# 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

American College of Cardiology Foundation Task Force on Expert Consensus Documents, Society of Thoracic Surgeons, Society for Vascular Medicine, Thomas M. Bashore, MD, FACC,, Stephen Balter, Ana Barac, John G. Byrne, Jeffrey J. Cavendish, Charles E. Chambers, James Bernard Hermiller, Jr, Scott Kinlay, Joel S. Landzberg, Warren K. Laskey, Charles R. McKay, Julie M. Miller, David J. Moliterno, John W.M. Moore, Sandra M. Oliver-McNeil, Jeffrey J. Popma, and Carl L. Tommaso

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**EXPERT CONSENSUS DOCUMENT**

# 2012 American College of Cardiology Foundation/ Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents

*Developed in Collaboration With the Society of Thoracic Surgeons and Society for Vascular Medicine*

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## Preamble

This document has been developed as an expert consensus document by the American College of Cardiology Foundation (ACCF) and the Society for Cardiovascular Angiography and Interventions (SCAI), in collaboration with the Society of Thoracic Surgeons (STS) and Society for Vascular Medicine (SVM). Expert consensus documents are intended to inform practitioners, payers, and other interested parties of the opinion of ACCF and document cosponsors concerning evolving areas of clinical practice and/or technologies that are widely available or new to the practice community. Topics chosen for coverage by this ECD are so designed because the evidence base, the experience with technology, and/or clinical practice are not considered sufficiently well developed to be evaluated by the formal ACCF/American Heart Association (AHA) Practice Guidelines process. Often the topic is the subject of considerable ongoing investigation. Thus, the reader should view the ECD as the best attempt of the ACCF and document cosponsors to inform and guide clinical practice in areas where rigorous evidence may not yet be available or evidence to date is not widely applied to clinical practice. When feasible, ECDs include indications or contraindications. Some topics covered by ECDs will be addressed subsequently by the ACCF/AHA Practice Guidelines Committee.

The ACCF Task Force on Clinical Expert Consensus Documents (TF CECD) makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as *relevant* to the writing effort. This information is documented in a table, reviewed by the parent task force before final writing committee selections are made, reviewed by the writing committee in conjunction with each conference call and/or meeting of the group, updated as changes occur throughout the document development process, and ultimately published as an appendix to the document. External peer reviewers of the document are asked to provide this information as well. The disclosure tables for writing committee members and peer reviewers are listed in Appendices 1 and 2, respectively, of this document. Additionally, in the spirit of complete transparency, writing committee members' *comprehensive disclosure information*—including relationships with industry and other entities that do not pertain to this document—is available online. Disclosure information for members of the ACCF TF CECD—as the oversight group for this document development process—is also available online.

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

## Executive Summary

The last expert consensus document on cardiac catheterization laboratory standards was published in 2001 (1). Since then, many changes have occurred as the setting has evolved from being primarily diagnostic based into a therapeutic environment. Technology has changed both the imaging and reporting systems. The lower risk of invasive procedures has seen the expansion of cardiac catheterization laboratories to sites without onsite cardiovascular surgery backup and even to community hospitals where primary percutaneous coronary intervention (PCI) is now being performed. This has increased the importance of quality assurance (QA) and quality improvement (QI) initiatives. At the same time, the laboratory has become a multipurpose suite with both diagnostic procedures to investigate pulmonary hypertension and coronary flow and with therapeutic procedures that now include intervention into the cerebral and peripheral vascular systems as well as in structural heart disease. These new procedures have impacted both the adult and pediatric catheterization laboratories. The approaches now available allow for the treatment of even very complex heart disease and have led to the development of hybrid cardiac catheterization laboratories where a team of physicians (including invasive cardiologists, cardiovascular surgeons, noninvasive cardiologists, and anesthesiologists) is required.

### The Cardiac Catheterization Laboratory Environments

Despite a growth in procedural sites and in procedural capabilities in the cardiac catheterization laboratory, the total number of coronary interventional procedures has steadily declined over the last few years.

#### Cardiac Catheterization at a Hospital With Cardiovascular Surgery

Full-service hospitals should provide, not only cardiovascular surgery, but also cardiovascular anesthesia and consulting services in vascular, nephrology, neurology, and hematology. Advanced imaging and mechanical support services should also be available. Not every hospital with onsite cardiovascular surgery should be offering all services unless the expertise is available to evaluate, treat, and handle any potential complications that occur. Patients requiring highly specialized procedures or pediatric procedures should have

studies only in facilities with the medical expertise and equipment to perform these procedures at the highest level.

### Cardiac Catheterization at a Facility Without Cardiovascular Surgery

Despite prior guidelines that suggest limitations to the expansion of cardiac catheterization without onsite surgical backup, the number of these sites has increased dramatically over the last decade. The Certificate of Need (CON) regulatory programs have had little impact on this expansion. Whether quality and outcomes are similar to hospitals with onsite cardiovascular surgery remains uncertain. The actual number of laboratories without surgical backup is difficult to confirm, but most estimates suggest it is around 25% to 35% of all laboratories in the United States. Because of fixed costs to maintain these facilities, costs and charges per patient at these sites may actually be higher than in facilities with onsite surgery.

The remarkably low risk now associated with *diagnostic cardiac catheterization* suggests that only a few cardiovascular patients cannot safely undergo procedures in these laboratories. The 2001 ACC/SCAI consensus document suggests limiting diagnostic procedures in laboratories without cardiovascular surgical backup to the very lowest-risk patients; the current document lifts almost all these restrictions. Limitations related to age, congestive heart failure (CHF) status, the severity in stress test abnormalities, left ventricular (LV) function, and the presence of valve disease have all been removed. It is still recommended that patients with pulmonary edema due to ischemia, patients with complex congenital heart disease, and pediatric patients still be treated only in full-service facilities.

Certain *therapeutic procedures* should still be done only in facilities with cardiovascular surgical backup. These include therapeutic procedures in adult congenital heart disease and pediatrics. It is generally believed that elective and primary PCI are permissible in sites without cardiovascular surgery, if there is strict adherence to national guidelines. In particular, there must be a documented working relationship with a larger facility with cardiovascular surgical services and an emergency transportation system operative. The document outlines the current guidelines where this is acceptable. The committee also believes that it is the responsibility of any facility performing coronary intervention without cardiovascular surgical backup to document that all national risk stratification and medication guidelines are being followed. In addition, a QA/QI system must be operative and active, and, if an ST-elevation myocardial infarction (STEMI) program is in place, the laboratory should be operational 24 hours a day, 7 days a week. Any national volume guidelines must also be strictly followed.

## Quality Assurance Issues in the Cardiac Catheterization Laboratory

The modern cardiac catheterization laboratory is a complex, highly sophisticated medical and radiological facility where patients with both chronic-stable and life-threatening illnesses are evaluated. With the expansion of laboratories and the increase in the complexity of procedures, it is essential to have an active QA/QI system in place regardless of the laboratory setting. The committee strongly encourages all laboratories to participate in national registries, such as the ACC's National Cardiovascular Data Registry (NCDR), to ensure data are systematically collected and available in a predefined format to allow for future analyses. In this manner, all laboratories can benchmark their performance and make appropriate corrections.

### Patient Outcomes

The rate of normal or insignificant coronary artery disease angiographically found at cardiac catheterization in any 1 laboratory obviously varies depending on the types of patients studied, but the range is high, varying anywhere from 20% to 39%.

Complications related to the catheterization procedure are very low and should be $<1\%$ for diagnostic procedures and $<2\%$ for elective PCI. The risk is obviously higher in the setting of an acute myocardial infarction (AMI), but even in that situation, the overall mortality should be $<4\%$. Complication rates $>5\%$ must be considered excessive and a cause for concern and programmatic review.

At least 60% of PCI procedures are done ad hoc following lesion discovery on a diagnostic angiogram. Although there is no evidence this practice has an adverse effect on outcomes, ad hoc procedures should be discouraged when the patient would benefit from a multidisciplinary discussion regarding options for therapy or when an interventional procedure at a later time would reduce the risk of contrast nephropathy. In the acute STEMI setting, when multivessel disease is evident, only the culprit lesion should undergo emergency intervention.

Data relating to outcomes in peripheral vascular and cerebrovascular intervention are incomplete. The technology continues to evolve as do the indications. Laboratories historically dedicated to coronary disease have had to transform themselves technically, logistically, and administratively to provide optimal care for this population. Large image detectors are often required and are not optimal for coronary angiography. This area is further complicated by the fact that noncardiologists (i.e., vascular surgeons and interventional radiologists) may also be participating, so guidelines, as well as credentialing issues, may vary among the groups. Because no clear benchmarks yet exist, participation in an ongoing national database for these procedures is particularly important.

### Peer Review Continuous QA/QI Programs

Most major QA problems are unrelated to equipment but are due to operational factors. These tend to include inadequate laboratory space, lack of a physician director or advocate, lack of specific operating rules, and a poor feedback mechanism. More than ever, a continuous QA/QI

program must be considered an essential component of the cardiac catheterization laboratory. It should be dedicated to the lab but not be independent of the other hospital programs. It must be adequately staffed and appropriately funded. The basic components must include a committee with a chair and staff coordinator, a database, and a means of data collection. There should be goals to eliminate outliers, reduce variation, and enhance performance. Feedback mechanisms should be clearly in place. The committee should also be committed to educational opportunities for the staff and incorporating practice standards and guidelines into the laboratory operation. Some composite "scorecard" methods should be included that address cognitive knowledge, procedural skill, clinical judgment, and procedural outcomes. These data need to be collected in a systematic manner and analyzed appropriately. Often a simple comparison of outcomes among physicians in the laboratory is effective in modifying behavior.

To help facilitate organization of a QA/QI process, the current document outlines the major organizational indicators, provides a representative case review form, and outlines the minimum components that should be included in a standard cardiac catheterization form.

Quality indicators should include structural, patient care, system-specific, guideline-driven, and cost-related items. Structural indicators include factors such as training, continuing medical education (CME), procedural volume, awards, presentations, publications, and credentialing. Patient care indicators include issues such as quality of procedures, report generation, timeliness, and appropriateness. System-specific indicators incorporate items such as lab turnover, preprocedural processes, emergency response time, and staff performance. Guideline-driven indicators should focus on infection control, radiation safety, medication and contrast use, procedural indications, and new device usage. Cost-related issues include such things as length of stay, disposables, types and adequacy of supplies, staffing, and use of off-label devices.

In addition to the above, there should be defined outcomes-related indicators collected. These include individual physician complications, service outcomes (e.g., access, door-to-intervention times, and satisfaction surveys), and financial outcomes.

To do this properly requires a serious commitment from the facility administration to ensure that a robust QA/QI program is in place and the program committee is active and aggressive regarding its responsibilities.

### Minimum Caseload Volumes

Using minimum case volumes as a surrogate for quality presumes that a high procedural volume equates to a high skill level and that low-volume operators are less skilled. In fact, there is limited statistical power to make judgments in the low-volume instance, and the relationship between procedural volume and outcome remains controversial. This applies to the laboratory facility as well as the physician operator. The particular issue of minimum case volumes is currently being addressed by a forthcoming update to the "ACCF/AHA/SCAI Clinical Competence Statement on Cardiac Interventional Procedures." This document simply outlines the currently available data; the final recommendation awaits the decisions of the competence statement writing committee.

Establishing an appropriate oversight QA/QI process is more important than focusing on minimum volumes. All major complications should be reviewed by the QA committee at least every 6 months, and any individual operator with complication rates above benchmarks for 2 consecutive 6-month intervals should have the issue directly addressed by the QA director and followed up with written consequences. Ideally, some subset of all operators should be randomly reviewed at least annually. All operators should be required to attend regularly cardiac catheterization conferences and obtain a minimum of 12 CME hours per year. Stimulation training may assist in improving skills.

The very low complication rate for diagnostic catheterization makes suggestions for a minimum volume threshold particularly difficult. The prior catheterization standards document suggested 150 cases per year as a minimum, but that committee acknowledged this was arbitrary and had no data to support the recommendation (1). This committee feels that there is no clear minimum volume for diagnostic catheterization that can be supported and prefers to emphasize the QA process to ensure the procedures are of the highest quality.

The annual minimum operator interventional procedural volume of 75 cases per year has become an accepted standard. Numerous publications and editorials have addressed this issue in detail. Although some relationships between operator and/or institutional volumes and outcomes have been described in certain reports, many publications have struggled to confirm these data. Obviously the relationship between volume and outcomes is complex, and many confounding issues are evident. Low-volume operators in high-volume laboratories tend to fare better. Complicating the issue further, however, is the fact that many competent interventional cardiologists do not perform >75 procedures each year. Some cardiologists perform PCI primarily when on-call, and some are at the beginning or the end of careers and are either ramping up or winding down a practice. Some perform procedures at multiple facilities, and the data for such individuals are often incomplete.

The data for primary PCI are particularly difficult to categorize because of the low volumes being performed. This committee believes that it is appropriate for all primary PCIs to be evaluated by the institutional QA committee, regardless of operator volume. Operators wishing to participate in primary PCI should be required to attend these review sessions.

The guidelines for the performance of both elective and primary PCI in a facility without cardiovascular surgical backup are also evolving. Recent prospective studies and meta-analyses of available data both suggest these procedures can be done safely under restrictions. The minimum

volume issue in this setting will be another focus of the ACCF/AHA/SCAI Writing Committee to Update the 2007 Clinical Competence Statement on Cardiac Interventional Procedures. Because these patients are at highest risk for complications, national guidelines for the proper PCI, particularly in the setting of an AMI, must be strictly followed. The facility must have a robust QA program, clear and documented systems for the urgent transfer of patients to a facility with cardiovascular surgical support, documentation that all medication and indication guidelines are being observed, and 24/7 availability.

### Training in Interventional Procedures

The use of minimum volumes and rotation duration for training in interventional cardiology procedures has been established by the ACCF Core Cardiology Training Symposium (COCATS). These are still the established requirements for Level 1, Level 2, and Level 3 training. These are summarized in this report, but the committee recognizes that even here, there is a gradual shift away from minimum numbers and toward a competence standard. The formal training to achieve credentials in peripheral vascular intervention is highlighted for cardiology fellows, and compared with that of interventional radiologists and vascular surgeons; little difference actually exists.

Training in structural heart disease intervention is clearly an area where volume numbers should not supplant evidence for competence by a QA review of outcomes. By definition, most of these procedures require a multidisciplinary approach and should not be attempted by casual operators. It is recommended that both the training and practice activity associated with structural heart disease intervention be concentrated among a limited number of laboratories and operators with a particular interest in these procedures. Often a close working relationship between adult and pediatric operators provides the optimal environment.

## Procedural Issues in the Cardiac Catheterization Laboratory

### Patient Preparation

A number of procedural issues are addressed. Heightened awareness of protective care from communicable diseases, such as human immunodeficiency virus (HIV) or hepatitis, is important. Each laboratory should have a written protocol for increased sterile technique for highly infectious cases. The protocol should include caps, masks, double gloving, and protective eyewear. Disposal methods and disinfectant techniques are also important.

Patient preparation should include a checklist of items to be reviewed when the patient first arrives at the laboratory. Appropriate consent should include risks, benefits, alternative therapies, and the potential need for ad hoc procedures. All PCI consent forms should outline the potential for emergency surgery. A "time-out" should be a required part of each procedure and should include the name, the procedure, the signed consent, allergies, antibiotic administration, the correct site, confirmation of the pre-wash, the need for any special equipment or imaging, and any pertinent clinical factors (including labs such as the creatinine level). If the radial artery is to be used, the Allen test results should be noted.

The committee reviewed the minimum laboratory data in preparation for cardiac catheterization and found a wide variability in practice patterns. The following recommendations were made: 1) routine laboratory data should include the hemoglobin, platelet count, electrolytes, and creatinine obtained within 2 to 4 weeks of the procedure. These should be repeated if there has been a clinical or medication change within that period or recent contrast exposure; 2) unless there is known liver disease, a hematologic condition of concern, or the ongoing use of warfarin, a protime is not deemed necessary prior to the procedure; 3) for overnight tests, a nothing by mouth (NPO) order is not always in the best interest of the patient; fasting should be no more than 2 hours after clear liquids or 6 hours after a light meal. Hydration should be considered an important component prior to contrast administration; and 4) women of childbearing age should have a urine or serum beta-HCG test within 2 weeks of the procedure. There is little fetal risk during the first 2 weeks of gestation. In addition, the committee could find no data to suggest a concern regarding nitinol device use in patients with nickel allergies.

