Percutaneous transluminal coronary angioplasty

Background

Percutaneous transluminal coronary angioplasty (PTCA), often referred to as percutaneous coronary intervention (PCI), is a noninvasive procedure that restores blood flow to the heart tissue and opens blocked coronary arteries caused by coronary artery disease. Cardiologists often perform PTCA instead of open-heart surgery, which can be more risky and invasive.

The physician threads a guide wire into the femoral artery, uses a diagnostic catheter to advance into the blood vessel, then places the tip of the catheter at the opening of the coronary artery. Physicians use a type of x-ray called a fluoroscopy in conjunction with a contrast dye to determine where the blockage has occurred. Then, the diagnostic catheter (which is tipped with a balloon) is inflated to compress the fatty tissue in the artery and improve blood flow to the heart. Providers may also use a technique called intravascular ultrasound (IVUS) that uses ultrasonic sound waves to create images of blood vessels and provide additional visual verification of blockages.

The physician may repeat the procedure several times, pumping the balloon-tipped catheter more each time to widen the passage. Recently physicians have also begun using a stent (a tiny, expandable metal coil) to keep the artery from narrowing again.

For more information, please refer to Clinical Privilege White Paper, Interventional cardiology—Practice area 404.

Involved specialties

Interventional cardiologists

Positions of specialty boards

ABIM

The American Board of Internal Medicine (ABIM) certifies physicians in the subspecialty of interventional cardiology. ABIM requires 12 months of clinical fellowship training in interventional cardiology to qualify for certification. During that training, candidates must have performed at least 250 therapeutic interventional cardiac procedures, which are documented in a case list and attested to by the program director.
In order to receive credit for completion of an interventional cardiac procedure, fellows must meet the following requirements:

➤ Participate in procedural planning, including indications for the procedure and the selection of appropriate procedures or instruments.

➤ Perform critical technical manipulations of the case. (Regardless of how many manipulations are performed in any one “case,” each case may count as only one procedure.)

➤ Be substantially involved in post-procedural management of the case.

➤ Be supervised by the faculty member responsible for the procedure. (Only one fellow can receive credit for each case even if others were present.)

In order to become certified, candidates must meet all of the following:

➤ Have a current, valid ABIM certification in cardiovascular disease

➤ Complete the requisite formal training and procedural requirements listed above

➤ Demonstrate clinical competence, procedural skills, and moral and ethical behavior in the clinical setting

➤ Hold a valid, unrestricted, and unchallenged license to practice medicine

➤ Pass the interventional cardiology certification exam

AOBIM

The American Osteopathic Board of Internal Medicine (AOBIM) offers a certificate of added qualifications certification in interventional cardiology.

Candidates for added qualifications certification in interventional cardiology must have three years of American Osteopathic Association (AOA)–approved subspecialty training in cardiology followed by one year of training in interventional cardiology in an AOA- or Accreditation Council for Graduate Medical Education (ACGME)–accredited program. During interventional cardiology training, candidates must have participated in a minimum of 300 cardiac interventional procedures and serve as the primary operator in a minimum of 200 of these cases, which must be attested to by the training program director.

Positions of societies, academies, colleges, and associations

ACCF/AHA/SCAI

In 2007, the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and the Society for Cardiovascular Angiography and Interventions (SCAI) released an *Update of the Clinical Competence Statement on Cardiac Interventional Procedures*. This served as an update to the original cardiac competence statement published by the ACCF/AHA/American College of Physicians Task Force on Clinical Competence.
The document reads: “PCI is often a complex, demanding procedure. To perform PCI optimally, an operator must possess a substantial cognitive knowledge base as well as considerable technical skill. In addition, the technical difficulty of a particular procedure can vary greatly from one patient to another. Furthermore, serious complications of coronary interventional procedures may occur unpredictably in procedures that initially appear to be straightforward. Recognition and management of complications are critical components of PCI procedures that require skill, knowledge, experience, and judgment.”

The group notes that ACGME-approved interventional training programs address the core knowledge base for interventional cardiology, and the ABIM offers a subspecialty certification in interventional cardiology. Training programs require interventional cardiologists be knowledgeable in anatomy, physiology, and pathophysiology of the cardiovascular system, in particular the biology of coronary artery disease. Providers should also be familiar with the polymers and drugs incorporated into stents, and have knowledge of indications for PCI.

Clinical skills should build on cognitive knowledge, with decisions based on symptoms, anatomy, and associated risk factors, and physicians should be aware of applicable guidelines for PCI procedures.

