experience with considerable previous PCI experience
- Cardiac surgeon
- CV training program directors
- Cath lab directors who have managed a broad cross-section of interventional operators
- General cardiologists

Document Peer Review and Approval Process

- Over 36 Peer Reviewers
- Over 316 Comments Received
- Committee Responded to each comment and revised document
- Official approval from Boards of ACCF, AHA, and SCAI

Incorporation of ACGME Core Competencies

Components of operator competence are identified utilizing the 6 ACGME Core Competencies:

- Medical Knowledge
- Patient Care & Procedures
- Practice-Based Learning & Improvement
- Systems-Based Practice
- Professionalism
- Interpersonal Skills & Communication

Core Competency Components for PCI

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 non-atherosclerotic 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 in 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 & bleeding—including coronary vascular (e.g., dissection, thrombosis, perforation, embolization), and other vascular (e.g., pseudoaneurysm, retroperitoneal hemorrhage, arteriovenous fistula, and stroke) complications.
14. 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; maintenance of ABIM-IC certification (MOC)(see section 2.7.1.); accredited CME*

Patient Care & 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, and treat hemodynamic instability, including the appropriate emergent use of pharmacologic 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*
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 to regional and national benchmarks for improving quality of care.
1. Incorporate risk/benefit and cost awareness factors in clinical decisions and management of patients undergoing PCI.
2. Effectively lead the catheterization laboratory team in the performance of the procedure and care of the patient.
3. 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*

Percutaneous Coronary Interventions:

Summary of Key Recommendations

Physical Facility Requirements

- 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.
- Physiologic 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.
- 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

- System ‘stress test’ drills to assess logistics flow capabilities of both the referring and receiving centers can help refine a well-coordinated emergent transfer

Endorsement of ACCF/AHA/ACC PCI Guideline Recommendations

- 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)

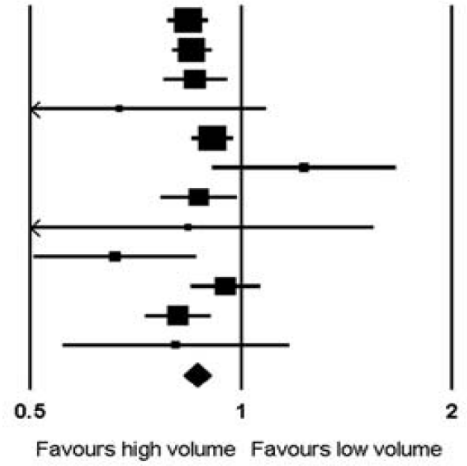
- Primary or elective PCI should not be performed in hospitals without onsite cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without hemodynamic support capability for transfer (Class III)

Institutional
Maintenance of Quality

- 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.

Results of Meta-analysis of Studies Investigating the Effect of Centre Volume on In-hospital Mortality after PCI

Model	Study name	Mean study year	Odds ratio	Lower limit	Upper limit
	Ho[4]	1986	0.840	0.787	0.897
	Ho[4]	1990	0.850	0.797	0.907
	Hannan *et al.*[23]	1993	0.860	0.775	0.954
	Vakili *et al.*[15]	1995	0.670	0.414	1.084
	Ho[4]	1995	0.910	0.852	0.972
	Kimmel *et al.*[13]	1995	1.230	0.910	1.662
	Canto *et al.*[12a]	1996	0.870	0.767	0.986
	Tsuchihashi *et al.*[10]	1997	0.840	0.456	1.547
	Hannan *et al.*[24]	1999	0.660	0.505	0.862
	Carey *et al.*[14a]	2000	0.950	0.849	1.063
	Allareddy *et al.*[22]	2002	0.813	0.731	0.904
	Shirashi *et al.*[11]	2003	0.807	0.557	1.169
Random			0.865	0.827	0.905



[a]Unpublished results.

CI indicates confidence interval and PCI, percutaneous coronary intervention.

Reprinted from Post PN, Kuijpers M, Ebels T, et al. The relation between volume and outcome of coronary interventions: a systematic review and meta-analysis. Eur Heart J. 2010;31:1985-92.

