ACE Cath-PCI

Data Requirements



Accreditation for Cardiovascular Excellence Quality in Invasive Cardiovascular Care

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1. It is required that all Diagnostic Cardiac Catheterization and Percutaneous Coronary Intervention programs seeking accreditation routinely collect and review outcomes data and benchmark against like facilities

2. Participation in the NCDR-CathPCI Registry fulfills the data collection requirements for both diagnostic and percutaneous coronary intervention procedure complications.

- 2.1. In the absence of participation in the CathPCI Registry, the complications assessed must include procedure-related death, MI, stroke, cardiogenic shock, emergency CABG, peripheral vascular/ access site complications (significant hematoma, pseudoaneurysm, AV fistula, loss of radial pulse, need for vascular surgery or blood transfusion), pericardial tamponade, and the occurrence of contrast-associated nephropathy. Facilities must have written definitions of the complications preferably with risk-adjustment of these complications using a documented methodology. Complications should be assessed through hospital discharge.
- 2.2. If a facility does not participate in NCDR, then data definitions must be consistent with those used in NCDR.
- 2.3. Each lab shall report the incidence of non-obstructive disease in elective patients defined as patients undergoing elective diagnostic cath and coronary angiography with all native coronary territories <50%. Exclusions: Patients with prior CABG, cardiac transplant evaluation; pre-op evaluation for non-cardiac surgery and diagnostic cath treatment recommendation of "other cardiac therapy without CABG or PCI".

3. A quality assurance (QA) monitoring program must be present and integrated with a quality improvement (CQI) effort (1)

- 3.1. Structural indicators should include but not limited to: a) credentialing and re-credentialing criteria, b) licensure and board certification status, c) documentation of CME participation.
- 3.2. Process indicators should include but not limited to: a) quality of angiographic studies, b) completion of accurate and informative reports, c) emergency response times, d) total procedure and fluoroscopy times, e) contrast usage, f) radiation dose.
- 3.3. Outcome indicators assessed should be part of an overall quality assurance (QA) program
- 3.4. The quality assurance program must include a peer-review process with randomly selected diagnostic and interventional procedures reviewed for their indications and complications and a periodic review of all major laboratory complication rates (2)
- 3.5. The QA program must include an assessment of: a) the rate of "normal diagnostic catheterization procedures", b) an assessment of complication rates for all types of procedures performed, and c) an assessment of the diagnostic accuracy and adequacy of angiograms as defined in detail in section 9.2.2 of the Cath/PCI Standards Document.

- **4.** Clinical performance metrics are now being tracked and reported publically in several sources (eg. www.hospitalcompare.hhs.gov). For ACE accreditation, the laboratory performance metrics that will be reviewed and performance level for accreditation are shown in the table below.
- **5.** Metrics:

Performance Metrics

STEMI process metrics	Requirement
STEMI patients receiving ASA on arrival (no contraindication to ASA)	≥ 95%
STEMI patients receiving ASA at discharge (no contraindication to ASA)	≥ 95%
Heart Attack Patients Given ACE Inhibitor or ARB for Left Ventricular Systolic Dysfunction (LVSD) (no contraindication to ACE and ARBs)	≥ 90%
Statin at discharge in patients with dyslipidemia (no contraindications to statin use))	≥ 95%
Heart Attack Patients Given Smoking Cessation Advice/Counseling	≥ 95%
Heart Attack Patients Given Beta Blocker at Discharge (no contraindication to beta-blocker use)	≥ 95%
Heart Attack Patients Given PCI Within 90 Minutes Of Arrival	> 80%
Readmission within 30 days for an unanticipated problem related to the initial STEMI	< 20%
STEMI outcome metrics	
In-hospital risk-adjusted mortality for STEMI patients receiving PCI	≤ 7.5%
Unadjusted in-hospital mortality for STEMI patients	≤ 10%
Transfusion of whole blood or RBCs post PCI (excluding CABG patients)*	< 7%
Major bleeding (excluding CABG patients)**	< 12%

PCI process metrics	Requirement
ASA at discharge for all PCI patients (no contraindication to ASA)	≥ 99%
Additional antiplatelet drug for stent patients at discharge (no contraindications noted	≥ 99%
Lipid lowering agent at discharge in patients with dyslipidemia (no contrain- dications to statin use)	≥ 90%
Measurement of case appropriateness in a minimum of 75% of all cases per- formed. (The case appropriateness metrics will be reported in future versions of the NCDR)	
PCI outcome metrics	
Vascular access injury requiring surgery or major bleeding**	< 2.0%
Emergency CABG	< 1.0%
Transfusion of whole blood or RBCs post PCI*	< 5.0%
Post-procedure stroke	< 1.0%
In-hospital risk-adjusted mortality (excluding STEMI)	< 1.0
In-hospital risk-adjusted mortality for all patients	< 2.0%
Diagnostic Cath Process Metrics	
Incidence of non-obstructive disease in elective patients, diagnostic only labs	< 50%
Incidence of non-obstructive disease in elective patients at all other labs †	< 40%
Diagnostic Cath Outcome Metrics	
Vascular access injury requiring surgery or major bleeding**	< 1.0%

* Patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Exclusions: Patients having CABG or other major surgery during the same admission.