Interventionists should also have thorough knowledge of equipment associated with the procedure, including:

➤ The theoretical and practical aspects of x-ray imaging, radiation physics and safety, and other equipment to generate digital images; quality control of images; image archiving; consequences of exposure of patients and personnel to ionizing radiation; and methods of reducing patient and staff radiation exposure
➤ Specialized catheterization recording and safety equipment (physiological data recorders, pressure transducers, blood gas analyzers, defibrillators)
➤ Catheters, guide wires, balloon catheters, stents, atherectomy devices, ultrasound catheters, intra-aortic balloon pumps, puncture site sealing devices, contrast agents, distal protection devices, and thrombus extraction devices

Technical skills, including manual dexterity and the ability to obtain percutaneous arterial and venous access with a sterile surgical technique, are also important. Many of the skills associated with PCI can only be achieved by performing actual procedures under the direction of experienced interventionalists. Some specific skills include manipulation and operation of guide catheters, coronary angioplasty guide wires, coronary angioplasty balloon catheters, specialized atherectomy devices, stents, and intracoronary ultrasound catheters. These specialized skills should be covered in ACGME-approved programs.
In terms of maintaining competence, institutions should have a monthly catheterization laboratory conference to review literature and quality patient data as part of the institution’s quality assessment program. Facilities that perform less than 400 interventions each year should consider holding conferences with a partnering, more highly experienced institution.

For individual competency maintenance, practitioners should attend at least 30 hours of interventional cardiology CME every two years. To ensure quality, the catheterization laboratory director should randomly select and evaluate five cases each year. Any practitioner performing less than 75 cases a year should have 10 cases reviewed. These cases should be compared to national quality benchmarks, with recommendations for quality improvement and reassessment in the following six months if data proves unsatisfactory.

In 2011, ACCF/AHA/SCAI published ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. In these guidelines the group acknowledges that every PCI program should operate a quality improvement program that reviews quality outcomes of the entire program and individual providers, as well as random case reviews, which should be measured against national standards.

All physicians who perform PCI should be certified by the ABIM in interventional cardiology and participate in a maintenance of certification program. PCI procedures should be performed by operators with an annual volume greater than 75 procedures, in a center with more than 400 procedures. Providers that have fewer than 75 annual PCI procedures should only work in institutions that do more than 600 procedures each year and should develop a defined mentoring relationship with a practitioner who does more than 150 PCI procedures each year.

ACCF/AHA/SCAI recognizes that these numbers may be modified at the institutional level, as long as quality outcomes are met.

**ACCF**

In 2008, the ACCF published a training statement, Training in Diagnostic and Interventional Cardiac Catheterization.

ACCF divides training into three levels that cover diagnostic and interventional cardiac catheterization. All levels must be fully accredited by the ACGME. For Level 1 and 2 training in diagnostic cardiac catheterization, if the program does not include training in interventional cardiology, exposure to an active interventional cardiology program should be provided. Training should include indications and contraindications for the procedures, pre- and post-procedure care,
management of complications, and analysis and interpretation of the hemodynamic and angiographic data. Levels of training are categorized as follows:

➤ Level 1 (minimum four months in cardiac catheterization lab): Trainees practice noninvasive cardiology and invasive activities confined to the critical care unit. Training will also include indications for the procedure and the accurate interpretation of data obtained in the catheterization laboratory. Trainees must perform a minimum of 100 diagnostic cardiac catheterization procedures.

➤ Level 2 (minimum of eight months in the cardiac catheterization lab over a three-year period): Trainees practice diagnostic but not interventional catheterization. Trainees must perform a minimum of 300 diagnostic catheterization procedures. Level 2 technical skills include:
  – Performing vascular access from the femoral route
  – Performing coronary angiography
  – Understanding radiologic imaging, including x-rays

➤ Level 3: Trainees practice diagnostic and interventional catheterization during the fourth year of fellowship, dedicated primarily to cardiovascular interventional training. Trainees must participate in a minimum of 250 coronary procedures. Trainees should also possess knowledge about percutaneous management of access site complications, coronary perforation, and stent thrombosis.

**Councils on Cardiovascular Radiology, Cardiothoracic and Vascular Surgery, and Clinical Cardiology**

The AHA’s Councils on Cardiovascular Radiology, Cardiothoracic and Vascular Surgery, and Clinical Cardiology published *Training Standards for Physicians Performing Peripheral Angioplasty and other Percutaneous Peripheral Vascular Intervention*. In this document, the councils state that physicians requesting privileges in PTCA must demonstrate evidence of relevant training or experience as well as current competence. According to the councils, physicians should have experience with at least 50 percutaneous transluminal angioplasties.