Maintenance of Quality: **Individual Operator**

Procedure volume is one of <u>MANY</u> factors affecting outcome and quality of PCI

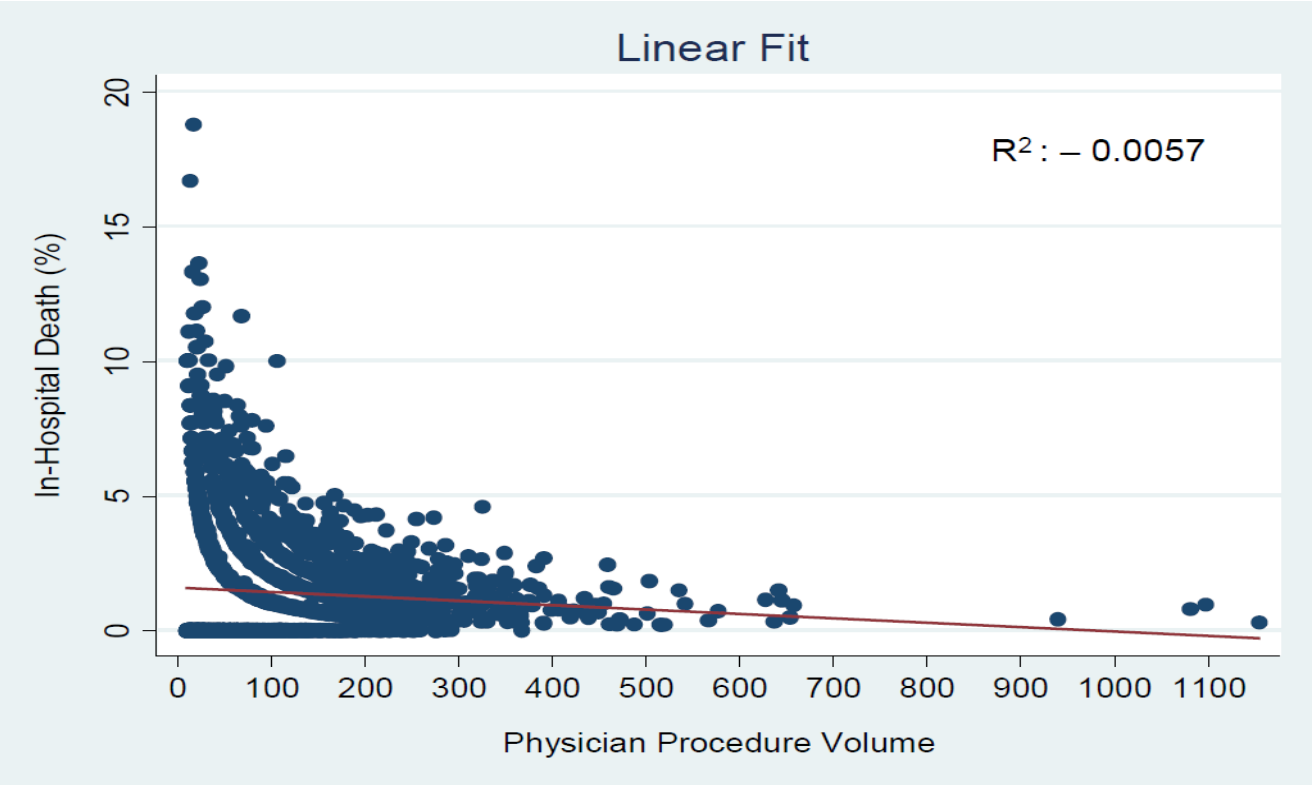
Other Factors to Consider in Assessing Operator Competency

- Lifetime experience
- Institutional volume
- Individual operator's other cardiovascular interventions
- Quality assessment of the operator's ongoing performance

Maintenance of Quality: **Individual Operator**

- 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.
- 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.