- **Vascular access site injury requiring treatment or major bleeding is defined as: 1) Bleeding at access site, hematoma at access site, or retroperitoneal bleed that occur within 72 hours of the procedure. To qualify, the event must be associated with a hemoglobin drop of >3 g/dL; transfusion of whole or packed red blood cells, or a procedural intervention/surgery at the bleeding site to reverse/stop or correct the bleeding. This excludes "GI", "GU" and "Other" bleeds. 2) Major access site related injury requiring treatment includes access site occlusion, peripheral embolization, dissection, pseudoaneurysm, AV fistula requiring treatment anytime from the procedure until discharge.
- † Defined as patients with undergoing elective diagnostic cath and coronary angiography with all native coronary territories <50%. Exclusions: Patients with prior CABG, cardiac transplant evaluation; pre-op evaluation for non-cardiac surgery and diagnostic cath treatment recommendation of "other cardiac therapy without CABG or PCI".

Note: Performance levels for these metrics were developed from the reported results on the CMS website (www.hospitalcompare.hhs.org); the NCDR CathPCI Registry version 4.0 report and the NCDR ACTION-GWTG Registry for STEMI patients Q2, 2010.

6. Patient Management/Process Indicators:

- 6.1. Quality of Angiographic Studies
 - 6.1.1. The completeness and accuracy of diagnostic procedures should be assessed as part of the QA process.
 - 6.1.2. The number of inadequate or incomplete diagnostic procedures should not be > 10% for any operator.
 - 6.1.3. Variables assessed may include but are not limited to: a) adequate visualization of all coronaries in multiple views, b) complete study of all existing bypass grafts, c) left ventriculograms performed with adequate visualization, d) adequacy of pressure measurements in valve disease cases, e) others as defined by the laboratory
- 6.2. Report Generation and quality of Interpretation
 - 6.2.1. The reporting standards of The Joint Commission (TJC) for operative procedures must be followed. These include:
 - 6.2.1.1. Preliminary procedure reports must be written or dictated immediately after the procedure
 - 6.2.1.2. There must be enough information in the record immediately after the procedure to manage the patient throughout the post-procedure period. This information could be entered as the procedure report or as a hand-written operative progress note.

- 6.2.1.3. If the procedure report is not placed in the medical record immediately after the procedure due to transcription or filing delay, then a progress note should be entered in the medical record immediately after the procedure to provide pertinent information for anyone required to attend to the patient. Immediately after the procedure is defined as "upon completion of procedure, before the patient is transferred to the next level of care".
- 6.2.2. The procedure progress note should contain at a minimum information including:a) name of the operator, b) procedures performed and description of each procedure,c) findings, d) estimated blood loss, e) specimens removed if appropriate f) complications,g) post operative diagnosis and h) recommendations.
 - 6.2.2.1. Summary of major findings or diagnoses
 - 6.2.2.2. Disposition of the patient as a result of the procedure and comments
- 6.3. Infection Control Practices
 - 6.3.1. All labs should have sterile/infection control protocols in place for access site prep, universal precautions, airflow, and other issues. (2) Masks, eye shields, and protective caps are probably more important for keeping the patient's blood from splattering onto the operator than for protecting the patient from infection. There is wide variation in their use for routine cardiac catheterization procedures. Universal precautions should be followed with respect to sharp objects (e.g., never re-capping needles). Appropriate receptacles for sharp objects should be available
- 6.4. Radiation Safety Practices
 - 6.4.1. Each CCL should have a program to document the radiation exposure to patients and staff
 - 6.4.2. Each CCL facility must establish a radiation safety education program either in conjunction with the hospital Health Physics Department/ Medical Physicist and/or an outside consultant and/or assistance from a web-based tutorial. (6) Documentation of personnel training in radiation safety must be provided.
 - 6.4.3. This program should have the following mandated components: a) initial training or verification of prior training for all physicians and staff using fluoroscopy in the CCL; b) annual updates on radiation safety; c). hands on training for new operators in a facility and existing operators on newly purchased equipment
 - 6.4.4. Patient radiation dose needs to be monitored and recorded.
 - 6.4.4.1. This should include the fluoroscopic time (FT, min), and total air kerma at the interventional reference point (Ka,r, Gy) and/or air kerma area product (PKA, Gycm2). Peak skin dose (PSD, Gy) should be included if technology permits its measurement.