For patients on warfarin, the drug is usually stopped 3 days prior to the procedure. An acceptable international normalized ratio (INR) of $\leq$1.8 for femoral or $<$2.2 for radial cases is suggested. Vitamin K reversal is discouraged. Patients on aspirin, unfractionated heparin, low-molecular-weight heparin, or glycoprotein IIb/IIIa inhibitors need not have the drugs stopped before catheterization. Dabigatran should be stopped 24 hours prior if the estimated glomerular filtration rate (eGFR) is $>$50 mL/min and 48 hours before if the eGFR is between 30 mL/min to 50 mL/min.

For patients with chronic kidney disease (CKD), there is a risk of contrast nephropathy following the procedure. The highest-risk patients are those with eGFR $<$60 mL/min and diabetes mellitus. It is recommended that patients with CKD have nephrotoxic drugs, such as nonsteroidal anti-inflammatory drugs (NSAIDs), held on the day of the procedure and that adequate hydration with either intravenous (IV) saline or sodium bicarbonate at 1.0 mL/kg/min to 1.5 mL/kg/min for 3 to 12 hours prior and 6 to 12 hours postprocedure should be completed as well. Contrast media should be minimized, and either low-osmolar or iso-osmolar contrast should be used. A contrast volume/creatinine clearance ratio of $>$3.7 has been suggested as a ceiling for contrast use to reduce nephrotoxicity risk. A follow-up creatinine level should be obtained in 48 hours. Acetylcysteine is no longer recommended.

Patients with a strong atopic history or prior contrast allergy should be considered for pre-medication with steroids and/or H1 and H2 blockers. Shellfish allergies are not

considered important for contrast reactions. Diabetic patients usually have the insulin dose reduced by half the night prior and then held the morning of the procedure. Diabetic patients should have procedures early in the schedule, if possible, to avoid hypoglycemia. Metformin should be held regardless of the creatinine clearance and not restarted until there is postprocedural documentation that the creatinine has returned to baseline. An awareness of the treatment of anaphylactoid reactions to contrast is important. Delayed hypersensitivity rashes should not be confused with reactions to new drugs initiated after the procedure.

### Procedural Issues

Radial artery use for access has increased over the last few years. Though the procedure may take slightly longer and radiation exposure is slightly higher, the radial access site has less vascular complications than the femoral approach. In addition, it allows for earlier ambulation and is particularly efficacious in the obese. Medications during the procedure and sterile techniques have not changed over the last decade.

### Technical and Hemodynamic Issues

Except for the equipment advances, the actual performance of coronary angiography has changed little over the last decade. Facilities with biplane capabilities are less common now. Biplane coronary angiography may reduce total contrast load in patient with CKD and is important in structural heart intervention. Hemodynamics are less stressed in most laboratories despite accurate hemodynamic measurements being critical in certain disease states (such as constrictive pericarditis). Intracoronary hemodynamics have most recently focused on the use of the pressure wire. The cardiac catheterization procedure can provide information regarding ventricular performance, cardiac output, vascular resistance, and shunt magnitude. The hemodynamics before and after pulmonary vasodilators are also critical to the decision algorithm on therapy for patients with pulmonary hypertension. Vasodilator or inotropic stress testing in patients with low-gradient, low-valve area aortic stenosis, likewise, provides vital information on the best therapeutic option in these patients. Transseptal catheterization has had resurgence with the success of such procedures as balloon mitral valvuloplasty and atrial fibrillation ablation. Entry into the left atrium (LA) provides percutaneous therapeutic options for pulmonary vein stenosis and, for some cases, with mitral regurgitation. Myocardial biopsies are useful in restrictive heart disease and in heart transplant patients. Within the hybrid laboratory environment, LV puncture allows for percutaneous aortic valve replacement via an apical approach. Intracardiac ultrasound and Doppler imaging methods have proven their value in a number of situations, including atrial septal visualization during percutaneous patent foramen ovale (PFO) or atrial septal defect (ASD) closure, left-sided electrophysiological ablation studies, mitral valvuloplasty, and LA appendage occluder deployment.

In addition, there are now therapeutic options to augment cardiac output using placement of an intra-aortic balloon pump or the use of catheters, either connected to a rotary pump or that have a rotary micropump within the catheter itself. The percutaneous application of extracorporeal membrane oxygenation (ECMO) can now be performed in the cardiac catheterization laboratory as well.

The known vagaries of contrast angiography in defining vascular lesion severity and composition has led to the development of a range of intravascular imaging devices, including intravascular ultrasound (IVUS) and other devices that provide plaque imaging with virtual histology and tissue ingrowth assessment using optical coherence technology. Although many are still investigational, they all carry some inherent risk of vessel injury that should be appreciated.

## Postprocedural Issues

### Vascular Hemostasis

In cases of femoral access where no vascular closure device is being used, if heparin has been used during the procedure, the activated clotting time (ACT) should return to near normal (<180 s) before sheaths are removed and manual compression applied. Common practice is to confine the patient to bed after sheath removal. Bed rest for 1 to 2 hours after either 4- or 5-F sheaths and 2 to 4 hours after 6- to 8-F sheaths is suggested. The radial approach obviates prolonged bed rest. All patients should have the access site auscultated prior to discharge. Should a pseudoaneurysm occur, most can be closed with compression and percutaneous thrombin.

A bleeding risk score for PCI has been developed from the NCDR database. It provides an opportunity to identify those at highest risk for a vascular complication.

The use of vascular occlusion devices has grown rapidly despite evidence their application does not reduce overall vascular complications. An AHA Scientific Statement regarding these devices recommends a femoral arteriogram with identification of sheath site and vascular features be done before their use. The use of any vascular device is considered a Class IIa (Level of Evidence: B) indication.

### Medication Use

Little has changed in the use of sedative and pain control medications after the procedure. Hypertension should be aggressively managed with agents such as labetalol, hydralazine, metoprolol, or nicardipine. Vagal reactions can be quite serious, and pre-medication with narcotics prior to sheath removal may help reduce their occurrence. Hypotension after cardiac catheterization is potentially multifactorial and includes diuresis, ischemia, retroperitoneal bleeding, as well as vagal reactions. If a retroperitoneal bleed is suspected, the most effective rapid response is to return to the laboratory for contralateral access and identification of the bleeding site.

## Personnel Issues

Little has changed over the last decade in regard to personnel issues. A cardiac catheterization procedure requires a critical mass of interdisciplinary personnel to allow safe and optimal performance of the procedure. Technical staff should be certified. The staff should be provided opportunities for ongoing continuing education.

Defined physician personnel in the cardiac catheterization include the attending or operating physician (the individual in charge), the teaching attending physician (often supervising cardiology fellows), and secondary operators.

A laboratory director is a prerequisite for all laboratories and should be an experienced (generally >5 years) interventionalist, board-certified, and familiar, if not proficient, with the various procedures and technical equipment being used in the laboratory. In small or new laboratories, a physician director may be just starting his practice. If the director does not have >500 PCI procedures performed, his or her cases should be randomly reviewed by the QA process until that minimum number is achieved and competence established. The laboratory director may or may not be the interventional fellowship director. However, he or she should work closely with the fellowship training program. The director is responsible for monitoring physician and staff behavior and ensuring their competence. The director should be the laboratory's advocate for adequate resources. He or she should collaborate with hospital personnel to ensure safety and compliance with all regulations and possess strong management skills as well.

Cardiovascular trainees may perform all aspects of the procedure as their skill level matures, but they cannot be primary operators and must function under the direct supervision of the attending physician. Physician extenders (nurse practitioners and physician assistants) are primarily used for the pre- and postprocedural evaluations and follow-up, but in monitored situations, they can directly assist the primary operator in the actual procedure.

The number and type of nursing personnel varies widely, but a supervising nurse's role is to manage nonphysician nursing and technical personnel to ensure patient care is optimal and that the staff is properly trained and respected. The committee notes there is currently no formal certification for this position (despite its complexity) and endorses a movement toward such a certification option on a national level.

With the movement away from cine film to digital storage and archival systems, it is important to have access to computer technical support. Because of the increased importance of patient and staff radiation safety, laboratories should have routine access to qualified medical and health physicists. Support is needed beyond meeting the minimum regulatory safety regulations.

All members of the cardiac catheterization team must have Basic Life Support certification in cardiopulmonary resuscitation (CPR) techniques, and the committee strongly urges certification in advanced cardiac life support as well.

## The Hybrid Cardiac Catheterization Laboratory

The hybrid cardiac catheterization laboratory/operating room is an integrated procedural suite that combines the tools and equipment available in a cardiac catheterization laboratory with anesthesia and surgical facilities and possesses the sterility of an operating room. It must meet all of the standard features of both an operating room and a cardiac catheterization facility. Procedures suited for a hybrid room include those that require surgical access (i.e., percutaneous valve replacement, thoracic or abdominal stented grafts, and large-bore percutaneous ventricular assist devices), those where conversion to an open surgical procedure may be required (i.e., bailout or apical approach to percutaneous aortic valve replacement, vascular plug deployment in paravalvular prosthetic valve regurgitation, and percutaneous ventricular septal defect closure), hybrid treatments (i.e., combined PCI or other vascular stenting with surgical approaches and epicardial atrial fibrillation ablation), electrophysiology (EP) device implantation or removal, and certain emergency procedures such as ECMO insertion or emergent thoracotomy.

The staff must be comfortable with both the surgical suite and the cardiac catheterization laboratory environment. This is generally done by using a specific team to allow for the necessary training. As the room is neither a standard operating room nor catheterization laboratory, physician training on its use is also a requirement.

The laboratory location can be either in proximity to the operating rooms or to the catheterization suite. It must be located on a clean core or semirestricted corridor where scrubs, hats, and masks are required. Scrub alcoves are a necessity along with a separate control room with wide windows. These rooms are larger than the standard cardiac catheterization laboratory room, though radiation shielding and video equipment are similar. A wide range of lighting is required (dim for viewing images and bright for surgical procedures). The mounting of the x-ray gantry is important so as not to interfere with laminar airflow or the anesthesiologist. The table also differs from the routine laboratory as surgeons need a fully motorized table and tabletop, yet it must be compatible with the production of high-quality x-ray images.

In short, the hybrid laboratory requires considerable planning and a firm understanding of how the room is to be used before its construction. Its dual function provides an opportunity to expand the procedures in the catheterization laboratory. Its stringent requirements demand a cooperative working relationship with a variety of disciplines to be a safe and successful endeavor.

## Ethical Concerns

A detailed discussion of ethical issues is beyond the scope of this document. The physician's primary obligation is always

to the patient and to no one else regardless of financial, regulatory, or social pressures otherwise. Physician responsibilities have increased dramatically with mandates from payers and the government for an ever-increasing amount of documentation. Much of this is time-consuming and creates unnecessary redundancy with little direct impact on the primary obligation. The changing healthcare reimbursement landscape has driven many physicians to align with larger health systems where there may be a further increase in the pressure for increased productivity in the face of declining reimbursement. With the decline in the fee-for-service system and the approaching shift toward reimbursement bundling, the physician must never leverage patient interests to produce a better profit margin.

A few of the major ethical concerns are addressed in this section. They include the inappropriateness of the sharing of fees, fee splitting, and fee fixing. Unnecessary procedures performed, especially those justified as malpractice protection, are improper and not in the patient's interest. Guidelines for appropriate use in many areas are now emerging to address this. Physician self-referral concerns led to the introduction of the Stark laws in 1989, and these regulations are designed to limit procedures being done to simply augment profit. Informed consent continues to get more and more complex, but a clear and understandable description of the procedure, the alternatives, the benefits, and the risks is simply a mainstay of good patient care. Teaching hospitals have a particular obligation to inform the patient of the skill level of all personnel involved. Cardiology has been the leader in developing evidence-based medicine, and clinical research involving patients requires strict adherence to safety guidelines and the protocol being employed. The opportunity for monetary rewards or self-promotion should never override patient safety and respect. Physicians and industry must work together to advance medical knowledge and avoid bias. Physicians should not accept industry gifts. Conflict of interest committees are designed to oversee any potential conflict and are in place to protect both the physician and the institution.

## X-Ray Imaging and Radiation Safety

Substantial changes in the x-ray equipment have occurred over the last decade. The movement from cine film to a digital medium has been completed, and the transition from the standard image intensifier to the flat-panel image detector is in progress. Flat-panel detectors enhance image uniformity and brightness and have a much greater dynamic range compared to the standard image intensifier. Radiologists routinely receive formal training in understanding how x-ray images are created, but this learning process is much more informal in cardiology. This section provides an overview of how x-ray images are made and discusses the role of each of the pieces of equipment. The major changes over the last decade include changes in the generator, x-ray tube, image detector, image processing, and image display. The dose-area product (DAP) is a measure of the total radiation exposure and is derived from an ionizing chamber on the output of the x-ray tube. It does not address the amount of radiation to specific organs. The use of the interventional reference point (IRP) is recommended to estimate the amount of skin dose the patient receives.

The biological risk from x-rays is due to disruption to the cellular DNA backbone either by direct or indirect (free-radical) injury. A deterministic injury results in enough individual cellular death to create organ dysfunction. These types of injury are dose-dependent (such as skin burns). A stochastic injury to the DNA results in mutations or cancers, and a single x-ray can be at fault. Although the likelihood of this happening increases with the dose, it is not dose dependent. The effective dose encompasses the stochastic risk and is used to provide a metric of radiation safety. It is the weighted sum of the estimates of dose to each individual organ. The breast, bone marrow, and lungs are among the most sensitive organs in this model. The effective dose correlates with the DAP.

The IRP dose at the isocenter of the gantry (usually the midportion of the patient) is derived by estimating the dose in the midportion of the patient and then dropping back 15 cm (assuming that is where the skin on the patient's back is located). It provides an estimate of the deterministic injury dose.

Recommended guidelines for patient and operator dose limits to reduce deterministic and stochastic injury are provided in the document and reflect current National Council on Radiation Protection and Measurements (NCRP) reports. The NCRP now accepts as a minimum the wearing of a single monitoring device on the thyroid collar; however, the recommended 2-monitor technique provides the best estimate of risk. A pregnant worker must also wear a monitor at waist level under the lead apron. Maximum allowable radiation for medical workers is 50 millisieverts (mSv) per year whole body and a lifetime cumulative dose of 10 mSv $\times$ age.

An understanding of x-ray image formation and basic radiation safety principles allows for the understanding of means to limit exposure to both the patient and operator. Exposure to the patient can be reduced by minimizing the framing rate, reducing imaging time, use of retrospectively stored fluoroscopy instead of acquisition, use of pulse fluoroscopy, and limiting use of "high-dose" fluoroscopy, avoiding magnification when possible, using collimation and other filters at the output of the x-ray tube, keeping the image detector close to the patient, and avoiding angulation that increases the source-to-image distance. For the operator, the same rules apply. Plus it is important to remember time, distance, and barriers. The impact of x-rays decreases in proportion to the inverse-square law ($1/d^2$). Lead shielding is effective if use properly.

All cardiac catheterization laboratories manufactured since 2005 are required to provide real-time exposure information, including reference point air kerma. Most fluoroscopes also

provide DAP readings. A summary of these data should be incorporated in the patient record and part of the QA/QI process.

## Special Concerns for the Pediatric Catheterization Laboratory

There are 120 specialized children's hospitals in the United States, and all have cardiac catheterization facilities. All facilities that perform cardiac catheterization on pediatric-aged patients must have the full complement of resources available, including cardiovascular surgery. Pediatric laboratories may be dedicated facilities or shared with an adult program.

### Differences in Goals Between the Pediatric Laboratory and the Adult Laboratory

Diagnostic catheterizations in children are essentially always focused on structural heart abnormalities. Hemodynamic measures plus chamber and vessel angiography are much more commonly done than in adult laboratories. Because of the variability in patient size, most data are indexed to body surface area. Often the procedure requires significant sedation or general anesthesia. Due to improvements in noninvasive imaging, three fourths of all pediatric catheterizations are therapeutic and not simply diagnostic. A substantial number of unique procedures are performed in congenital heart disease (such as atrial septostomy) and are not applicable to adults. Therapeutic procedures that might also be performed in certain adult congenital patients include PFO and ASD closure, valvuloplasty, angioplasty, stent implantation in pulmonary and arterial vessels, vascular closure (patent ductus arteriosus, fistulae, anomalous vessels), devise closure of a ventricular septal defect, transcatheter pulmonary or aortic valve replacement, foreign body retrieval, pericardiocentesis, endomyocardial biopsy, and a range of electrophysiological procedures. Hybrid procedures are becoming more important where novel access may be provided (i.e., palliation of the hypoplastic left heart patient with access provided directly through the anterior right ventricle).