Scatter Plot of PCI Volume Versus In-hospital Mortality

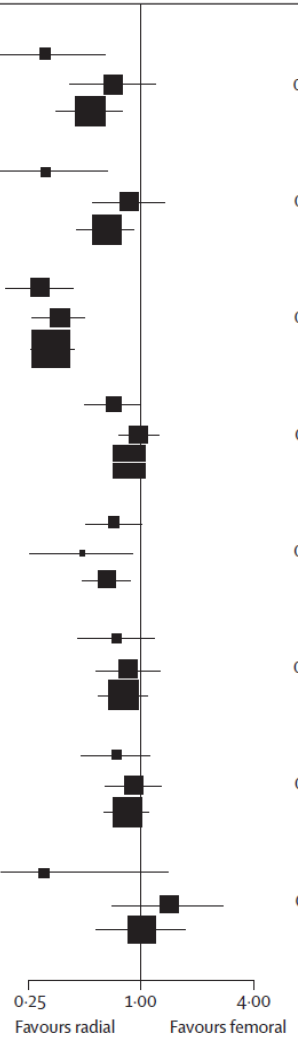


PCI indicates percutaneous coronary intervention

Reprinted with permission from Minges KE, Wang Y, Dodson JA, et al. Physician annual volume and in-hospital mortality following percutaneous coronary intervention: a report from the NCDR: American Heart Association 2011 Annual Scientific Sessions. Circulation. 2011;124:A16550.

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

	Total	Radial (n/N [%])	Femoral (n/N [%])	OR (95% CI)	p value	p value heterogeneity
Non-CABG major bleeds						
Pre-RIVAL	3946	4/1967 (0·2)	23/1979 (1·2)	0·25 (0·12–0·52)	0·0003	
RIVAL	7021	24/3507 (0·7)	33/3514 (0·9)	0·73 (0·43–1·23)	0·23	0·40
Combined	10967	28/5474 (0·5)	56/5493 (1·0)	0·51 (0·33–0·79)	0·002	
Non-CABG transfusion						
Pre-RIVAL	3841	4/1917 (0·2)	22/1924 (1·1)	0·25 (0·12–0·54)	0·0004	
RIVAL	7021	39/3507 (1·1)	45/3514 (1·3)	0·87 (0·56–1·33)	0·52	0·19
Combined	10862	43/5424 (0·8)	67/5438 (1·2)	0·65 (0·44–0·94)	0·023	
Major vascular access complication						
Pre-RIVAL	6772	21/3269 (0·6)	86/3503 (2·5)	0·28 (0·19–0·42)	<0·0001	
RIVAL	7021	49/3507 (1·4)	131/3514 (3·7)	0·39 (0·29–0·53)	<0·0001	0·41
Combined	13793	70/6776 (1·0)	217/7017 (3·1)	0·35 (0·28–0·44)	<0·0001	
Death, MI, or stroke						
Pre-RIVAL	5466	66/2905 (2·3)	84/2561 (3·3)	0·71 (0·51–0·99)	0·041	
RIVAL	7021	112/3507 (3·2)	114/3514 (3·2)	0·98 (0·75–1·28)	0·90	0·72
Combined	12487	178/6412 (2·8)	195/6075 (3·3)	0·87 (0·70–1·06)	0·170	
Death, MI, or stroke (radial experts)*						
Pre-RIVAL	4087	61/2217 (2·8)	76/1870 (4·1)	0·72 (0·51–1·01)	0·059	
RIVAL	2255	15/1129 (1·3)	30/1126 (2·7)	0·51 (0·28–0·91)	0·023	0·67
Combined	6342	76/3346 (2·3)	106/2996 (3·5)	0·66 (0·49–0·88)	0·005	
Death						
Pre-RIVAL	3830	29/2090 (1·4)	37/1740 (2·1)	0·73 (0·45–1·20)	0·21	
RIVAL	7021	44/3507 (1·3)	51/3514 (1·5)	0·86 (0·58–1·29)	0·48	0·92
Combined	10851	73/5540 (1·3)	88/5208 (1·7)	0·81 (0·59–1·10)	0·18	
MI						
Pre-RIVAL	3582	39/1958 (2·0)	47/1624 (2·9)	0·74 (0·48–1·14)	0·18	
RIVAL	7021	60/3507 (1·7)	65/3514 (1·8)	0·92 (0·65–1·32)	0·66	0·52
Combined	10603	99/5465 (1·8)	112/5138 (2·2)	0·85 (0·64–1·11)	0·23	
Stroke						
Pre-RIVAL	3559	2/1940 (0·1)	7/1619 (0·4)	0·31 (0·08–1·15)	0·08	
RIVAL	7021	20/3507 (0·6)	14/3514 (0·4)	1·43 (0·73–2·80)	0·30	0·31
Combined	10580	22/5447 (0·4)	21/5133 (0·4)	1·04 (0·57–1·89)	0·90	



OR indicates odds ratio; CABG, coronary artery bypass graft surgery; MI, myocardial infarction, and RIVAL, Radial vs. Femoral Access for Coronary Angiography and Intervention in Patients with Acute Coronary Syndromes 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.