**AOA**

The AOA publishes requirements for residencies in internal medicine, as well as subspecialty fellowships. According to the AOA, residencies in internal medicine must be 36 months long and cover a broad spectrum of medical issues and procedures.

Interventional cardiology fellowships are 12 months in duration after completion of a three-year general cardiology fellowship. Eleven of those 12 months must be spent in interventional cardiology laboratory. Fellows must gain knowledge of indications for urgent catheterization in patients with acute coronary syndromes, indications for proper technical placement of intra-aortic...
balloon counter pulsation devices, and the selection and use of vascular access
devices, guiding catheters, guide wires, and balloon catheters. Fellows must
perform a minimum of 400 interventional procedures and function as the
primary operator in no fewer than 250 cases.

**ACGME**

The ACGME offers requirements for fellowships in interventional cardiol-
ogy, a subspecialty of internal medicine. Interventional cardiology fellow-
ships consist of 12 months of continuous clinical training, after completion
of a three-year ACGME-accredited program in cardiovascular disease or at
least three years of cardiovascular education from a non-ACGME-accredited
program.

Fellows must demonstrate care of patients before and after interventional pro-
cedures. It is required that interventional cardiology fellows perform at least
250 coronary interventions, including:

➤ Application and usage of balloon angioplasty, stents, and other commonly
used interventional devices

➤ Femoral and brachial/radial cannulation of normal and abnormally located
coronary ostia

Fellows should also have experience with IVUS, Doppler flow, intracoronary
pressure measurement and monitoring, and coronary flow reserve. They should
also acquire medical knowledge in a wide range of coronary interventions,
including:

➤ Physiology of coronary flow and detection of flow-limiting conditions

➤ Radiation physics, biology, and safety related to the use of x-ray imaging
equipment

➤ Strengths and limitations of both noninvasive and invasive coronary evalua-
tion during the recovery phase after acute myocardial infarction

➤ Strengths and limitations, both short and long term, of differing percutaneous
approaches for a wide variety of anatomic situations related to cardiovascular
disease

➤ The role of emergency coronary bypass surgery in the management of
complications of percutaneous intervention

**Positions of subject matter experts**

_Ehrin Armstrong, MD_

_San Francisco_

Training and education standards for privileging physicians to perform PTCA are
highly regulated. Interventional cardiologists should be the only physicians per-
forming this procedure because they receive the appropriate training during their
interventional cardiology fellowship, says **Ehrin Armstrong, MD**, an interventional cardiology fellow in the Mentored Clinical Research Training Program at the University of California Davis in San Francisco.

“Only interventional cardiologists perform that procedure, so that’s something you need specific training for as an interventional cardiologist,” Armstrong says. “There is no other medical specialty that does that procedure.”

This specificity makes privileging interventional cardiologists easy, since professional organizations and medical boards specify specific areas of training needed to competently perform the procedure. According to the ACCF, practitioners need one year of interventional cardiology that includes 250 coronary angioplasty procedures.

“Doing 250 procedures doesn’t necessarily mean you can do any coronary angioplasty procedure,” Armstrong says. “To be very good at it you need to have done probably 400 or 500, but the minimum requirements are 250.”

PTCA is the general procedure that often involves the use of stents and balloon catheters, but some interventional cardiologists will receive additional training doing niche procedures with lasers or drills to open up blockage. Traditionally, that requires additional training by the manufacturer.

During the fellowship program for interventional cardiology, hands-on training for PTCA is very intense, Armstrong says. Since PTCA is much riskier than other cardiology procedures, even advanced fellows are closely observed by the program director.

“They tend to be standing right there and oftentimes assisting or telling you exactly what to do in order to make sure there isn’t a problem,” he says.

The ACCF also has specific requirements for maintaining competency: Interventional cardiologists need to perform at least 75 coronary angioplasties each year to maintain certification. But Armstrong says that’s not always an absolute requirement. In California, for example, the median number of procedures that interventional cardiologists perform each year is in the range of 60.

“So there are a lot of interventional cardiologists in California that don’t perform a high volume of procedures on a routine basis, but that doesn’t mean they lose their credentialing,” he says.