### Who Should Perform Pediatric Catheterizations?

All pediatric catheterizations should have a director responsible for all aspects of the laboratory operation, similar to the adult laboratory. Attending physicians should be board-certified in pediatrics and at least board eligible in pediatric cardiology. There may be exceptional cases where a competent operator can be granted privileges, but this should not be common practice.

The pediatric age range is from 0 to 18 years. It is recommended that catheterizations in patients within this age range be done by a pediatric cardiologist. Adult congenital heart disease patients may have procedures performed by a pediatric cardiologist or with an adult and pediatric cardiologist together. The only exception is the adult cardiologist with a special interest and expertise in adult congenital heart disease.

### Quality Assurance Issues in the Pediatric Cardiac Catheterization Laboratory

Complication rates differ substantially from the adult laboratory and are much higher due to the serious nature for many of the disease processes and the critical hemodynamic state at the times encountered. In 1 registry, adverse events in the pediatric laboratory were found to be 16% overall, with 10% related to diagnostic catheterization and 19% related to interventional procedures. Death occurred in 0.9%. The latest addition of pediatric data to the ACC-NCDR via the IMPACT (Improving Pediatric and Adult Congenital Treatment) registry should provide ongoing monitoring of these procedures. By necessity, informed consent is usually provided by the patient's parents. Similar concerns regarding informed consent in the adult laboratory still apply.

### Inpatient Versus Outpatient Settings for Procedures

For most children, an overnight stay following the procedure is medically prudent. This is especially the case with young children where it is difficult for them to remain still after the procedure. Any blood loss may be significant in small children. Often families have traveled long distances, and local medical attention to a problem may not exist. Despite the small size, the sheaths used during pediatric catheterizations are similar to those in adults (5-F to 8-F). Each laboratory should establish a written policy on who might be expected to be discharged immediately following the procedure.

### Operator and Laboratory Volumes

Similar to the discussion regarding adult laboratories, the heterogeneity of the patient population and the low volume of procedures make specific minimum volumes problematic. The American Academy of Pediatrics Guidelines suggests the use of specific outcome benchmarks rather than minimum operator or laboratory volumes as a guide to competence. The committee consensus, however, suggests a minimum operator volume of 50 per year and a minimum laboratory volume of >100 per year seems reasonable.

Having a robust QA/QI program in pediatric laboratories is of great importance. There should essentially be no "normal" cardiac catheterization procedures. The same rules outlined for an adult QA/QI program apply to the pediatric laboratory otherwise.

### Procedural Differences Compared With the Adult Cardiac Catheterization Laboratory

The need for specific baseline laboratory data greatly differs in the pediatric catheterization laboratory. Many patients do not have noncardiac disease and are not on any medications. There is no standard laboratory data required before the procedure, and no standard pre-medication regiment. Se-

dation is almost always required to perform the procedure. Vascular access is also individualized depending on whether the patient is a neonate, young or older child, or is of adult size. Most procedures are performed via the femoral artery and vein. Transseptal procedures are common. Newborn procedures are performed generally via the umbilical vein. Venous access can also be accomplished via the internal jugular, subclavian, basilica, and transhepatic approaches. In very young children, balloon aortic valvuloplasty or stenting open the patent ducts may require a carotid artery cut-down. Heparin is variably used during the procedure, whereas vascular occluders are not used in children. As more invasive percutaneous methods are being developed, the potential for catastrophic events increases. There should be access to ECMO in addition to routine resuscitation equipment.

Biplane x-ray capabilities should be standard, though certain procedures can be done with single-plane systems satisfactorily.

### Hemodynamics and Angiography

Right and left heart hemodynamics and angiography are routine procedures and require high-resolution equipment to ensure the diagnosis. The framing rates depend on the patient's heart rate and 30 frames per second (fps) is often required to capture all the necessary information. Due to the high heart rates, contrast must be injected at a higher rate (i.e., over 1 to 2 s).

### Laboratory Personnel

There is essentially no difference in the types of personnel needed to run an efficient pediatric catheterization laboratory dedicated to the highest standards compared with an adult laboratory.

### Radiation Protection and Pregnant Patients

The same principles apply in this age group as with adults. Children are more susceptible than adults to the stochastic effects from ionizing radiation (they live longer and that increases the risk of a cancer developing). A urine or serum beta-HCG level should be obtained within 2 weeks of the procedure in menstruating women. If a pregnant patient must be studied, all of the previously described means to reduce radiation exposure should be followed, and the abdominal and groin area should be shielded from direct x-ray exposure. Scattered radiation still occurs, however.

### Summary

The cardiac catheterization laboratory has undergone major changes in the last decade. It is a much more sophisticated environment where a gradual shift in emphasis from a diagnostic laboratory to a therapeutic environment is occurring. As the risk of both diagnostic and interventional procedures has declined, there has been liberalization in the types of patients who may safely have procedures performed in both outpatient settings and in laboratories without cardiovascular surgical backup. The influence of peripheral vascular and structural heart intervention has also required a change in focus for many laboratories and has given rise to the hybrid cardiac catheterization facility. The advances in percutaneous therapies for structural heart disease are just now beginning to impact both the adult and pediatric catheterization laboratory.

Some of the routine practices in many laboratories are being questioned. For instance, the committee no longer suggests a protime be obtained before a procedure, unless an abnormality is anticipated. Overnight NPO orders should be replaced with shorter-term fasting as hydration is important. Acetylcysteine is no longer recommended to reduce contrast nephropathy.

QA is a focus of this report, and its importance is mounting as it becomes harder to justify minimum volume requirements for both the operator and the laboratory. The importance of national databases to provide benchmarks is emphasized.

Radiation safety has also entered into the discussion more prominently as patients and regulators have expressed concern regarding the amount of medical radiation the public receives. Measures of the amount of radiation exposure should be a routine part of the cardiac catheterization report.

The cardiac catheterization laboratory and its functions will continue to evolve and grow over the next decade as newer devices and treatment options emerge. The cardiac catheterization laboratory of today differs significantly from that of a decade ago. It is anticipated that the cardiac catheterization laboratory 10 years from now will undergo a similar evolution.

## 1. Introduction

The last expert consensus document on cardiac catheterization laboratory standards from the ACCF and SCAI was published in 2001 (1). Although the fundamentals of invasive cardiovascular procedures remain unchanged, many changes have occurred related to the catheterization laboratory and its operational environment. Modifications and evolution have occurred with the imaging equipment technology, the range of diagnostic modalities, the spectrum of pharmacological therapies and mechanical interventions, and the local delivery of cardiovascular health care. Community hospitals without surgical backup have begun performing diagnostic catheterizations on higher-risk patients as well as elective interventional procedures on lower-risk patients, and community programs have been developed that permit onsite primary angioplasty on patients with AMI. At the same time, the cardiac catheterization laboratory has become a multipurpose interventional suite undertaking many therapeutic procedures for the coronary, cerebral, and peripheral vessels, providing corrective intervention for congenital and structural heart disease, sometimes merging with surgical suites into hybrid procedure rooms for valvular and

complex nonvalvular interventions. This document is designed to update the latest information regarding the catheterization laboratory environment and its operation.

## 1.1. Document Development Process and Methodology

The development of consensus documents involves multiple healthcare professionals and often 2 or more medical societies. Given the importance of practice guidelines and expert consensus documents, governing principles have been established to ensure the accuracy, balance, and integrity of the content, as well as the composition of committees responsible for these documents. The ACCF has created a methodology manual for expert consensus document writing committees that can be accessed at www.cardiosource.org (2).

### 1.1.1. Writing Committee Organization

This writing committee was commissioned by the ACCF TF CECD in conjunction with SCAI. Coordination and staff support were provided by the ACCF. Nominations for writing group membership were made to the TF CECD with representatives and liaisons solicited from the TF CECD, SCAI, STS, and SVM. Care was taken to select acknowledged experts in cardiovascular catheterizations and interventions with members from both the academic and private practice sectors and representing a diverse geography. The committee consisted of 16 members: 12 from ACCF, 3 from SCAI, 1 from STS, 1 from SVM, and 1 invited radiation physicist content expert.

### 1.1.2. Relationships With Industry and Other Entities

As part of the nomination and application process, all writing committee candidates were required to provide an up-to-date disclosure of their relationships with industry and other entities (RWI). Both the ACCF and SCAI believe that including experts on writing committees who have relationships with industry strengthens the writing effort, though a stringent approach to keeping all relationships transparent and appropriately managed is necessary. As such, it was required that the majority (>50%) of writing committee members had no RWI relevant to the entire document. All relevant relationships occurring in the prior 12 months were required to be disclosed (Appendix 1), including the nature and extent of the relationship, as well as the establishment of new industry relationships at any time during the document writing process. Members with relevant RWI were not allowed to draft or vote on document sections where a conflict may have been perceived present.

The writing committee chair was selected by the TF CECD chair, and it was required that this individual have no relevant RWI. The writing committee chair along with support staff created and reviewed a tentative outline of sections for the consensus document. Companies, vendors, and other entities that had products or services related to the catheterization laboratory document were identified and categorized according to which sections of the document a relationship might exist. Writing committee members were then selected and assigned to specific sections. Each section had a primary author who could have no relevant RWI for that section or topic area. Each section also had 1 primary (internal) reviewer from the writing committee.

### 1.1.3. Consensus Development

The writing committee convened by conference call and e-mail 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. All participating organizations participated in peer review, resulting in reviewers representing 371 comments. A group of 10 experts, separate from the writing committee, was selected for official review: 3 were nominated by ACCF, 3 by SCAI, 2 by STS, and 2 by SVM. In addition, 21 content reviewers from 3 ACCF Councils provided comments. There were no restrictions regarding the reviewers' RWI, though all reviewers were required to provide full disclosure regarding relevant relationships. This information was made available to the writing committee and is included in Appendix 2.

Comments were reviewed and addressed by the writing committee. A member of the ACCF TF CECD served as lead reviewer to ensure that all comments were addressed adequately. Both the writing committee and TF CECD approved the final document to be sent for board review. The ACCF Board of Trustees and SCAI Board of Directors reviewed the document, including all peer review comments and writing committee responses, and approved the document in February 2012.

The STS and SVM endorsed the document in February 2012. This document is considered current until the TF CECD revises or withdraws it from publication.

### 1.1.4. Document Methodology

The writing committee for this expert consensus document on cardiac catheterization laboratory standards began by reviewing the 2001 "ACC/SCAI Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards" (1). At the same time, the group conducted a brief review of the literature and clinical practice evolution relative to the catheterization laboratory environment. With this insight, it was agreed that there was enough important information to warrant a new consensus document. A formal review of the literature was performed and clinical data were reviewed considering a range of cardiovascular topics including, but not limited to, the following: hospitals and clinical environments with and without surgical back-up for complex diagnostic and interventional procedures; QA, proficiencies, and patient safety; procedural and postprocedural management issues including unique patient groups; new pharmacological and mechanical therapies; laboratory designs, imaging equipment, and technologies.

### 1.2. Purpose of This Document

The workplace and function of the cardiac catheterization laboratory has steadily evolved over the last 70 years. Although numerous historic events have occurred during this time, and the developmental phases of the catheterization laboratory are not strictly delineated, 4 broadly defined intervals can be considered. In the earliest phase, roughly from 1940 to 1960, procedures were primarily focused on hemodynamic assessments and structural heart disease. With the development of radiographic techniques and subsequently surgical revascularization, anatomy-focused diagnostic studies became the mainstay of laboratory activity in the interval from 1960 to 1980. The advent of PCI and multiple percutaneous revascularization devices were the hallmarks requiring changes in the catheterization laboratory in the era from 1980 to 2000. Most recently, interventions on peripheral and cerebrovascular disease, structural cardiac abnormalities, and percutaneous valve therapies are influencing the needs and resources of the catheterization laboratory.

## 2. The Cardiac Catheterization Laboratory Environments

### 2.1. The Current Landscape

Over the 10 years since the publication of the "ACC/SCAI Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards" (1), much has changed in the cardiac catheterization laboratory. The importance of invasive hemodynamic assessment has been supplanted by major improvements in noninvasive imaging technologies. With this change, there has been an unfortunate loss in the capability of many laboratories to provide complex hemodynamic information, even when it might be of value clinically. The focus has now shifted primarily to coronary anatomy assessment, where sophisticated tools now allow for low-risk coronary interventions that were completely unavailable just a decade ago. Improved techniques have also reduced the overall risk for cardiac catheterization and transformed diagnostic catheterization into an outpatient procedure. Similar advances in interventional methods have nearly eliminated the need for immediate surgical standby for low-risk procedures, and a substantial amount of interventional procedures are now being performed in settings without an in-house coronary surgical team even available—something the prior consensus document condemned.

Of the 5,099 hospitals in the United States, the 2007 National Healthcare Cost and Utilization Project statistics note that a remarkable number of hospitals, a total of 4,345 (85.2% of all), now provide cardiac catheterization services, and 1,061 (20.8%) provide cardiac surgical services (3). As reported in the 2009 Update on Heart Disease and Stroke statistics from the AHA (4), the total number of inpatient cardiac catheterizations, however, actually declined slightly from 1996 to 2006, despite the incidence of inpatient PCI rates increasing from 264 to 267 per 100,000 population. During the same period, the incidence of coronary artery bypass grafting (CABG) declined from 121 to 94 per 100,000 patients (5). It is clearly a very dynamic time in the cardiac catheterization laboratory.

### 2.2. General Complications From Cardiac Catheterization Procedures

With the increase in the widespread use of cardiac catheterization, there has been a general decline in the risk of the procedure. Complication rates from diagnostic catheterization are quite low. As suggested by the "ACCF/AHA/SCAI Clinical Competence Statement on Cardiac Interventional Procedures" in 2007 (6), complications can generally be divided into 3 major categories: coronary vascular injury, other vascular events, and systemic nonvascular events. Major adverse cardiac and cerebrovascular events (MACCE) include death, stroke, myocardial infarction (MI), and ischemia requiring emergency CABG. MACCE for diagnostic procedures occurs in <0.1% of diagnostic procedures (6). Additional complications include vascular access site complications, contrast nephropathy, excessive bleeding, and other miscellaneous complications such as arrhythmias, hypotension, coronary perforation, and cardiac tamponade. The specific definitions of cardiac catheterization complications have been standardized to a great extent and outlined by the ACC-NCDR (7).

In a single-center review of diagnostic cardiac catheterization for 7,412 patients over a 10-year period (8), only 23 (0.3%) had major complications, and there were no deaths related to the diagnostic procedure. Complications were least common after procedures done by more experienced physicians, when smaller catheter sizes were used and when only left heart (and not left and right heart) procedures were performed. Obese patients had more vascular complications. Data from the ACC-NCDR database regarding PCI for both elective procedures and for acute coronary syndromes (ACS) are shown in Table 1 (9). These data reveal a trend toward fewer complications from PCI and a low risk-adjusted in-hospital mortality of 2.0% for ACS patients who had undergone PCI and 0.5% for elective PCI patients.

In 2009, the Mayo Clinic published 25-year trend data regarding their experience with 24,410 PCI procedures (10) (Fig. 1). The authors analyzed the first 10 years (1979 to 1989), the period from 1990 to 1996, the period from 1996 to 2003, and then finally the period from 2003 to 2004. They found that despite an older and sicker population with more comorbid conditions, the success rate from PCI had improved from initially 78% to 94%, hospital mortality had fallen from 3.0% to 1.8%, and the need for emergency CABG had dropped from 5% to 0.4%. In their latest assessment, major adverse complications following PCI occurred in only 4.0% of in-hospital patients.