From Jolly SS, Yusuf S, Cairns J, et al. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial. Lancet. 2011;377:1409-20.

Unadjusted and Adjusted Odds Ratios of In-Hospital Mortality Based on Primary PCI Volume [a]

Model	Odds Ratio (95% Confidence Interval)					
	Low- vs High-Volume Hospitals	*P* Value	Medium- vs High-Volume Hospitals	*P* Value	Volume as a Continuous Variable[b]	*P* Value
Unadjusted	1.21 (0.87-1.69)	.26	1.00 (0.77-1.31)	.99	1.08 (0.93-1.26)	.32
Adjusted for demographics and hospital characteristics	1.23 (0.87-1.74)	.24	1.04 (0.79-1.38)	.77	1.11 (0.93-1.32)	.23
Adjusted for demographics, hospital characteristics, and past medical history	1.30 (0.91-1.87)	.15	1.09 (0.81-1.47)	.56	1.13 (0.95-1.36)	.17
Adjusted for demographics, hospital characteristics, past medical history, and acute use of aspirin and β-blockers	1.22 (0.78-1.91)	.38	1.14 (0.78-1.66)	.49	1.13 (0.93-1.37)	.23

[a] Crude in-hospital mortality rates were 3.9% for low-volume hospitals, 3.2% for medium-volume hospitals, and 3.0% for high-volume hospitals.
[b] For every decrease in 50 procedures/year.
PCI indicates percutaneous coronary intervention.

From Kumbhani DJ, Cannon CP, Fonarow GC, et al. Association of hospital primary angioplasty volume in ST-segment elevation myocardial infarction with quality and outcomes. JAMA. 2009;302:2207-13.

Maintenance of Quality: **Primary PCI**

- Primary PCI for STEMI should be performed by experienced operators who perform:
  - A minimum of 50 elective PCI procedures per year
  - 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.

Recent Studies Comparing PCI with and without Onsite Cardiac Surgery

Study (year)	Design	Population (n)	Endpoints	Mortality	Other results	Conclusion
SCAAR (2007) (40)	Registry of all PCIs in country	Elective = 28911 STEMI = 5452	30-day mortality, 1-year mortality, Emergency CABG	Elective On site surgery = 0.2% No onsite surgery = 0.4% Primary PCI On site surgery = 6.7% No onsite surgery = 7.0%	Emergency CABG On site surgery = 0.2% No onsite surgery = 0.1% (p=0.025)	No difference in 30-day mortality, 1-year mortality, stroke or emergency CABG between groups
Singh (2009) (41)	Matched case-controlled	Elective = 1842 Non-elective = 667	In-hospital mortality, Emergency CABG, MACE*	Elective On site surgery = 0.4% No onsite surgery = 0.2% Non-elective On site surgery = 3.1% No onsite surgery = 2.5%	Emergency CABG Elective On site surgery = 0.2% No onsite surgery = 0% Non-elective On site surgery = 0.7% No onsite surgery = 0.6%	In-hospital mortality and MACE not different for elective and non-elective patients at sites with and without onsite surgery. Emergency CABG higher for elective patients at sites with onsite surgery
Kutcher (2009) (42)	NCDR® Registry	Elective = 275114 Non-elective = 33033	In-hospital mortality, Emergency CABG	Non-primary PCI Onsite surgery = 0.8% No onsite surgery = 0.8% Primary PCI Onsite surgery = 5.2% No onsite surgery = 5.1%	Emergency CABG Non-primary PCI Onsite surgery = 0.3% No onsite surgery = 0.2% Primary PCI Onsite surgery = 1.2% No onsite surgery = 0.7%	Sites without onsite surgery had similar procedure success, in-hospital mortality and emergency CABG rates.
Singh (2011) (43)	Meta-analysis of 15 studies	Non-primary = 914288 Primary = 124074	In-hospital mortality, Emergency CABG	Non-primary PCI Onsite surgery = 0.8% No onsite surgery = 0.9% Primary PCI Onsite surgery = 5.1% No onsite surgery = 4.6%	Emergency CABG Non-primary PCI Onsite surgery = 0.29% No onsite surgery = 0.17% Primary PCI Onsite surgery = 1.03% No onsite surgery = 0.22%	STEMI patients: Mortality and emergency CABG not different. Non-primary patients: Overall, emergency CABG and mortality not different, but after adjustment for publication bias, mortality 25% higher at sites without surgery.