**George Stouffer, MD**  
**Chapel Hill, N.C.**

In this day and age, only interventional cardiologists should be privileged to perform PTCA, says **George Stouffer, MD**, distinguished professor at the
University of North Carolina and interventional cardiologist at the University of North Carolina Heart Center in Chapel Hill. This requires certified physicians to complete a full year of interventional cardiology training with a minimum of 250 interventional procedures.

Prior to the interventional cardiology fellowship, practitioners will have undergone a three-year cardiology fellowship, which provides a basic understanding of diagnostic catheterizations and some observation of interventional procedures. During the year of interventional training, the program transitions into much more hands-on clinical training specifically involving coronary angioplasties.

“ACGME has a very detailed description of what qualifies as a procedure,” Stouffer says. “The fellow has to be the primary operator and it has to be coronary intervention. In the fellowship the individuals may do many more procedures, but the 250 percutaneous coronary angioplasties are well defined in what they have to be.”

To maintain competency, interventional cardiologists should do a minimum of 75 procedures each year. When they are up for recertification through the ABIM every 10 years, they need to send a letter saying they did at least 150 procedures during the prior two years of practice, Stouffer says.

In addition to actually performing the procedure, physicians should also acquire training in pre- and post-procedure standards of care, as well as related procedures like peripheral angioplasty.

Interventional cardiologists are also measured in terms of quality of PTCA procedures. Most hospitals report all of their cases to the American College of Cardiology database, which is benchmarked against national quality criteria.

“We are very closely tracked on our outcomes, who undergoes procedures, and who does them,” Stouffer says. Failure to meet those standards could affect a physician’s PTCA privileges.

**Positions of accreditation bodies**

**CMS**

CMS has no formal position concerning the delineation of privileges for PTCA. However, the CMS *Conditions of Participation* (CoP) define a requirement for a criteria-based privileging process in §482.22(c)(6) stating, “The bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”
§482.12(a)(6) states, “The governing body must assure that the medical staff bylaws describe the privileging process. The process articulated in the bylaws, rules or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

➤ Individual character
➤ Individual competence
➤ Individual training
➤ Individual experience
➤ Individual judgment

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.”

Specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Privileges are not granted for tasks, procedures, or activities that are not conducted within the hospital, regardless of the practitioner’s ability to perform them.

Each practitioner must be individually evaluated for requested privileges. It cannot be assumed that every practitioner can perform every task, activity, or privilege specific to a specialty, nor can it be assumed that the practitioner should be automatically granted the full range of privileges. The individual practitioner’s ability to perform each task, activity, or privilege must be individually assessed.

CMS also requires that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

CMS’ CoPs include the need for a periodic appraisal of practitioners appointed to the medical staff/granted medical staff privileges (§482.22[a][1]). In the absence of a state law that establishes a time frame for the periodic appraisal, CMS recommends that an appraisal be conducted at least every 24 months. The purpose of the periodic appraisal is to determine whether clinical privileges or membership should be continued, discontinued, revised, or otherwise changed.

**The Joint Commission**

The Joint Commission has no formal position concerning the delineation of privileges for PTCA. However, in its Comprehensive Accreditation Manual for Hospitals, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).
In the introduction for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission introduces MS.06.01.05 by stating, “The organized medical staff is responsible for planning and implementing a privileging process.” It goes on to state that this process typically includes:

➤ Developing and approving a procedures list
➤ Processing the application
➤ Evaluating applicant-specific information
➤ Submitting recommendations to the governing body for applicant-specific delineated privileges
➤ Notifying the applicant, relevant personnel, and, as required by law, external entities of the privileging decision
➤ Monitoring the use of privileges and quality-of-care issues

MS.06.01.05 further states, “The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.”

The EPs for standard MS.06.01.05 include several requirements as follows:

➤ The need for all licensed independent practitioners who provide care, treatment, and services to have a current license, certification, or registration, as required by law and regulation
➤ Established criteria as recommended by the organized medical staff and approved by the governing body with specific evaluation of current licensure and/or certification, specific relevant training, evidence of physical ability, professional practice review data from the applicant’s current organization, peer and/or faculty recommendation, and a review of the practitioner’s performance within the hospital (for renewal of privileges)
➤ Consistent application of criteria
➤ A clearly defined (documented) procedure for processing clinical privilege requests that is approved by the organized medical staff
➤ Documentation and confirmation of the applicant’s statement that no health problems exist that would affect his or her ability to perform privileges requested
➤ A query of the NPDB for initial privileges, renewal of privileges, and when a new privilege is requested
➤ Written peer recommendations that address the practitioner’s current medical/clinical knowledge, technical and clinical skills, clinical judgment, interpersonal skills, communication skills, and professionalism
➤ A list of specific challenges or concerns that the organized medical staff must evaluate prior to recommending privileges (MS.06.01.05, EP 9)
A process to determine whether there is sufficient clinical performance information to make a decision related to privileges