**Table 1. Complication Rates for PCI Reported From the ACC-NCDR Database**

| | Percutaneous Coronary Intervention | | | |
|---|---|---|---|---|
| | ACS | | Non-ACS | |
| Variable | Q1 to Q2 (2005) (n=92,534) | Q1 to Q2 (2009) (n=144,989) | Q1 to Q2 (2005) (n=50,532) | Q1 to Q2 (2009) (n=79,892) |
| Lesion information, % | | | | |
| Previously treated | 7.5 | 7.3 | 8.2 | 7.5 |
| Bypass graft lesion | 7.7 | 6.4 | 6.9 | 5.9 |
| High-risk (Type C) lesion | 43.3 | 46.9 | 33.7 | 38.7 |
| Lesion length >25 mm | 20.4 | 21.3 | 17.9 | 18.5 |
| Bifurcation lesion | 11.4 | 12.3 | 11.2 | 12.1 |
| Procedural information, % | | | | |
| Radial access | 1.2 | 2.0 | 1.6 | 2.3 |
| Multivessel PCI | 13.9 | 12.9 | 15.5 | 15.3 |
| Stents used during PCI | | | | |
| DES | 83.6 | 65.5 | 85.7 | 73.0 |
| BMS | 9.6 | 27.3 | 7.6 | 20.4 |
| Angioplasty only | 6.8 | 7.2 | 6.7 | 6.6 |
| Procedural complications and results, % | | | | |
| Dissection | 2.4 | 2.1 | 2.2 | 2.0 |
| Acute closure | 0.7 | 0.7 | 0.5 | 0.5 |
| Perforation | 0.3 | 0.3 | 0.3 | 0.3 |
| Procedural success | 93.0 | 94.3 | 94.0 | 94.8 |
| Vascular complications, % | | | | |
| Access site occlusion | 0.07 | 0.03 | 0.03 | 0.02 |
| Peripheral embolization | 0.08 | 0.04 | 0.02 | 0.02 |
| Access vessel dissection | 0.20 | 0.17 | 0.24 | 0.19 |
| Pseudoaneurysm | 0.42 | 0.46 | 0.38 | 0.84 |
| Arteriovenous fistula | 0.07 | 0.05 | 0.27 | 0.27 |
| Bleeding complications, % | | | | |
| Access site bleeding | 1.20 | 0.78 | 0.67 | 0.49 |
| Retroperitoneal bleeding | 0.33 | 0.42 | 0.25 | 0.17 |
| Gastrointestinal bleeding | 0.54 | 0.67 | 0.27 | 0.15 |
| Genitourinary bleeding | 0.20 | 0.13 | 0.07 | 0.05 |
| Other bleeding | 0.60 | 0.97 | 0.27 | 0.27 |
| In-hospital outcomes, % | | | | |
| Transfusion after PCI | 5.1 | 4.7 | 2.6 | 2.3 |
| Stroke | 0.3 | 0.3 | 0.1 | 0.1 |
| Emergency bypass | 0.4 | 0.4 | 0.2 | 0.2 |

Note: all outcomes are self-reported with only a small portion validated. Modified with permission from Roe et al. (9). Source of new data: ACC-NCDR Cath PCI Registry.

ACS = acute coronary syndrome (includes unstable angina); BMS = bare-metal stent; DES = drug-eluting stent; Non-ACS = those without any acute ischemic criteria; PCI = percutaneous coronary intervention.

## 2.3. The Cardiac Catheterization Laboratory at a Hospital With Cardiovascular Surgical Capability

Table 2 outlines the optimal onsite support services that allow for cardiac catheterization to be performed safely in any patient with heart disease. A hospital with all of these services is considered a "full-service" facility. Although cardiac surgical capability is the defining service, the other important support services listed are critical for optimal patient care and management. The catheterization laboratory in this setting is fully equipped for the most complex studies. Although direct surgical intervention is infrequently needed during percutaneous interventional procedures, the associated depth of expertise within the facility (technology, equipment, personnel, and specialized physicians such as anesthesiologists, perfusionists, and surgeons) have experience with the most complex cases and greater experience with emergent and critically ill patients. Often associated higher volumes translate into improved patient care and outcomes for high-risk patients. Therefore, although surgical service may not be directly required, the associated local expertise is available should the need arise. Essentially all laboratories that have full support services are located in a hospital setting. There may be special situations where a mobile laboratory is temporarily attached to or in an adjacent facility beside the hospital. In this latter setting, the situation should be considered similar to the inpatient laboratory with full support services in the hospital.

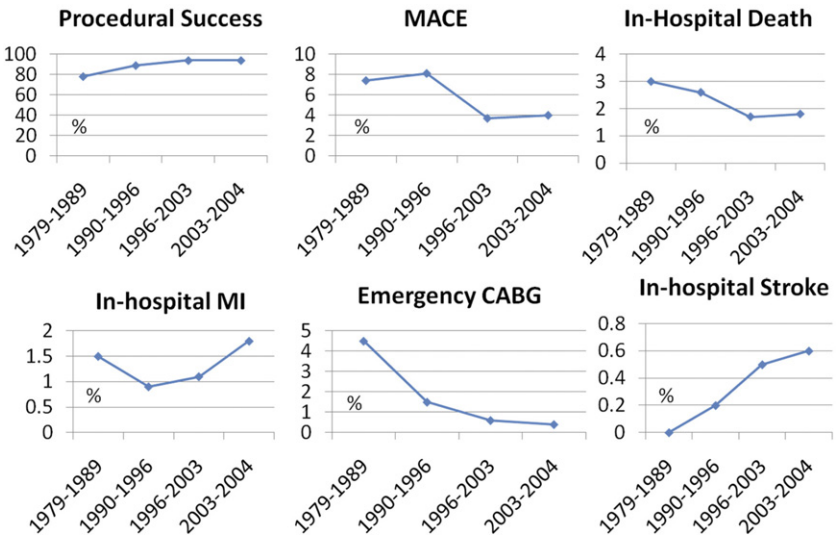


**Figure 1. Trends in In-Hospital Outcomes Following PCI: The Mayo Clinic Experience**

Modified with permission from Singh et al. (61). In-hospital MI = Q-wave MI; MACE = major adverse cardiovascular events.

### 2.3.1. Patients Eligible for Invasive Cardiovascular Procedures at a Hospital With Full Support Services (Including Cardiovascular Surgery)

In this environment, all patients and all procedures can, in general, be safely undertaken, provided the operators are sufficiently experienced and competent in the procedures being performed. Even though a hospital may have the appropriate support services as outlined above, some patients should still be referred to an even more highly specialized center if the technical expertise and experience required (e.g., transseptal puncture, valvuloplasty, assessment of complex congenital disease, and percutaneous ASD occlusion) are not available. To this end, there is a growing number of centers focused on structural heart disease. This is particularly true for the pediatric patient population. The laboratory setting appropriate for the pediatric population is outlined in Section 10.7 of this document.

**Table 2. Optimal (Recommended) Onsite Support Services for Invasive Cardiac Procedures**

| |
|---|
| Cardiovascular surgery |
| Cardiovascular anesthesia |
| Intensive care unit |
| Vascular services |
| Nephrology consultative services and dialysis |
| Neurology consultative services |
| Hematologic consultative and blood bank services |
| Advanced imaging services (echocardiography/Doppler, MRI, CT) |
| Mechanical circulatory support services |
| Endovascular surgery/interventions |
| If a pediatric catheterization laboratory, similar services for pediatric-aged patients |

CT = computed tomography; MRI = magnetic resonance imaging.

## 2.4. The Cardiac Catheterization Laboratory at a Hospital Without Cardiovascular Surgical Capability

With the increase in the number of cardiovascular laboratories over the last couple decades, the performance of both diagnostic and interventional coronary procedures is now becoming more commonplace in settings without cardiovascular surgery, despite guideline recommendations limiting PCI in these settings. Perhaps surprisingly to many, evidence exists that having a strict CON regulatory program is only modestly associated with lower rates of cardiac catheterization. In fact, in 1 review, only minimally reduced rates of equivocally or weakly indicated procedures for AMI were found in CON states, whereas the presence of a CON requirement had no effect on strongly indicated procedure rates (11).

The actual number of laboratories without onsite surgical backup providing either elective or primary PCI is difficult to confirm. Data from the ACC-NCDR database suggests that about one third of the laboratories performing cardiac catheterization do not have cardiovascular surgery backup, with at least elective PCI being performed without surgical backup in around one fourth (ACC-NCDR database information).

These data are similar to other databases. For instance, from July 2000 through December 2006, according to the National Registry of Myocardial Infarction (NRMI), 35.1% of participating hospitals providing primary PCI reportedly did not have onsite surgery. Of note, only a little more than half (53.6%) were in rural settings (12), suggesting the possibility of multiple primary PCI sites in an urban environment.

There are limited data on comparative costs, but 1 report suggests that the costs and charges of elective PCI at a hospital without cardiovascular surgery might be considerably more than those at a full-service hospital ($3,024 more in costs and $6,084 more in charges) (13). Based on the available information, therefore, anywhere from about one fourth to one third of

the currently operating cardiac catheterization laboratories do not have onsite cardiovascular surgery. This is quite a large number considering that most national organizational guidelines have discouraged the practice over the last decade.

Some insight into which patient groups might benefit from undergoing PCI can be gained by considering risk factors for periprocedural death. The latest data from the New York State Cardiac Advisory Committee (2005 to 2007) is of interest and summarized in Table 3. It seems appropriate to be cognizant of the patients at greatest risk for developing an adverse outcome when considering whether PCI can be safely done in low-volume settings or in those institutions without cardiovascular surgical programs.

**Table 3. Multivariate Risk Factors for Deaths Within 30 Days Following PCI, 2005–2007**

| Risk Factor | Prevalence | Odds Ratio |
|---|---|---|
| Non-emergent PCI risk factors | | |
| Demographic | | |
| Body surface area squared | | 3.0 |
| Ventricular function | | |
| LVEF 40% to 49% | 13.3% | 1.9 |
| LVEF 30% to 39% | 6.1% | 2.8 |
| LVEF 20% to 29% | 3.2% | 2.1 |
| LVEF <20% | 0.8% | 3.9 |
| Preprocedural MI | | |
| MI; 1 to 7 days prior | 12.9% | 3.4 |
| MI; 8 to 14 days prior | 1.3% | 3.4 |
| Comorbidities | | |
| Cerebrovascular disease | 8.0% | 2.0 |
| CHF, current | 5.4% | 2.6 |
| COPD | 6.4% | 2.6 |
| Malignant ventricular arrhythmias | 0.4% | 4.1 |
| Peripheral vascular disease | 7.3% | 1.8 |
| Renal failure, creatinine 1.6 to 2.5 (mg/dL) | 5.9% | 1.9 |
| Renal failure, creatinine >2.5 (mg/dL) | 1.4% | 2.4 |
| Renal failure, dialysis | 2.1% | 4.2 |
| Vessels diseased | | |
| Three-vessel disease | 13.7% | 1.8 |
| Left main disease | 3.9% | 1.9 |
| Emergency PCI risk factors | | |
| Demographic | | |
| Female gender | 27.1% | 1.8 |
| Hemodynamic state | | |
| Unstable | 4.1% | 4.4 |
| Ventricular function | | |
| LVEF 20% to 29% | 6.2% | 2.2 |
| LVEF <20% | 1.2% | 3.7 |
| Comorbidities | | |
| CHF, current | 5.1% | 2.3 |
| Malignant ventricular arrhythmias | 1.6% | 3.3 |
| Renal failure, creatinine 1.1 to 1.5 (mg/dL) | 38.2% | 1.7 |
| Renal failure, creatinine 1.6 to 2.0 (mg/dL) | 4.7% | 3.2 |
| Renal failure, creatinine >2.0 (mg/dL) | 1.8% | 6.0 |
| Renal failure, requiring dialysis | 0.7% | 7.0 |
| Severity of CAD (1-, 2-, or 3-vessel disease): no severity with odds ratio >1.5 | | |

Only those with odds ratio of >1.5 listed. Modified with permission from King et al. (58).

CAD = coronary artery disease; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention.

### 2.4.1. Patients Acceptable for Diagnostic Cardiac Catheterization at a Facility Without Cardiovascular Surgical Capability

Diagnostic cardiac catheterization is increasingly being performed in facilities without onsite surgical backup. These facilities include hospital settings (often rural), freestanding laboratories, and mobile cardiac catheterization units (either parked at a hospital or occasionally at a cardiovascular clinic). With diagnostic cardiac catheterization now principally an outpatient procedure, these types of laboratories have become more accepted and widespread. To ensure these sites are properly monitored, and that contingencies are in place for urgent transfer if a complication occurs that may require surgical intervention, SCAI has proposed a list of requirements for offsite surgical backup of PCI procedures (14). Before performing elective procedures, the cardiothoracic surgeon must be available and the receiving hospital must be capable of accepting patients before the procedure is initiated. These requirements are outlined in Table 4 and have been modified by this committee. Although primarily designed for programmatic backup of interventional procedures, similar requirements should be in place even for diagnostic procedures in a setting without onsite cardiovascular surgery. The focus of these requirements is to ensure that a written and monitored program is in place before any invasive cardiovascular procedures are considered acceptable in a facility without onsite cardiovascular surgery.

Given the low risk of complications outlined above and the favorable reports regarding both safety and the quality, the committee feels that the prior relatively stringent restrictions regarding eligibility for undergoing diagnostic cardiac catheterization suggested in the 2001 cardiac catheterization standards document may now be relaxed. The highest-risk patients are still better served clinically in a laboratory with onsite cardiovascular surgical backup. For the most part, however, the vast majority of stable patients can safely undergo diagnostic cardiac catheterization in this setting. Table 5 outlines the current recommendations regarding the specific types of patients who should be excluded from laboratories without cardiovascular surgical backup and contrasts them with the previous document (1). The committee feels these newer recommendations better reflect the reality of the clinical care currently being provided in the cardiology community. The data to support this change are based on available literature for identifying the high-risk patient and a general consensus of the committee.

### 2.4.2. Patients Acceptable for Elective Coronary Intervention in a Facility Without Cardiovascular Surgical Capability

There are now multiple reports that the performance of elective PCI in hospitals without onsite cardiovascular surgery has acceptable outcomes and risk, if proper patient

**Table 4. Minimum Requirements for the Performance of Invasive Cardiovascular Procedures in a Setting Without Onsite Cardiovascular Surgical Services**

1. A working relationship between the interventional cardiologists and cardiothoracic surgeons at the receiving hospital must be established.
2. The cardiothoracic surgeon must have privileges at the referring facility to allow review of treatment options.
3. Surgical backup must be available for urgent cases at all hours and for elective cases at mutually agreed times.
4. Ideally, face-to-face meetings between cardiothoracic surgeons and cardiologists involved should occur on a regular basis.
5. Before performing elective procedures, the cardiothoracic surgeon must be available and the receiving hospital must be capable of accepting the patient before the diagnostic or PCI procedure is started.
6. The interventional cardiologist must review with the surgeon the immediate needs and status of the patient should an urgent transfer be required.
7. The interventionalist should be familiar with and have available appropriate life support devices, such as an intra-aortic balloon pump.
8. The interventionalist should be qualified to deal with emergencies such as pericardial tamponade (pericardiocentesis) and embolization, should either event occur.
9. Hospital administrations from both facilities must endorse a transfer agreement.
10. Both the referring and the receiving hospital must have a rigorous and detailed protocol for rapid transfer of patients, including a listing of the proper personnel.
11. A transport provider must be available to begin transfer within 20 minutes of a request and must have appropriate life-sustaining equipment.
12. The transferring physician should obtain surgical consent prior to transfer.
13. The initial diagnostic and PCI consent should inform the patient that the procedure is being done without onsite surgical backup.

Modified with permission from Dehmer et al. (14).
PCI = percutaneous coronary intervention.

selection, procedural precautions, and backup preparations are in place. Data from the ACC-NCDR reveal an increase in the number of such facilities from 8.7% to 16% during the period from 2004 to 2005 (15), despite national guidelines to the contrary. As suggested by the NRMI database, the number may be as high as 25% to 35% in 2010.

**Table 5. General Exclusion Criteria for Invasive Cardiac Procedures in a Setting Without Cardiothoracic Surgery**

| Exclusions: Catheterization Laboratory Without Cardiothoracic Surgical Backup | |
|---|---|
| **2001 Document** | **Current Document** |
| Diagnostic procedures | |
| Age >75 years | No age limitation |
| NYHA functional class 3 or 4 | No limitation |
| Pulmonary edema due to ischemia | Pulmonary edema due to ischemia |
| Markedly abnormal stress test with high likelihood of LM or 3-vessel disease | No stress test result limitation |
| Known LM coronary disease | No coronary anatomic restriction |
| Severe valvular dysfunction with reduced LV function | No valvular or LV function limit unless severe (Class 4) symptoms |
| Patients at risk for vascular complications | Permissible only if vascular services are available |
| Complex congenital heart disease | Complex congenital heart disease |
| Acute or intermediate coronary syndromes | ACS except where PCI procedures are approved |
| All pediatric procedures | All pediatric procedures |
| Therapeutic procedures | |
| Diagnostic or therapeutic pericardiocentesis | Pericardiocentesis allowed if operator competent |
| All therapeutic procedures in adult congenital | All therapeutic procedures in adult congenital |
| All pediatric therapeutic procedures | All pediatric therapeutic procedures |
| Elective PCI | Elective PCI permissible under specified guidelines (55) |
| Primary PCI (not available at time) | Primary PCI permissible under specified guidelines (55) |

The current recommendations are compared to the prior consensus document (1).
ACS = acute coronary syndrome; LM = left main; LV = left ventricular; NYHA = New York Heart Association; PCI = percutaneous coronary intervention.