Study (year)	Design	Population (n)	Endpoints	Mortality	Other results	Conclusion
Zia (2011) (44)	Meta-analysis of 11 studies	Non-primary = 909,813 Primary = 105,993	In-hospital mortality, Emergency CABG	Non-primary PCI Onsite surgery = 2.1% No onsite surgery = 1.6% Primary PCI Onsite surgery = 7.6% No onsite surgery = 6.1%	Emergency CABG Non-primary PCI Onsite surgery = 0.9% No onsite surgery = 1.0% Primary PCI Onsite surgery = 3.4% No onsite surgery = 3.0%	Sites without onsite surgery were not associated with higher in-hospital mortality or emergency CABG. Substantial hospital variability in outcomes for non-primary PCI
CPORT-E (2012) (45)	Randomized	Elective only	6-week mortality, 9 month MACE†	Onsite surgery = 1.0% No onsite surgery = 0.9%	9-month MACE Onsite surgery = 11.2% No onsite surgery = 12.1%	PCI at hospitals without onsite surgery was not inferior to sites with onsite surgery

CABG indicates coronary artery bypass graft surgery; CPORT-E, Cardiovascular Patient Outcomes Research Team (CPORT) Non-Primary PCI (CPORT-E); MACE, major adverse cardiac events; NCDR®, National Cardiovascular Data Registry; PCI, percutaneous coronary intervention; SCAAR, Swedish Coronary Angiography and Angioplasty Registry; and STEMI, ST-segment elevation myocardial infarction.

*MACE defined as in-hospital death, q-wave MI, urgent, emergent CABG, stroke

†MACE defined as death, target vessel revascularization, Q-wave myocardial infarction

Quality Assurance:
Institutional Requirements

- Establish an ongoing mechanism for valid and continuous peer review of its quality and outcomes
- Operate a quality improvement program that routinely:
  - reviews quality and outcomes of the entire program
  - reviews results of individual operators
  - includes risk adjustment
  - provides peer review of difficult or complicated cases
  - performs random case reviews
- 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.

Quality Assurance:
Institutional Requirements

- Institution must 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.
- Independent and dedicated committee should be established and ideally include both physicians and relevant health care 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, conducting analyses, and support other aspects of the QI process.

Institutional Resources & Support

- 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

Participation in regional and national registries is strongly encouraged

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

- Quality assurance must include 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
  - 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
- Operators should be reviewed for the appropriateness of procedures and indications criteria to assure the clinical necessity of the procedures

Quality Assessment and Implementation

- **ALL** operators should undergo periodic peer review, with more intensive review process for low-volume operators.

- 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.

Quality Assessment and Implementation

- QA 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.
- 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.

Quality Assessment and Implementation

- A formal method of oversight for perceived conflicts of interest among peer reviewers should be used and carefully scrutinized.
- 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 cine-angiography 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.

Key Recommendations for Other Coronary Interventions:

- HOCM
- Ventricular Tachycardia
- Coronary Fistulae

Multidisciplinary Approach

- Coronary interventions in patients with hypertrophic cardiomyopathy, ventricular tachycardia and coronary fistulae are rare and complex
- Team approach important for optimal results to include:
    - Coronary interventionalists
    - Cardiothoracic surgeons
    - Cardiothoracic anesthesiologists
- Dedicated personnel should be identified and a regular review of program activity and results documented

Institutional Requirements

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

Operator Competence

- ACGME Core Competencies outlined for each procedure
- HOCM Alcohol Ablation
  - First 5 procedures proctored by a skilled operator
  - Maintenance of Competence: performance of 5 procedures per year

Alcohol Ablation for HOCM

Experienced operator defined as:

- performance of >20 procedures or procedures have all been performed at a facility with cumulative volume of 50
- If facility has cumulative volume <50:
  - QA committee should review first 20 cases performed
  - Maintenance of skills: individual operators should perform at least 10 procedures per year