- A decision (action) on the completed application for privileges that occurs within the time period specified in the organization’s medical staff bylaws
- Information regarding any changes to practitioners’ clinical privileges, updated as they occur

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission states that the information review and analysis process is clearly defined and that the decision process must be timely. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges. The criteria must be consistently applied and directly relate to the quality of care, treatment, and services. Ultimately, the governing body or delegated governing body has the final authority for granting, renewing, or denying clinical privileges. Privileges may not be granted for a period beyond two years.

Criteria that determine a practitioner’s ability to provide patient care, treatment, and services within the scope of the privilege(s) requested are consistently evaluated.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in which the type of information collected is determined by individual departments and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.

**HFAP**

The Healthcare Facilities Accreditation Program (HFAP) has no formal position concerning the delineation of privileges for PTCA. The bylaws must include the criteria for determining the privileges to be granted to the individual
practitioners and the procedure for applying the criteria to individuals requesting privileges (03.01.09). Privileges are granted based on the medical staff’s review of an individual practitioner’s qualifications and its recommendation regarding that individual practitioner to the governing body.

It is also required that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

Privileges must be granted within the capabilities of the facility. For example, if an organization is not capable of performing open-heart surgery, no physician should be granted that privilege.

In the explanation for standard 03.01.13 related to membership selection criteria, HFAP states, “Basic criteria listed in the bylaws, or the credentials manual, include the items listed in this standard. (Emphasis is placed on training and competence in the requested privileges.)”

The bylaws also define the mechanisms by which the clinical departments, if applicable, or the medical staff as a whole establishes criteria for specific privilege delineation.

Periodic appraisals of the suitability for membership and clinical privileges is required to determine whether the individual practitioner’s clinical privileges should be approved, continued, discontinued, revised, or otherwise changed (03.00.04). The appraisals are to be conducted at least every 24 months.

The medical staff is accountable to the governing body for the quality of medical care provided, and quality assessment and performance improvement (03.02.01) information must be used in the process of evaluating and acting on re-privileging and reappointment requests from members and other credentialed staff.

**DNV**

DNV has no formal position concerning the delineation of privileges for PTCA. MS.12 Standard Requirement (SR) #1 states, “The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.”

The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.
Regarding the Medical Staff Standards related to Clinical Privileges (MS.12), DNV requires specific provisions within the medical staff bylaws for:
➤ The consideration of automatic suspension of clinical privileges in the following circumstances: revocation/restriction of licensure; revocation, suspension, or probation of a DEA license; failure to maintain professional liability insurance as specified; and noncompliance with written medical record delinquency/deficiency requirements
➤ Immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner’s Medicare/Medicaid status
➤ Fair hearing and appeal

The Interpretive Guidelines also state that core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined.

DNV also requires a mechanism (outlined in the bylaws) to ensure that all individuals provide services only within the scope of privileges granted (MS.12, SR.4).

Clinical privileges (and appointments or reappointments) are for a period as defined by state law or, if permitted by state law, not to exceed three years (MS.12, SR.2).

Individual practitioner performance data must be measured, utilized, and evaluated as a part of the decision-making for appointment and reappointment. Although not specifically stated, this would apply to the individual practitioner’s respective delineation of privilege requests.

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding PTCA.

**Minimum threshold criteria for requesting privileges in PTCA**

- **Basic education:** MD or DO
- **Minimal formal training:** Successful completion of an ACGME- or AOA-accredited training program in interventional cardiology.
- **Required current experience:** Current demonstrated competence and evidence of the performance of at least 75 PTCA procedures in the past 12 months, or completion of training in the past 12 months.

**References**

If the applicant is recently trained, a letter of reference should come from the director of the applicant’s training program. Alternatively, a letter of reference
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may come from the applicable department chair and/or clinical service chief at the facility where the applicant most recently practiced.

Reappointment

Reappointment should be based on unbiased, objective results of care according to a hospital’s quality assurance mechanism.

Demonstrated current competence and evidence of the performance of at least 150 PTCA procedures in the past 24 months based on results of ongoing professional practice evaluation or outcomes should be required.

In addition, continuing education related to PTCA should be required.

For more information

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