This issue remains controversial. This may especially be the case when other active PCI programs are located within the same geographic area. It behooves the cardiology community to foster these programs only when such programs improve access to a higher level of cardiovascular care than would otherwise be available. This has become a particular hot button issue since the publication of certain politically provocative articles such as COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) (16), which suggests PCI did not improve the rates of death or MI in patients with stable angina, or SYNTAX (Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) (17), which asserts that PCI with drug-eluting stents is inferior to CABG for left main and multivessel disease. There is a declining volume of PCI despite the improvement in outcomes from stent technology and consistent with a better appreciation of which procedures provide optimal benefit to patients. These types of studies suggest maturation of the technology so that further expansion may be limited despite concerns regarding a need for more procedures in an aging population. To this end, some have called for a moratorium on allowing any further expansion of PCI services, especially to low-volume facilities without cardiovascular surgical backup (18).

If the financial and marketing incentives are ignored, however, when patients are appropriately selected, most published studies regarding the risks of elective PCI at facilities without onsite cardiovascular surgical backup have shown the procedure to be relatively safe. The Swedish Coronary Angiography and Angioplasty Registry (19) of 34,383 patients found no difference in outcomes of elective PCI between hospitals with or without surgical backup. Similarly community sites in the United States (10,13,20–22), Germany (23), Japan (24), the Netherlands (25), the United Kingdom (26), and Australia (27) all confirm there is little or no difference in the outcomes among patients undergoing elective PCI in hospitals with or without onsite surgery. A similar finding was suggested by an analysis of 4 controlled trials (28–31) involving 6,817 patients (32). A meta-analysis of nonprimary PCI (elective and urgent; n=914,288) also found no difference in outcomes in PCI performed at sites with onsite cardiovascular surgery compared with those without (33).

The issue is further complicated due to the fact the published literature to date is limited by its methodology (registries, cohort studies, self-reported, and unmonitored data) and lack of long-term follow up. In addition, the exceeding low event rate in the elective setting makes it difficult to demonstrate differences in smaller studies (type II error). Finally, there is simply a lack of large, randomized studies with independent monitoring of events in this arena.

In 2007, SCAI addressed the issue and concluded that although they were unable to support the widespread use of PCI without onsite surgery, they acknowledged that many of these programs are now in existence and suggests that criteria be met in order to ensure patient safety. They proposed that certain patient characteristics and lesion characteristics should be considered "high risk," and these features should be taken into account before deciding whether a patient is a candidate for PCI in this setting. It is the consensus of this committee that high-risk patients or those with high-risk lesions should not undergo elective PCI in a facility without onsite surgery (Table 6).

In the 2007 "ACCF/AHA/SCAI Update of the Clinical Competence Statement on Cardiac Interventional Procedures" (6), similar patient and lesion characteristics were found to be associated with higher short-term mortality after PCI and would thus be considered high risk. That statement also included the following groups as high risk: the advanced in age, females, and those with ACS, a peripheral vascular disease, or impaired renal function (especially in diabetic patients with regard to contrast nephropathy). High-risk target-lesion anatomic features included the modified 1990 classification scheme proposed by the ACC/AHA Clinical Task Force on Clinical Privileges in Cardiology (34). In that scheme, lesions were classified as Type A, Type B1, Type B2, or Type C. Type C lesions were considered the highest risk and had an angioplasty success rate of 61%, in those days, and a complication rate of 21%. The characteristics of a high-risk Type C lesion included

**Table 6. Elective PCI Patient and Lesion Characteristics That Identify High-Risk Patients Who May Be Unsuitable for PCI in a Facility Without Cardiothoracic Surgical Backup**

High-risk patient

1. Decompensated CHF (Killip Class 3 to 4)
2. Recent (<8 weeks) cerebrovascular accident
3. Known clotting disorder
4. Left ventricular ejection fraction ≤30%
5. Chronic kidney disease (creatinine >2.0 mg/dL or creatinine clearance <60 mL/min)
6. Serious ongoing ventricular arrhythmias

High-risk lesion

1. Left main stenosis ≥50% or 3-vessel disease (>70% proximal or mid lesions) unprotected by prior bypass surgery
2. Target lesion that jeopardizes an extensive amount of myocardium. Jeopardy scoring systems, such as SYNTAX, may be useful in defining the extent.
3. Diffuse disease (>20 mm length)
4. Greater than moderate lesion calcification
5. Extremely angulated segment or excessive proximal or in-lesion tortuosity
6. Inability to protect side branches
7. Older SVG grafts with friable lesion
8. Thrombus in vessel or at lesion site
9. Vessel characteristics that, in the operator's judgment, would impede stent deployment
10. Chronic total occlusions
11. Anticipated probable need for rotational or other atherectomy device, cutting balloon, or laser

Modified with permission from Dehmer et al. (14) and high-risk features from the New York State Percutaneous PCI Registry 2006–2007 (58).

CHF = congestive heart failure; PCI = percutaneous coronary intervention; SVG = saphenous vein grafts; SYNTAX = Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery.

chronic total occlusion, a high grade (80% to 99% diameter stenosis), stenosis bend of >60 degrees, and excessive tortuosity. The data from these resources suggest that high-risk patients and target lesions can be defined prior to the performance of an elective PCI procedure and that it is appropriate to avoid these patients when there is no onsite cardiovascular surgery available.

In 2011, the initial results from the randomized Atlantic Cardiovascular Patient Outcomes Research Team (Atlantic C-Port-E) trial was reported (35). Only those sites with >200 PCIs per year and performing 24/7 PCIs were eligible for enrollment. Individual operators were required to meet the standard of >75 PCI cases per year. Sixty sites participated, and 13,981 patients were enrolled at sites without cardiovascular surgery whereas 4,515 patients were enrolled at sites with surgery. The authors concluded that PCI success was >90% in both situations, but this was lower in hospitals without onsite surgery (a success rate difference of 1.1% on per-patient basis and 0.7% on lesion basis). In addition, slightly more unplanned catheterization and PCI procedures occurred in patients undergoing PCI at a nonsurgical site. Emergency CABG was rare, but it was slightly higher in sites without surgery (0.2% versus 0.1%). Overall mortality and catheterization complications were similar between the 2 groups. Their conclusion was that PCI was safe within the bounds established by the trial.

Finally, further support for the safety of PCI in facilities without cardiovascular surgery comes from the ACC-NCDR data registry (36). These data revealed that centers without onsite cardiovascular surgery were predominantly in nonurban areas, had lower PCI volumes, treated a higher percentage of patients who presented with subsets of MI, and had better reperfusion times in primary PCI than centers with onsite facilities. There was also no difference in procedure success, morbidity, emergency cardiac surgery rates, or mortality (regardless if elective PCI or primary PCI). Although the data are observational, voluntarily submitted, and included from only 60 sites without cardiovascular surgery, it does suggest the current usage of these facilities may be safe and emphasizes the importance of reporting outcomes to a national data registry.

### 2.4.3. Patients Acceptable for PCI in ACS in a Facility Without Cardiovascular Surgical Capability

Primary PCI has now been shown to be more effective than fibrinolytic therapy in obtaining coronary reperfusion in patients with STEMI (37). Based on GRACE (Global Registry of Acute Coronary Events) data from 1999 to 2005, the use of primary PCI increased worldwide from 16% to 53%, whereas fibrinolytic therapy decreased from 50% to 28% (38). The improvement in patient outcomes as a result of this shift has led to a growing interest in offering primary PCI to as many patients as possible. Due mostly to access issues, however, only about 33% of patients with STEMI in the United States receive primary PCI, whereas 56% still receive fibrinolytics, and the remainder receives neither (39). This has provided the impetus to consider regionalization of STEMI care in the United States and a relook at the potential advantage of primary PCI particularly at rural hospitals without onsite cardiovascular surgery (40).

A standard treatment protocol using rapid interhospital transfer of STEMI patients between 6 referral centers and 2 STEMI accepting hospitals (41) revealed that 87.7% of patients received primary PCI. Door 1-to-departure time averaged 46 minutes, and Door 1-to-balloon time at the accepting hospital averaged 117 minutes. The authors suggested that, in a coordinated healthcare system, primary PCI can be centralized.

An NRMI report compared 58,821 STEMI patients from 214 hospitals with onsite cardiovascular surgery to 52 hospitals without. The authors found no difference in mortality among patients undergoing primary PCI at the different sites. They did report, however, that the overall STEMI mortality was higher, and the patients were less likely to receive guideline-recommended medications at the hospitals without surgical backup (42). In an NRMI database follow-up report (42) involving 100,071 patients from 2004 to 2006, the in-hospital mortality was found to be lower at hospitals with cardiovascular surgical support compared with those without (5.0% versus 8.8%). Hospitals with surgical services had higher use of guideline-recommended medical therapies, which may have contributed to better outcomes.

Support for the concept of performing primary PCI at the local facility also comes from a small randomized trial (43) and 2 registries (44,45) with favorable outcomes, though a study from Michigan also suggests that expanding a primary PCI program to hospitals without onsite cardiovascular surgery only improves access to a modest degree (46). A recent meta-analysis of primary PCI for STEMI of 124,074 patients demonstrated no increase in in-hospital mortality or emergency bypass at centers without onsite surgery compared with those that had cardiovascular surgery available (33). Despite the mixed data, there remains much enthusiasm from rural and hospitals without cardiovascular surgery to offer this service. Some of this is driven by the importance of providing timely access to early reperfusion strategies for STEMI patients in the local community. It is also driven by fear of loss of profitable cardiac patients and the concern that without the service, the hospital will be perceived as less than a full-service facility.

Some of these programs are also only providing primary PCI during working hours and not during off-hours. A review from the NRMI database has pointed out that there is a 70% less likelihood of patients with STEMI undergoing primary PCI if the presentation is off-hours (12). Since no clinical characteristics explain the reason a smaller percentage of these patients undergo primary PCI, the conclusion is that the procedure is just not available when the patient arrives in the emergency department. In fact, the authors note that 47% of the hospitals in the study perform <10 primary PCIs per year, suggesting that the volume of such

procedures may be too low to provide optimal care when primary PCI is only performed during normal daytime laboratory hours and not 24/7.

The 2009 Focused Update of the ACC/AHA Guidelines for the Management of Patients With STEMI also focused on the strategy to be followed, depending on whether the patient initially presents to a PCI-capable facility or to a non–PCI-capable facility (47). It does not specifically address whether the hospital has onsite cardiovascular surgery. A consensus document from the SCAI notes that there is no justification for providing elective PCI procedures without onsite surgery and without providing primary PCI 24 hours a day (14). AHA has also endorsed the principle that a facility providing primary PCI care should be operating around the clock (48). There are few data in this regard, but in 1 small study, the results of primary PCI done during off-hours appears similar to those done during regular working hours (49).

The ACC/AHA guidelines for the management of acute STEMI patients focus on the development of a community-wide system. Table 7 outlines their current recommendations for triage and transfer of STEMI patients for PCI. Included in the table are definitions for the "high-risk" STEMI patient. Although it is tempting to recommend that patients with these high-risk features be excluded from primary PCI at a hospital without cardiovascular surgery services, there are no data to confidently support that recommendation. In addition, coronary anatomic features are only discovered after angiography has been performed, so it is difficult to include such features as contraindications for intervention.

In an attempt to gather data on the wisdom of the use of primary PCI in the community at large, several ongoing programs have been undertaken including regionalization of care across the United States (50): the AHA's Mission: Lifeline program (48), the Reperfusion of Acute Myocardial Infarction in Carolina Emergency Departments (RACE) (51), and the ACCF's D2B Alliance (www.d2balliance.org). These programs are all working to develop community-based approaches to providing the optimal reperfusion strategy in STEMI patients, and they are tracking the results. Regionalization and improvements regarding in-field diagnosis, transfer and triage improve access times (door to balloon [D2B], emergency medical serivces to balloon [E2B], and/or S2B [symptoms to balloon]) and can optimize the use of primary PCI while avoiding duplication of local services. Given that fibrinolytic therapies are still in use in about 25% of U.S. hospitals, and even at PCI-capable hospitals (12), the choice of a reperfusion strategy is complex.

In many geographic situations, the ability to provide primary PCI at a hospital without surgical backup is suggested as a necessary step if other systematic approaches are unable to minimize the time from symptom onset to reperfusion. Evidence from the TRANSFER-AMI (Trial of Routine Angioplasty and Stenting After Fibrinolysis to Enhance Reperfusion in Acute Myocardial Infarction) study and CARESS (Combined Abciximab Reteplase Stent Study in Acute Myocardial Infarction) studies suggest a pharmacoinvasive approach with immediate transfer to a PCI center improves outcome (52–54). If the pharmacoinvasive approach is verified, this semielective approach to PCI at a tertiary hospital may reduce the concern over needing to offer primary PCI services in the local community or all local hospitals.

The Atlantic Cardiovascular Patient Outcomes Research Team (C-Port) trial randomized 451 AMI patients at

**Table 7. Recommendations From the 2009 Joint STEMI/PCI Focused Update on the Appropriate Performance of Primary PCI in Settings Without Onsite Cardiovascular Surgery**

**Class I:** Each community should develop a STEMI system of care that follows standards at least as strong as those developed for the American Heart Association's national initiative, *Mission: Lifeline*, to include the following:

- Ongoing multidisciplinary team meetings that include emergency medical services, non–PCI-capable hospitals/STEMI referral centers, and PCI-capable hospitals/STEMI receiving hospitals to evaluate outcomes and quality improvement data;
- A process for prehospital identification and activation;
- Destination protocols for STEMI receiving centers; and
- Transfer protocols for patients who arrive at STEMI referral centers who are primary PCI candidates, are ineligible for fibrinolytic drugs, and/or in cardiogenic shock. *(Level of Evidence: C)*

**Class IIa:** It is reasonable for "high-risk" patients who receive fibrinolytic therapy as primary reperfusion therapy at a non–PCI-capable facility to be transferred as soon as possible to a PCI-capable facility where PCI can be performed either when needed or as a pharmacoinvasive strategy.

Consideration should be given to initiating a preparatory antithrombotic (antiplatelet plus anticoagulant) regimen before and during patient transfer to the catheterization laboratory. *(Level of Evidence: B)*

**Class IIb:** Patients not at high risk under the same conditions as listed in Class IIa recommendation. *(Level of Evidence: C)*

High risk is defined in CARESS-in-AMI (59) as STEMI patient with ≥1 high-risk features. High-risk features include extensive ST-segment elevation, new-onset LBBB, previous MI, Killip Class >2, LV ejection fraction ≤35% for inferior MI; any anterior MI with ≥2 mm ST-segment elevation in ≥2 ECG leads.

High risk is defined in TRANSFER-AMI (60) as STEMI patient with ≥2 mm ST-segment elevation in 2 anterior leads or ≥1 mm ST-segment elevation in inferior MI along with at least 1 of the following: systolic BP <100 mm Hg, heart rate >100 bpm, Killip Class 2 to 3, ≥2 mm ST-segment depression in anterior leads, or ≥1 mm ST elevation in right-sided $V_4$ lead, indicative of RV involvement.

Reprinted from Kushner et al. (47).

BP = blood pressure, BPM = beats per minute; CARESS = Combined Abciximab Reteplase Stent Study in Acute Myocardial Infarction; ECG = electrocardiogram; LBBB = left bundle-branch block; LV = left ventricular; MI = myocardial infarction; ST = the ST segment of the ECG; STEMI, ST- elevation myocardial infarction; PCI = percutaneous coronary intervention; RV = right ventricular; TRANSFER = Trial of Routine Angioplasty and Stenting After Fibrinolysis to Enhance Reperfusion in Acute Myocardial Infarction.

hospitals without onsite cardiovascular surgery, and at 6 months, found better composite outcome (driven primarily by a reduction in reinfarction), in the primary PCI group compared with the fibrinolytic cohort with no significant difference in mortality (43). The newest PCI guidelines have reflected the more recent data since the last Catheterization Standards document and have elevated the use of elective PCI from a Class III indication to a Class IIb (55). Primary PCI in facilities without onsite cardiovascular surgery is considered a Class IIa instead of Class IIb indication in the latest revision of these guidelines.

**Recommendation:** Because of the current lack of definitive data in this area, this committee recommends that all facilities that perform primary PCI in a setting without cardiovascular surgical backup comply with all current guidelines on the establishment of such a program (as outlined in this section and in the accompanying tables). It is critical the facility documents that all medication and risk stratification guidelines are being followed as well, and that the facility has availability for STEMI patients 24 hours per day, 7 days per week. The committee cannot recommend any PCI programs without cardiovascular surgical backup that only provide primary PCI coverage during daytime and weekday hours.