- 6.4.5. A surveillance program should be in place for patients whose recorded total air kerma at the interventional reference point (Ka,r,) is 5 Gy or greater, Pka of 500 Gycm2, and/or fluoroscopy doses that exceed 60 minutes. This program should include the dose and a reason for this dose, patient notification, medical physicist/health physics involvement for Ka,r >10Gy, and a mechanism for patient follow up of potential adverse effects from radiation
- 6.5. Adherance to Treatment Protocols (Contrast, drugs,)
 - 6.5.1. Facilities should have a written protocol or standardized order sets for the anticoagulated patient undergoing procedures and for the use of radial access.
 - 6.5.2. Facilities should have a written protocol or standardized order sets for the management of patients at risk of contrast-induced nephropathy. This should pre- and post procedure hydration and follow-up. (4)Facilities should have a written protocol or standardized order sets for the treatment of patients with known radiographic contrast allergy or those at increased risk for contrast allergy and a readily available protocol for the treatment of anaphylaxis should it occur. (5)
- 7. Outcomes data items to review as part of regular QA process and for accreditation are listed in tables 7.1 and 7.2

Table 7.1

Data element name	Acceptable responses	NCDR Reference CathPCI element #
Total volume of cases in this period	Ν	N/A
Diagnostic cases, n	n	5310
PCI cases, n	n	5305
For all cath lab cases:		
Status	Elective, n Urgent, n Emergency, n Salvage, n	6040
Presentation	Asymptomatic, n Symp. Unlikely ischemia, n Stable angina, n Unstable angina, n NSTEMI, n STEMI, n	5000

Data element name	Acceptable responses	NCDR Reference CathPCI element #
For all elective cases (6040):		
Stress or imaging studies per- formed pre-procedure	Yes, n No, n	5100
For PCI procedures:		
Status	Elective, n Urgent, n Emergency, n Salvage, n	7020
PCI Indication	Immediate PCI for STEMI, n PCI for STEMI (>12h, stable), n Rescue PCI, n PCI for STEMI (>12h, unstable), n PCI for STEMI (stable after lytic), n PCI for NSTEMI/UA, n Staged PCI, n Other, n	7035
Guidewire across lesion	Yes, n No, n	7205
Device deployed	Yes, n No, n	7220
Door-to-balloon time	minutes (m±sd)	
% of cases with lesion < 70% with stress test, FFR, or IVUS testing		
Diagnostic cases:		
Average fluoro time	minutes (m±sd)	5320
Average fluoro dose	mGy (m±sd)	5321
Average contrast dose	ml (m±sd)	5325
PCI cases:		
Average fluoro time	Minutes (m±sd)	5320
Average radiation dose (Air Kerma at Reference Point (Gy) and/or Air Kerma Area Product (Gy cm2)	mGy (m±sd)	5321
# cases with >/= 6 grays		
Average contrast dose	ml (m±sd)	5325
# cases with contrast over 350 cc		

Table 7.2

Data element name	Acceptable responses	NCDR Reference CathPCI element #
For all cath lab cases:		
Death	Yes, n No, n	9040
CABG	Yes, n No, n	9000
CABG status	Elective, n Urgent, n Emergency, n Salvage, n	9005
CABG indication	PCI complication, n PCI failure w/o deterioration, n No PCI preceding CABG, n Hybrid procedure, n	9010
MI (+ biomarkers)	Yes, n No, n	8000
Cardiogenic shock	Yes, n No, n	8005
Heart failure	Yes, n No, n	8010
CVA/Stroke	Yes, n No, n	8015
Tamponade	Yes, n No, n	8025
New req't for dialysis	Yes, n No, n	8030
Vasc. Complic req Rx	Yes, n No, n	8035
Transfusion	Yes, n No, n	8040
Bleeding event <72h	Yes, n No, n	8050

ACE Standards for Catheterization Laboratory Accreditation



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- 2. Heupler FA Jr, Chambers CE, Dear WE, Angello DA, Heisler M. Guidelines for internal peer review in the cardiac catheterization laboratory. Laboratory Performance Standards Committee, Society for Cardiac Angiography and Interventions. Cathet Cardiovasc Diagn 1997;40:21-32.
- 3. Chambers CE, Eisenhauer MD, McNicol LB, Block PC, Phillips WJ, Dehmer GJ, Heupler FA, Blankenship JC; Members of the Catheterization Lab Performance Standards Committee for the Society for Cardiovascular Angiography and Interventions Infection control guidelines for the cardiac catheterization laboratory: society guidelines revisited. Catheter Cardiovasc Interv 2006;67:78-86.
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- Goss JE, Chambers CE, Heupler FA Jr. Systemic anaphylactoid reactions to iodinated contrast media during cardiac catheterization procedures: guidelines for prevention, diagnosis, and treatment. Laboratory Performance Standards Committee of the Society for Cardiac Angiography and Interventions. Cathet Cardiovasc Diagn. 1995;34:99-104.
- 6. Chambers CE, Fetterly K, Holzer R, Lin PJP, Blankenship JC, Balter S, Laskey WK. Radiation Safety Program for the Cardiac Catheterization Laboratory. 2010, In Press CCI.