To further ensure quality oversight, the facility should also be part of a defined registry to monitor outcomes and track all complications on a regular basis. D2B should be tracked closely, with goal D2B times of <90 minutes in >75% of cases. Regionalized systems of care may provide a more efficient system of diagnosis and triage and transfer, and they may or may not justify the current trend of establishing primary PCI capability at hospitals without surgical backup (56).

Finally, pharmacoinvasive strategies (54,57), if confirmed in other experiences, may provide superior, or at least comparable, outcomes to primary PCI at low-volume centers, and this should be evaluated further to determine whether increased centralization of services may result in improved outcomes.

## 3. Quality Assurance Issues in the Cardiac Catheterization Laboratory

The modern cardiac catheterization laboratory is an amalgamation of complex, highly sophisticated medical and radiological instrumentation used in the diagnosis and management of patients with both chronic stable disease and acute life-threatening illnesses. In any complex, procedure-oriented area, it is essential to have a QA program that incorporates QI to provide ongoing feedback within an established infrastructure for change. The Cardiac Catheterization Laboratory QA/QI committee should be considered a separate entity specific to the cardiac catheterization laboratory. Interactions with other medical staff and/or hospital QA/QI committees are critical, with personnel often assigned to work in multiple QA/QI committees and to share similar concerns, projects, and expertise.

The following discussion summarizes the key components of a QA/QI program for the diagnostic and interventional cardiac catheterization laboratory. These components are as follows: 1) clinical proficiency; 2) equipment maintenance and management; and 3) peer review. A fourth component, radiation safety, is discussed separately in this document. Table 8 outlines clinical proficiency based on cognitive skills, procedural conduct, and clinical judgment.

**Table 8. Assessment of Proficiency in Coronary Intervention**

| Type | Component | Mode of Assessment |
|---|---|---|
| Individual | Cognitive | • Formal training program |
| | | • Present requirement by ABIM: 3-year fellowship in ACGME-accredited program |
| | | • Board certification: requirement for added qualification in interventional cardiology: 12 months in ACGME-accredited program and pass grade on ABIM examination ("Board") for interventional cardiology |
| | Procedural | • Risk-adjusted outcomes |
| | | • Individual data benchmarked against the ACC-NCDR or similar database |
| | | • Peer recognition |
| | Judgment | • Appropriateness |
| Laboratory | Procedural outcomes | • Risk-adjusted outcomes |
| | | • Comparison with similar institutions |
| | | • Laboratory data benchmarked against national databases (e.g., ACC-NCDR database) |
| | Activity | • A minimum of 200 to 400 interventions per year |
| | | • Director with career performance of enough PCI cases to be a competent independent operator (ideally >500 interventions). Must be board certified in interventional cardiology |
| | | • QA staffing to monitor appropriate use, complications, and outcomes |
| | Support | • Experienced support staff to handle emergencies |
| | | • Regularly scheduled mortality and morbidity conferences and a review of all major complications |
| | | • Facilities and equipment for high-resolution fluoroscopy and digital video processing |

ABIM = American Board of Internal Medicine; ACC = American College of Cardiology; ACGME = Accreditation Council of Graduate Medical Education; NCDR = National Cardiovascular Data Registry; PCI = percutaneous coronary intervention; QA = quality assurance.

## 3.1. Patient Outcomes in the Diagnostic Catheterization Laboratory

### 3.1.1. Rate of "Normal Catheterizations"

The frequency of normal hemodynamic and angiographic findings at diagnostic catheterization is a function of the pretest likelihood of disease and the physician's clinical acumen. For purposes of definition, "normal" coronaries are defined pragmatically as those without a "significant" diameter reduction (<50%) on visual inspection. Since the publication of the 2001 Expert Consensus Document on Catheterization Laboratory Standards, there has been scant information reported on this topic in populations of patients undergoing diagnostic coronary angiography. New data from SCAI indicate that the frequency of normal angiograms is 20% to 27%, which appeared to vary little over a reporting period of several years (62,63). Notably, in a report from the ACC-NCDR, the proportion of patients undergoing elective diagnostic catheterization who were found to have minimal obstructive disease (<20% stenosis) was remarkably high at 39.2% (64).

It is recognized that many studies include patients with "insignificant disease," which is defined as <50% coronary diameter narrowing by visual estimate. Clearly, ACS occurs in patients without "significant" antecedent luminal narrowing on angiography. In addition, certain clinical syndromes may relate to coronary endothelial or microvascular dysfunction. Some laboratories may also have a high prevalence of patients studied for noncoronary issues, such as pulmonary hypertension, cardiomyopathy, valvular heart disease, or adult congenital heart disease. Ultimately, the rate of normal studies in any facility may more properly be viewed as a system performance metric as the outcome of any given angiographic study reflects pretest likelihood, complex decision pathways, local practice, and patient preference (65).

### 3.1.2. Specific Complication Rates Following Diagnostic Catheterization

There is extensive, albeit dated, literature on the major complications of diagnostic cardiac catheterization (62,63,66). Fortunately, the (composite) rate of MACCE is "acceptably" low at <1% to 2%. As expected, the likelihood of major complications increases significantly with the severity of the underlying cardiac and noncardiac disease (67). Patients with both valvular and coronary artery disease are slightly more likely to sustain a complication than patients with isolated coronary artery disease (68). Although complications encountered in patients with valvular or myocardial disease are more likely to reflect the patient's underlying clinical status, specific complication rates for transseptal catheterization (69) and endomyocardial biopsy (70) have been reported and fall within the previously referenced range. Because of patient selection, the likelihood of major complications during outpatient studies is less than that found during inpatient examinations (67), although the constantly changing definition of "outpatient" may blur this distinction. Current estimates from the NCDR continue to support the validity of the above-cited estimates for MACCE.

#### 3.1.2.1. ACCESS SITE COMPLICATIONS

Although not considered a "major complication" of diagnostic procedures, access site complications remain an important contributor to patient morbidity (71). It must be acknowledged that over the past decade, dynamic changes have occurred in the choice of access site for procedures, the caliber of diagnostic catheters, anticoagulation and antithrombotic protocols, and the means of achieving access site hemostasis (72,73). Progressive changes in the practice of invasive cardiology, in addition to advances in technology and technical competence, have led to significant reductions in access site complications for patients undergoing invasive diagnostic and therapeutic procedures (72).

#### 3.1.2.2. CEREBROVASCULAR COMPLICATIONS

Reported rates of clinically evident periprocedural cerebrovascular complications were generally <1 per 1,000 patients undergoing diagnostic cardiac catheterization and angiography (62). More recently, reports of subclinical manifestations of cerebrovascular events during and immediately following retrograde aortic valve catheterization in the setting of evaluation for aortic valve stenosis have appeared (74). Although admonitions against this practice have appeared in the literature (75), the true rate of clinical "stroke" in this setting is still unknown. However, in view of the increasing interest in catheter-based aortic valve repair/replacement techniques, this salient complication will remain an important focus of attention. Cerebrovascular complications in the setting of PCI will be discussed below.

### 3.1.3. Diagnostic Accuracy and Adequacy

An important, although generally ignored area, is that of the completeness and accuracy of diagnostic catheterization procedures. Incomplete procedures (aborted or technically inadequate procedures) that fail to obtain the critical information for diagnostic purposes and erroneous interpretation of the acquired information are markers of quality no less important than outcome data. Failure to selectively engage native coronary arteries or coronary bypass grafts often results in insufficient opacification of the lumen to accurately assess coronary anatomy or stenosis presence and/or severity. Inability to recognize the presence of anomalous coronary arteries contributes to this problem. The implications of inadequate or incomplete studies are significant and range from the need to repeat procedures to the performance of unnecessary and more invasive procedures. Inadequate opacification of the ventricle due to hand injections is inappropriate. In the coronary interventional era, the need for high-quality diagnostic angiography is great, as life-altering decisions are generally made on the basis of this information. This includes failure to opacify vessels fully due to inappropriate injection, incorrect catheter sizing, or failure to obtain adequate views that best characterize the

lesion. Inadequate attention to the details of accurate hemodynamic recordings in patients with valvular heart disease and the failure to accurately demonstrate coronary anatomy must be viewed as critical measures of outcome. For all the above reasons, it is reasonable to expect a rate of either inadequate or incomplete procedures to be <1%.

## 3.2. Patient Outcomes After Coronary Interventional Procedures

### 3.2.1. Major Adverse Cardiac or Cerebrovascular Events

Although patient outcomes are often considered the most important indicators of proficiency and competence in interventional cardiology (76), they are arguably the most difficult to accurately quantify. Moreover, the importance of risk adjustment for even crude event frequencies cannot be overstated (77). Therefore, it is essential that careful and complete preprocedural and intraprocedural information is accurately and reliably collected, sorted, and analyzed. Given that operator and institutional outcomes depend on many demographic, clinical, anatomic, and administrative variables, an adequate information system within the laboratory is mandatory, and the emphasis on both individual and institutional outcomes is appropriate (78–80). This is particularly so when attempting to risk-adjust outcomes for low-volume operators (81). The ability to estimate the likelihood of a significant complication (82,83), choose devices, and conduct procedures appropriately (84), promptly recognize and treat ischemic and other complications (85), and ultimately select (or refuse) cases appropriately are the hallmarks of an experienced, competent operator.

It is the responsibility of the director of the cardiac catheterization laboratory to establish a method of QA to track major events, (e.g., death and serious hemodynamic and/or arrhythmic events). Ongoing peer review of randomly selected cases from all operators is highly desirable and strongly encouraged. It should include the assessment of angiographic quality, technique, and thresholds being used for intervention. In addition, periodic review of less severe complications (e.g., hematoma or other vascular entry site injury) should be part of any ongoing QI program. Admittedly, some outcomes may be hard to standardize (e.g., periprocedural MI), but there is little ambiguity when outcomes for PCI are either consistently superior (e.g., <2% major complication rate) or consistently suboptimal (e.g., >5% major complication rate). At present, with overall in-hospital mortality averaging 1% and rates of emergent CABG averaging <1%, a composite major complication rate of <3% to 4% (95% confidence interval: 1.9% to 4.1%) for non-emergent PCI is to be expected (Tables 1 and 8, Fig. 1).

Since the 2001 "ACC/SCAI Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards" (1), much information has been added to the literature on PCI outcomes and complication rates in increasingly high-risk populations (e.g., advanced age, patients with CKD or ACS). Table 9 provides specific complication rates following PCI from large-scale clinical trials and "real-world" registries; Table 1 outlines data from a voluntary registry, the ACC-NCDR database. Each series includes patients undergoing PCI for a variety of indications under widely varying clinical conditions. The definitions of *elective, urgent,* and *emergent* vary among studies. Complication rates (especially bleeding and access site complications) in the GP IIb/IIIa inhibitor era vary, not only according to the definition applied, but in the rigor with which these outcomes are ascertained. For this reason, in-hospital complication rates in nonclinical trial, "real-world" settings remain a challenge in interpretation, given the unverified (nonadjudicated) and likely biased nature of such reporting. These results, however, can provide approximate boundaries for expected complication rates ("performance benchmarks") in "all-comers" undergoing PCI. The use of 30-day event rates to more completely assess PCI outcomes (86,87) and, by inference, benchmark operator performance (88) has also been proposed.

**Table 9. In-Hospital or Short-Term MACCE Following Elective PCI in the "Stent" Era**

| Study Population | Year | Reference | Death (%) | MI (%) | In-Hospital CABG (%) | Neurologic (%) | Major Vascular (%) | Significant Bleeding (%) |
|---|---|---|---|---|---|---|---|---|
| ACC-NCDR (registry) | 2002 | Anderson et al. (130) | 1.4 | 0.4 | 1.9 | . . . | . . . | . . . |
| SIRIUS (RCT) | 2003 | Moses et al. (131) | 0.09 | 1.9 | 0 | . . . | . . . | . . . |
| RESEARCH (registry)* | 2004 | Lemos et al. (132) | 1.6 | 0.8 | 1.0 | . . . | . . . | . . . |
| SYNERGY (RCT) | 2004 | SYNERGY (133) | 0.47 | 5.7 | 0.3 | 0.9 | . . . | 2.06§/2.46‖ |
| ACUITY (RCT)* | 2006 | Stone et al. (134) | 1.4 | 5.0 | . . . | <0.1 | 0.5 | 5.5 |
| NHLBI DR (registry)† | 2007 | Yatskar et al. (71) | . . . | . . . | . . . | . . . | 1.8 | . . . |
| NHLBI DR (registry) | 2009 | Venkitachalam et al. (93) | 0.2 | 2.0 | 0.3 | . . . | 6.0 | . . . |
| ACC-NCDR (registry) | 2009 | Aggarwal et al. (135) | . . . | . . . | . . . | 0.22 | . . . | . . . |
| ACC-NCDR (registry)‡ | 2009 | Mehta et al. (136) | . . . | . . . | . . . | . . . | . . . | 2.4 |
| EVENT (registry) | 2009 | Novack et al. (137) | 0.1 | 6.5 | . . . | . . . | . . . | . . . |

*30 days; †access site bleeding requiring transfusion; ‡transfusion requiring; §non-CABG bleeding, TIMI risk score; ‖non-CABG bleeding, GUSTO risk score.

. . . = not reported; ACC = American College of Cardiology; CABG = coronary artery bypass grafting; GUSTO = Global Utilization of Streptokinase and tissue Plasminogen Activator for Occluded Coronary Arteries; MACCE = major adverse cardiac or cerebrovascular events; MI = myocardial infarction; NCDR = National Cardiovascular Data Registry; NHLBI = National Heart Lung and Blood Institute; PCI = percutaneous coronary intervention; RCT = randomized controlled trial; TIMI = Thrombolysis In Myocardial Infarction.

Mortality, the least frequent but the most dire adverse outcome within the composite MACCE outcomes following PCI, has been the subject of intense interest since the early days of PCI (89). Efforts to predict its occurrence have been limited by its infrequency, resulting in studies of low statistical power and poor predictive ability. Accordingly, composite outcome variables, all of which included death, have been constructed and allow for improved precision in the estimate of an overall frequency of major complications following PCI (82,90,91). However, there are numerous limitations to the use of such composite variable constructs, particularly when inferences regarding an element (e.g., mortality) may be misinterpreted (92). As in-hospital mortality rates following PCI have declined in parallel with the many positive advances in interventional cardiology (93), larger sample sizes are necessary to estimate its frequency and to meaningfully predict its occurrence. The most robust estimate of the overall risk of in-hospital mortality, culled from large-scale, nonclinical trial registries published after 2001, ranges from 0.7% to 1.8% (94–96). These same studies are also in general agreement regarding the risk factors predictive of in-hospital mortality: age, gender, CKD, left ventricular ejection fraction (LVEF), antecedent MI, shock, prevalent heart failure, and peripheral vascular disease. Anatomic features (i.e., left main disease), procedural indication (i.e., urgent versus emergent), and intraprocedural variables (i.e., the number of lesions attempted and total occlusion attempted) are less agreed upon as predictors of mortality in these models.

#### 3.2.1.1. PCI IN THE SETTING OF ST-ELEVATION MYOCARDIAL INFARCTION

Table 10 summarizes outcomes from the latest published literature on PCI for STEMI—decidedly the highest-risk group of patients undergoing PCI. Event rates are unadjusted, and rates of access site and bleeding complications reflect a complex mix of systemic anticoagulation, systemic lytic activity, adjunctive use of platelet antagonists, and varying definitions and rigor of ascertainment. Nevertheless, some themes are evident across these diverse studies (e.g., the relative constancy of the risks of in-hospital death, stroke, and significant bleeding).

### 3.2.2. Ad Hoc PCI Issues

The performance of a coronary interventional procedure at the same laboratory visit as the diagnostic procedure is a strategy referred to as "ad hoc" PCI (97). If this is to be used, then it is important the discussion occurs with the interventionalist prior to entering the catheterization laboratory room. Ad hoc PCI should be discouraged in cases where the patient would benefit from a multidisciplinary discussion. Patients presenting with a STEMI or ACS, where the culprit vessel is readily identifiable, generally require an interventional procedure in conjunction with the diagnostic procedure for expeditious patient care and to reduce recurrent in-hospital ischemic events. However, when "routine" diagnostic procedures are immediately followed by "routine" coronary intervention, the considerations are more complex from a risk–benefit perspective. Considerations for when ad hoc procedures are encouraged include patient and physician convenience, the potential for a decrease in vascular access complications, a desire to avoid higher contrast load in patients with chronic kidney disease, and cost reduction.

Using the ACC-NCDR database, Krone et al. (98) published the outcomes of 68,528 patients undergoing PCI with the diagnosis of stable angina from 2001 to 2003, 60% of whom underwent ad hoc PCI. A multivariate analysis was performed to determine whether the performance of an ad hoc PCI had an independent association with procedure success or an adverse event. Patients categorized as high risk and those with significant renal disease were less likely to undergo PCI at the time of the diagnostic procedure. There was no difference in mortality, renal failure, or vascular complications when ad hoc patients were compared with patients undergoing staged procedures at a separate setting from the diagnostic case, so there appears to be no evidence that patient outcomes are affected.

When tracking outcomes for ad hoc versus separate setting PCI, important issues for the assessment of quality must be addressed. Complications encountered during the diagnostic catheterization and angiography (e.g., coronary dissection or abrupt occlusion) may be treated with prompt intervention but should not be considered ad hoc interventions. This leads to coding issues, as does the success of the

**Table 10. In-Hospital or 30-Day MACCE Following PCI for STEMI in the "Stent" Era**

| Study Population | Year | Reference | Death (%) | (Recurrent) MI (%) | Neurological (%) | Significant Bleeding (%) |
|---|---|---|---|---|---|---|
| CADILLAC* | 2002 | Stone et al. (138) | 2.7 | 0.8 | 0.2 | 2.5 |
| NHLBI-DR (registry) | 2007 | Abbott et al. (139) | 4.0 | 1.7 | 0.4 | 3.3 |
| HORIZONS-AMI (RCT) | 2008 | Stone et al. (140) | 2.58 | 1.75 | 0.5 | 6.6 |
| NRMI (registry) | 2009 | Pride et al. (42) | 3.56 | 1.0 | 0.5 | 7.19 |
| GRACE (registry) | 2009 | Steg et al. (141) | 3.7†/2.1‡ | 2.0/2.5 | 0.6/0.5 | 3.2/2.1 |
| Medicare (database) | 2010 | Chen et al. (142) | 10.3 | . . . | . . . | . . . |

*Outcomes at 30 days for the stent-plus abciximab arm; †PCI with bare-metal stent: ‡PCI with drug-eluting stent.
. . . = not reported; MACCE = major adverse cardiac or cerebrovascular events; MI = myocardial infarction; NHLBI = National Heart Lung and Blood Institute; NRMI = The National Registry for Myocardial Infarction; PCI = percutaneous coronary intervention; STEMI = ST-elevation myocardial infarction; RCT = randomized controlled trial.

intervention mitigating the inciting event. Although the composite procedure was "successful," how is the original complication recorded? Complications encountered during the interventional portion of the procedure should be attributed to the interventional procedure and not to the antecedent diagnostic study. Given the increasing use of the ad hoc approach, it will be important to continually and carefully define the indications, clinical outcomes, and overall cost effectiveness of this practice pattern (99).

### 3.3. Peripheral Vascular Intervention

The development of vascular medicine as a specialized discipline, which overlaps "traditional" medical, cardiological, radiological, and surgical disciplines, has led to the expansion of the types of angiographic procedures performed in cardiac catheterization laboratories. Laboratories historically dedicated to coronary angiography and cardiac diseases have had to transform themselves technically, logistically, and administratively in order to provide optimal care for a patient with cardiac and vascular disease. Large image intensifiers for vascular rooms are not optimal for coronary angiography. Performance criteria for training and credentialing in vascular medicine have been adopted by key stakeholders (100), and guidelines for maintenance of competence and technical proficiency have also been developed (101). Although minimum caseload volumes have been suggested, there currently is insufficient literature regarding performance metrics and outcomes analogous to coronary intervention (e.g., procedure-specific complication rates, patient-specific complication rates, and target organ or vascular bed versus overall clinical outcomes). From a catheterization laboratory standards standpoint, comparative outcome data are presently absent but are much needed in order to establish performance benchmarks and appropriate use criteria. The issue is further complicated by the fact that noncardiologists (e.g., vascular surgeons or interventional radiologists) are now participating in some of these studies, and guidelines regarding training and ongoing credentialing for these groups often differ from those of the invasive cardiologist. Laboratory participation in a centralized data repository is currently being developed by the NCDR. Data from resources as these will help define the ongoing changes in how the traditional cardiac catheterization laboratory is being used.

### 3.4. Peer Review Continuous QA/QI Program

A continuous QA/QI program is an essential component to the cardiac catheterization laboratory and must be in place for all laboratories. This should be a dedicated program to address the specific issues of the catheterization laboratory, but it need not be independent from other hospital QI programs. The peer review component for this process is designed to promote clinical proficiency under the broad rubric of system-level performance analyses, which should connote a more constructive (rather than punitive) context (102).

The core components of the Continuous Quality Improvement (CQI) program are data collection, feedback, and intervention (103). Table 11 outlines the essential components of the process. The CQI committee should be adequately staffed and resourced by the facility. It should be chaired by the medical director of the cardiac catheterization laboratory because he/she should be the individual primarily responsible for quality within the facility. The administrative co-chair should be a required staff position for this committee with specific job description assignments to QA/QI. Additional membership should include invasive/interventional physicians with nonpartisan representation from all physician groups. Finally, noninvasive cardiologists, noncardiology physicians, and support personnel from hospital administration may or may not be included, based on what the committee chairman deems appropriate for committee effectiveness. Though individual physician performance is being reviewed, the results of the entire process apply to the performance of the laboratory as a whole.

The peer review component of the QA program includes the challenge of assessing clinical proficiency of the operators in the cardiac catheterization laboratory and should not be limited to a simple "scorecard" analysis (102). Issues of cognitive knowledge, procedural skill, clinical judgment, and procedural outcomes are best assessed by a composite of a series of variables that reflect the overall quality of care (6). This information must be collected in a systematic manner and analyzed appropriately. Finally, an approach must be developed for quality improvement that involves not only a process for change but also a measure for feedback on the effectiveness of the solutions as well as educational opportunities for all involved (103).

**Table 11. Basic Components of the Continuous Quality Improvement Program for the Cardiac Catheterization Laboratory**

| |
|---|
| Committee with chairman and staff coordinator |
| Database and data collection |
| Data analysis, interpretation, and feedback |
| QA/QI implementation |
| Goals outlined to eliminate outliers, reduce variation, and enhance performance |
| Tools available to accomplish data collection and analysis |
| Feedback mechanisms in place |
| Educational provisions for staff and operators |
| Incorporation of practice standardization/guidelines |
| Professional interaction and expectation |
| Incentives for high-quality metrics |
| Adequate financial support for QI personnel |
| Administrative oversight and action plans |
| Thresholds for intervention |
| Appropriate use assessment |

QA = quality assurance; QI = quality improvement.

### 3.4.1. Overview of the Peer Review Process: Quality Indicators, Data Collection and Analysis, and QA/QI Interventions

A review of cardiac catheterization laboratory settings has outlined certain practical lessons learned by the Laboratory Survey Committee of the SCAI (104). This committee noted that the major QA problems were not usually related to equipment but rather to inadequate laboratory space, lack of a physician medical director, lack of specific operating rules for the laboratory space, and lack of a functioning QA program (104). Not only must a QA program provide procedural complication information, but the committee emphasized that a feedback mechanism to modify behavior must be in place.

A QA program is only as effective as the commitment of all involved in the process of healthcare delivery, with the most conspicuous components being the assessment of procedural outcomes and individual operator proficiency (6). It is the responsibility of each individual operator to actively participate in the QA process along with other team members as well as actively participate in both CME and maintenance of competence activities on a regular basis. Each interventionalist should be aware of his/her own volume, complications, and outcomes. These data should be used to direct personal improvement. However, a procedure must be in place to assure this information is both accurate and complete. Utilizing "indicators" to help quantify the quality of the physician's performance may be beneficial. The indicators for organizational purposes include structural, process, and outcomes (105).

***Structural indicators*** are those often considered by the hospital credentials committee and include staff credentialing/re-credentialing. This committee must assess medical training, licensure, board certification, procedure volume, and CME. Additionally, the committee/hospital may require, or consider appropriate, specific training courses/CME for a given procedure, society membership/offices held, awards/honors, and publications/presentations. Establishing a transparent standard for a given facility limits confrontation when physicians are either inadequately trained or fail to maintain required qualifications. The committee must be empowered to withdraw credentials when individuals fail to meet written minimum standards.

***Process indicators*** refer to patient management regarding evaluation and treatment. Table 12 lists examples of procedural or process indicators. Since these are less objective and potentially amenable to observer bias as opposed to "hard" clinical outcomes, they are more difficult to measure and validate. These indicators are, however, helpful in working through the entire process from protocols and staffing to the rapidity of room turnover and patient length of stay. By tracking these indicators, analysis of outcomes issues an assessment of cost containment can be addressed within the QA process (106).

***PCI appropriate use indicators*** are also important. The latest suggestions from the ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT should be valuable in ensuring that only appropriate patients are undergoing interventional procedures, and these guidelines can be used to help monitor appropriate use activity (107).

**Table 12. Examples of Patient Management/ Process Indicators**

| |
|---|
| Direct patient care–related indicators |
| Quality of angiographic studies |
| Radiation utilization (e.g., dose per procedure) |
| Report generation/quality of interpretation |
| Appropriateness |
| System-specific indicators |
| Patient transport/lab turnover/bed availability |
| Preprocedure assessment process and adequacy |
| Emergency response time |
| Cardiovascular surgery/anesthesia/respiratory care/perfusion performance |
| Guidelines-driven indicators |
| Infection control |
| Patient radiation dose (use of all available dose indicators, not only fluoroscopy time) |
| Treatment protocols (radiographic contrast issues, drugs usage) |
| Procedure indications |
| New device use |
| Cost-related indicators |
| Length of stay pre-/post-procedure |
| Disposables needed |
| Quality and adequacy of supplies |
| Number and qualification of personnel/staffing |

Modified with permission from Heupler et al. (102).

***Outcome indicators*** are outlined in Table 13. These are now often publicly available, and they are the most recognizable. Risk adjustment is the essential component to outcomes reporting and, therefore, dictates the need for detailed databases (7). Benchmarking individual physician and laboratory performance against national standards (e.g., the ACC-NCDR database) is an important component to this process (108). Though risk adjustment is essential to this process, awareness of the potential public health hazards with public reporting of inadequately risk-adjusted outcomes is of great concern (109). Although individual physician and hospital scorecards provide information on performance, they are not sufficient when used alone. Outcome data should not be used to punish an outlying practitioner but rather to search for causes that can be remedied and processes that can be improved (102,103).

Effective data collection requires a data repository and dedicated personnel for data acquisition. Information technology systems for the cardiac catheterization laboratory and the hospital should be integrated to allow for information transfer regarding patient demographics, catheterization data, and hospital laboratory data, thereby decreasing personnel data entry time. Hospital administration must be actively involved in this process to provide the needed staff support. Though identification of the most appropriate data collection instrument is still not standardized, an under-

**Table 13. Outcomes-Related Indicators**

| |
|---|
| I. Physical outcomes |
| Individual physician MACCE |
| Death |
| Stroke/nerve injury |
| MI |
| Respiratory arrest |
| Perforation of vessel of heart with sequelae |
| Nerve injury |
| Radiation injuries |
| Emergent cardiovascular surgery |
| Access site complications |
| Access site complications requiring surgery |
| Rate-based outcomes (outcomes related to volume) |
| Diagnostic cardiac catheterization completion rates |
| PCI success rates |
| Normal cardiac catheterization rates |
| II. Service outcomes |
| Access to facility information |
| Door-to-balloon times |
| Satisfaction surveys |
| III. Financial outcomes |
| Procedural costs (as laboratory and as individual physician) |
| Risk management/litigation costs |

Modified with permission from Heupler et al. (102).
MACCE = major adverse cardiac and cerebrovascular events; MI = myocardial infarction.

standing of entire catheterization laboratory process is essential for accurate and complete data acquisition with data entry verified for accuracy.

Data analysis requires a review of specific adverse events, as well as risk-adjusted event rates, for the facility/operator. Specific adverse events should be identified, and an individual case review should be performed. A potential list of case examples that should be reviewed might include those listed under clinical outcomes in Table 13 (102). Table 14 represents an example of an adverse event case report form. Such case reports should be completed by a "neutral" observer whenever possible to avoid confrontation. Results should be reviewed and discussed as indicated at regularly scheduled CQI meetings. In the case of possible litigation, the cardiac catheterization laboratory CQI process should work with the hospital risk management department and not be driven by the latter.

Interventions to improve performance should be the goal of the peer review process. The CQI process should focus on improving the performance of the "low-end physician" and not the elimination of this person, unless the performance is repeatedly below minimum standards and the individual is recalcitrant to positive suggestions. Once performance variance has been identified, programs should be established to correct these variances and address specifics issues to improve the total laboratory performance (102). Continuing employment of physicians not performing appropriately, despite efforts from the CQI process, should be the responsibility of hospital oversight committees, group practices, or departmental leadership.

The tools available for the CQI process are many. Establishing practice protocols and order sets helps standardize practice and reduce variation in individual performance. Appropriately used in a nonpunitive forum, scorecard benchmark performance can provide feedback that may allow outliers to see where potential areas of improvement are required. Identifying the need for an intervention is a clear component of this process. Counseling may be required with confidential but swift correction of unprofessionalism. Education, either with in-lab proctoring or external CME, can allow for any potential knowledge gap to be narrowed. Laboratory surveys provide feedback for both individuals as well as overall laboratory process performance. Working with hospital administration to consider incentives to improve performance and enhance educational opportunities may prove beneficial. Finally, administrative policy for intervention must be established to address the potentially "uncorrectable" outlier. SCAI has provided an outline of the components of an ideal quality control and inspection program and a Quality Improvement Toolkit (QIT) that is now available on their Web site (http://www.scai/QIT). Subspecialty "boards" in adult interventional cardiology are properly focused on proficiency, both cognitive and technical (6). For coronary interventional procedures, proficiency is most easily related to procedural volume, although proficiency and volume are only loosely associated. Some quantitative evidence now exists for selected volumetric cut points for interventional procedures (55) though controversy remains and enforcement is basically nonexistent, except at the credentialing committee level at each facility. The recent PCI guidelines acknowledge the controversial relationship between quality and volume. Risk-adjusted outcomes remain preferable to institutional and individual operator volumes as a quality measure (55). This issue is currently being addressed by the ACCF/AHA/SCAI Writing Committee to Update the 2007 Clinical Competence Statement on Cardiac Interventional Procedures. The situation is even less clear with respect to diagnostic catheterization. Given the absence of similar quantitative data for diagnostic procedures, as well as the significantly decreased associated morbidity and mortality associated with diagnostic catheterization, operator proficiency may be better assessed in a larger overall context. Rates of normal studies, peer review of the diagnostic quality of studies, rates of referral for intervention, and perhaps development of criteria for the appropriateness of these studies have all been suggested as methods of incorporating physician practice into the QI process for diagnostic procedures. The quality and the timeliness of catheterization reports should also be part of the QI process. A preliminary report should be immediately available and a final report completed within 24 hours. However, processes for credentialing and the assessment of proficiency must be developed in accordance with both local governance policies, as well as professionally developed

**Table 14. Data Quality Event Review Form (Representative Data Collection Form)**

**Patient Data**

Patient Name:_____ Age:_____ ID#:_____

Procedure:_____ Physician:_____ Date:_____

Reason for Review:

Potential for Patient Safety:_____; Sentinel Event:_____

Mortality: In Lab_____; In Hospital_____ 30 Day_____

Morbidity: Neuro:_____; Vascular:_____; Coronary:_____;

Arrhythmia:_____; Renal:_____; Radiation:_____

Other:_____

Case Summary:

_____

_____

Risk Group: Average/Low High Salvage

Clinical _____ _____ _____

Cath _____ _____ _____

**Process Review:**

Appropriate Uncertain Inappropriate

Indication :_____

Technique :_____

Management :_____

Related to: Disease:_____; Provider:_____; System:_____;

Preventable:_____; Not Preventable:_____; Comments:_____

Recommendation by
Reviewer:_____

_____

Reviewer:_____

Recommendation by
Committee:_____

_____

_____

Patient Safety/Risk Management Review: Y N; Hospital/Department Review: Y N;

Corrective Action: Y N; Education_____; Proctor_____; Other:_____

Date:_____ Signature:_____

standards. In particular, the granting of privileges by healthcare systems should fall within the legal purview of these institutions. It is hoped that these systems use criteria similar to those outlined in this document in association with the major cardiovascular societies to support the decision to credential physicians and monitor system performance.

Over a 10-year period, improvements in instrumentation, imaging, data recording, and procedural outcomes have proceeded rapidly. Consequently, continuing education for practitioners beyond the standard level of training programs has become the norm for the acquisition of many of these advanced skills. Training programs themselves are also changing from the traditional 1-year program in interventional cardiology to 2-year programs in some institutions. Subspecialty certification "boards" in interventional cardiology reflects this burgeoning knowledge base (6,110). All of this translates into the need to provide continuing education to all members of the team. The implementation of new technology requires a critical evaluation of both the experience in the literature as well as the experience within individual institutions. An organized didactic program coupled with cautious early clinical experience is an ideal mechanism for the introduction of new therapies. These types of programs, in conjunction with attendance at regional or national scientific meetings devoted to the unbiased presentation of new data, provide a solid infrastructure for credentialing purposes. Attention to this aspect of laboratory QI is critical to maintaining expertise.

### 3.4.2. Noncardiologists Performing Cardiac Catheterization

An independent operator in the cardiac catheterization laboratory must be proficient, not only in the technical aspects of the invasive procedure, but also in the cognitive aspects, including preprocedural evaluation, indications, cardiac physiology and pathophysiology, emergency cardiac care, radiation safety, and interpretation and clinical application of the cardiac catheterization data. ACCF has developed recommendations for training in diagnostic cardiac catheterization, as well as specific technical skills, including both education and case volume (111). Cardiology fellowship training requires completion of a 3-year program in order for the operator to be considered competent to perform diagnostic angiography and an

additional year of dedicated training for coronary interventions (76).

The spectrum of participation in cardiac catheterization is broad and includes physician-supervised assistance by nonphysicians, independent nonphysician performance, and noncardiologist performance of cardiac catheterization. Nonphysicians serving in an assistant role during the catheterization with a cardiologist present are standard practices in most training and teaching programs and not the issue here. There is limited literature regarding safety/outcomes of nonphysicians independently performing cardiac catheterization. This topic was reviewed by SCAI in a statement regarding nonphysicians performing cardiac catheterization as independent operators (112). No relevant data are currently available establishing either the safety or the healthcare manpower requirement for nonphysicians performing as independent operators in the cardiac catheterization laboratory, and this practice is not appropriate. Some exceptions to this policy include right-heart catheterization procedures performed by competent operators from intensive care units or electrophysiologists utilizing the cardiac catheterization facility.

Medical and surgical subspecialties create training requirements to establish and maintain patient safety and quality of care (76,100,111). Hospital privileges for specific procedures are based upon training requirements. It is an ethical obligation to honestly disclose relevant information to the patient (e.g., the training credentials of the primary operator for any procedure, including cardiac catheter procedures). Beneficence is the ethical obligation to act in the patient's best interest (112). Patients, the public, and the government are rightly seeking greater assurance that physicians hold the interests of their patients above their own. Diagnostic cardiac catheterization and percutaneous coronary intervention should be performed by trained cardiologists, or comparably trained noncardiology physicians, who have been trained specifically for this procedure (110,111). It is not appropriate for noncardiologists to perform percutaneous coronary interventions.

### 3.4.3. National Database Use

In assessing quality, adverse outcomes are often equated to a lack of quality which, in turn, is related to performance. However, it is obvious that adverse events will occur, even in the best hands and at the best centers (113). The frequency of these events is, in large part, related to the condition of the patient and experience of the operator and center. Volume alone may not be the best barometer of quality (114).

The SCAI Registry was developed to offer individual centers an opportunity to assess their results relative to the national reporting network of catheterization laboratories on a voluntary basis. This registry tracked both diagnostic and interventional procedures and was the standard for assessing quality in the 1980s and 1990s, though the information was not risk adjusted and the number of variables was limited. This database is no longer being supported. With the termination of this database, no effort, to date, has been attempted to track and risk adjust diagnostic adverse outcomes on a national basis. State Health Departments require low-volume diagnostic laboratories to complete a data form on all patients. However, comparative national data for diagnostic catheterization have not been available since the 1990s.

ACC-NCDR is a voluntary national registry that currently receives data from approximately 1,300 participating hospitals. The purpose of this registry is to provide risk-adjusted outcomes to individual institutions and their physicians. Such risk-adjusted outcomes are considered the most appropriate measure of quality (108). The data collection processes as well as the details regarding the dataset have been described in detail (7). Each data element is predefined, linked to ACCF/AHA PCI Guidelines, and available at www.cardiosource.org. Data at each participating facility are entered locally into ACC-NCDR–certified software. Compatibility with individual laboratory reporting systems and ACC-NCDR, or any regional/national database such as the Northern New England Cardiovascular Disease Study Group or the New York State Department of Health Database, is essential to allow for complete data entry and minimize duplication. Many local QA programs are based on these data, and the sites themselves are responsible for auditing the data for completeness and accuracy. In addition, the ACC-NCDR has a limited national audit system of approximately 5% of the data. This registry has developed and validated a number risk adjustment models for specific adverse outcomes (7,108,113,115). An example of the output from the ACC-NCDR Cath PCI dashboard is shown in Figure 2.

This writing committee strongly encourages all laboratories to participate in a national or regional registry to benchmark their results and provide an ongoing system for tracking complications. Benchmark data are important, and because the validity of these data are dependent on a high number of participating laboratories, this committee strongly recommends that all cardiac catheterization laboratories actively participate in such a data registry.

### 3.4.4. Catheterization Laboratory Reporting Requirements

The catheterization report should be individualized to a particular institution depending upon the recommendations of the medical director and participating physicians, the administrative and informational infrastructure of the institution, and the requests of the referring physicians. Table 15 presents standard information required in such a report (116). A complete procedural report, finalized within 24 hours of a procedure and inclusive of content in Table 15, is a requisite and standard of care. Furthermore, structured reporting using standardized data elements captured as discrete data is highly preferred to verbose (i.e., handwritten or dictated) reporting. An initiative to define best practice workflows for data acquisition, processing, and reporting is

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Additional Reports | File Delivery

AUC Patient Record Classification

**CathPCI Outcomes Dashboard** Timeframe: 2011Q3 Export

1. Exec. Summary | 2. Perf. Measures | 3. PCI Process | 4. PCI Outcomes | 5. Dx Cath | 6. Util.\Data Quality | 7. AUC

| Metric Name | My Hospital | US Hospitals 50th Pctl |
|---|---|---|
| **PCI Performance Measures** | | |
| 1 - PCI in-hospital risk adjusted mortality (all patients) | 0.90 | 1.34 |
| **PCI Process Metrics** | | |
| 2 - Proportion of elective PCIs with prior positive stress or imaging study | 75.1 | 60.1 |
| 3 - Median time to immediate PCI for STEMI patients (in minutes) | 52.5 | 62.8 |
| 4 - Proportion of STEMI patients receiving immediate PCI w/in 90' | 91.8 | 91.5 |
| 5 - Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients. | 73.5 | 84.7 |
| 6 - Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes) | 96.0 | 116.8 |
| 7 - Median fluoro time (in minutes) | 6.2 | 9.2 |
| 8 - Proportion of patients with aspirin prescribed at discharge | 99.4 | 98.2 |
| 9 - Proportion of patients with thienopyridine prescribed at discharge | 99.9 | 99.2 |
| 10 - Statins prescribed at discharge | 90.2 | 92.1 |
| **Diagnostic Cath Process\Outcomes Metrics** | | |
| 20 - Incidence of non-obstructive CAD (elective patients only) | 54.7 | 43.9 |
| 21 - Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding | 0.2 | 0.2 |
| **AUC Metrics** | | |
| 30 - Test Metric: Proportion of PCI procedures not classifiable for AUC reporting | 12 | 11.1 |
| 31 - Patients WITH Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were appropriate | 99.7 | 99.4 |
| 32 - Patients WITH Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were of uncertain appropriateness | 0.0 | 0.0 |
| 33 - Patients WITH Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were inappropriate | 0.5 | 0.5 |

| Metric Name | My Hospital | US Hospital 50th Pctl |
|---|---|---|
| **PCI Outcome Metrics** | | |
| 11 - Proportion of PCI procedures with vascular access site injury requiring treatment or major bleeding | 0.8 | 1.0 |
| 12 - Proportion of PCI patients with emergency CABG | 0.4 | 0.1 |
| 13 - Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers) | | 3.1 |
| 14 - Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers) | 1.3 | 1.3 |
| 15 - Proportion of PCI procedures with acute kidney injury | | 2.1 |
| 16 - Proportion of PCI procedures with post procedure stroke | 0.4 | 0.0 |
| 17 - Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization. | 2.1 | 2.3 |
| 18 - PCI in-hospital risk adjusted mortality (patients with STEMI) | 3.99 | 5.23 |
| 19 - PCI in-hospital risk adjusted mortality (STEMI patients excluded) | 0.30 | 0.63 |
| 25 - Proportion of PCI procedures with transfusion of whole blood or RBCs | 1.5 | 1.7 |
| **Utilization Metrics \ Data Quality Metrics** | | |
| 22 - Median post-procedure length of stay (in days) for PCI patients with STEMI | 2.0 | 2.7 |
| 24 - Proportion of PCI procedures with creatinine assessed pre and post PCI | 58.4 | 86.5 |

**Figure 2. Example of the NCDR CathPCI Executive Summary Quality Dashboard**

NCDR = National Cardiovascular Data Registry; PCI = percutaneous coronary intervention.

underway to develop a standardized, structured report format for diagnostic and therapeutic cardiac catheterization procedures. Prior to this, institutional preference for the use of a vendor-based versus a "home-grown" standardized reporting system should be viewed in the context of ensuring compatibility with a national database for complete data entry while minimizing duplicated effort. Appropriate immediate post procedure chart documentation is required for inpatient procedures if the completed catheterization report is not immediately available. Notification of findings to the patient, family, and referring physician/primary care physician should be expected standard practice.

**Table 15. Minimum Components of the Standard Catheterization Report**

1. Indications for the procedure
   a. Patient demographics
   b. Pertinent patient history including risk factors
   c. Specific indication for each component of the procedure (e.g., right-heart and renal angiography)
2. Procedure information
   a. Primary operator and additional staff present
   b. Procedures performed
   c. Access site information
   d. Equipment utilized
3. Procedure documentation
   a. Medications, including dose and duration of antiplatelet therapies
   b. Radiographic contrast used and dose
   c. Fluoroscopic time
   d. Radiation dose (mGy and Gy $\times$ cm$^2$)
4. Diagnostic findings
   a. Coronary anatomy (diagram optional but ideal)
   b. Ventricular functional assessment (EF, LVEDP)
   c. Other hemodynamic information (HR, BP)
   d. Other angiography
      i. Aortography (thoracic, abdominal)
      ii. Renal angiography
   e. Relevant hemodynamics
      i. Right and left heart
      ii. Response to medications or maneuvers
      iii. Oxygen saturations
      iv. Cardiac output-result and method
      v. Valvular assessment (gradients; valve areas when appropriate; estimation of regurgitation severity; summary of mild, moderate, and severe disease assessment)
5. Interventional procedure(s)
   a. Separate listing for each procedure including site and procedure performed
6. Documentation of equipment and medications in catheterization laboratory results (i.e., ACTs)
7. Complications encountered in lab
8. Conclusion (a diagram provides visual information and is much preferred over textual alone reporting)
   a. Summary of appropriate of findings
      i. Coronary anatomy
      ii. Ventricular function
      iii. Hemodynamics
      iv. Valvular pathology
      v. Interventional procedures
   b. Recommendations or patient disposition (optional) based upon physician and laboratory preference

It is suggested that a preliminary report of the findings be made available immediately and the complete report made available within 24 hours. A catheterization report should focus on the coronary tree diagram as the preliminary report. Procedural details can be reserved for a second and more complete report.

ACT = activated clotting time; BP = blood pressure; EF = ejection fraction; HR = hemodynamic response; LVEDP = left ventricular end-diastolic pressure.

#### 3.4.4.1. STORAGE OF INFORMATION (LENGTH AND TYPE)

There are several essential components to an information storage system for the cardiac catheterization laboratory, regarding both written word and recorded images. Important considerations for an individual institution are price, performance, capacity, and function. In choosing a system, users must first be considered so as to select a system that is operator- and institution-friendly. Linking the catheterization laboratory reporting system with the hospital information system improves information availability and patient care. In-laboratory and postprocedural complications and hospital outcomes should be tracked and reported regularly by the CQI committee. If possible, 1-month and intermediate-term outcomes and readmissions should also be monitored. Staff efficiency is improved when demographics are entered once into a system that "talks" throughout the hospital and/or health system. Additionally, inventory and billing can be linked to this system. This seamless interface between report generation and the information management system, not only provides an accessible report for patient care, but also enhances inventory maintenance and verifies billing (117).

As with all information systems, compliance with the 1996 Health Insurance Portability and Accountability Act (HIPAA) must be assured. Though physician access for patient care is important, all patient information interactions must be verified as HIPAA compliant, whether that be accessing lab values or signing reports (118).

Information storage strategies may take several forms. Varying redundant array of independent disks (RAID) schemes provide different levels of data access performance and system failure protection (119). The RAID schemes divide and replicate data among multiple hard drives, writing identical data as well as splitting data on more than 1 disk. Error correction is accomplished through redundancy, allowing read/write problems to be detected and corrected. This technology is particularly useful when large files (i.e., cine images) require storage.

The more advanced the data storage system, the more data replication mechanisms and storage servers are likely to be available. Long-term archiving provides for expanded storage, data protection, or both, when the primary space capacity is reached. Disaster recovery is essential to any storage system to prevent permanent data loss. Having a disaster recovery system in a nondirect access format prevents a computer virus, for example, from infecting and erasing data. Data duplication via a mirror image server, often at a remote facility, may be

done in real time allowing for near instantaneous data replacement (120).

The Integrating Health Care Enterprise (IHE) was originally developed with support of the Radiological Society of North America and the Health Information and Management Society. In 2003, a cardiology domain was initiated by the ACCF, American Society of Echocardiography, American Society of Nuclear Cardiology, SCAI, and European Society of Cardiology to focus on integration of information within the cardiology department. IHE does not create standards but rather provides integration profiles from existing standards for specific clinical needs. Multiple profiles can be developed creating a cardiac catheterization laboratory workflow integrating ordering, scheduling, image acquisition, storage, and viewing (121). This can be integrated with echocardiography, electrocardiogram, and stress testing to display reports as well incorporate workflow through procedure/postobservational areas.

The transition from cine film to digital acquisition and storage in the catheterization laboratory was made possible with the creation of the Digital Image Communication in Medicine (DICOM) Standard (122,123). The DICOM Standard is a set of rules that allow medical images to be exchanged among all medical imaging devices. In the digitally enabled catheterization laboratory, digital images are stored for short-term archival on the proprietary digital storage unit of the specific imaging equipment or network servers with only limited storage capacity for immediate access.

Cine image storage in the digital imaging era is challenged by the pure volume of data (124). Various compression ratios have been employed in order to optimize storage capacity requirements, but the latter in anything greater than a 4:1 compression ratio frequently resulted in nondiagnostic images. Therefore, to preserve image quality, only lossless compression is currently used. A diagnostic cardiac catheterization with 5 to 10 cine runs of 6 to 7 seconds at a frame rate of 30 fps contains approximately 2,000 images. With minimum specifications of a 512 × 512 matrix and a pixel depth of 1 to 1.5 bytes, a standard diagnostic study results in 500 to 750 MB at 30 fps. At 15 fps, this is approximately 350 MB/case. In a facility that performs 5,000 cases per year for 7 years, this requires a storage capacity of 10.5 terabytes. This calculation does not consider the improvement in spatial resolution with a matrix size of 1,012 × 1,012 to 2.5 to 3.0 LP/mm (line pairs/mm). The latter is the preferred imaging technology to properly visualize stents in the right coronary artery in the right anterior oblique projection (125).

Long-term archival technology of these massive files has similarly progressed over time from stacked magnetic disks, to digital archival tapes, to large optical disks ("jukebox"), to current generation RAID 5 subsystems (119). Speed for recovery from long-term archival has dramatically improved. A picture archiving and communication system (PACS) is integral to hospital image storage and access. The inclusion of cardiac catheterization laboratory studies into the traditional radiology PACS system was generally precluded due to the file size requirements. Modern PACS may now comfortably accommodate catheterization laboratory images (120).

Duration of storage has been based more upon tradition than written policy. The "standard" cine film storage was 7 years. Currently, in the digital era, storage duration is based upon storage capabilities. However, the potential usefulness of adult cine storage >7 years is in question, although pediatric image storage may well require lifetime access to appreciate anatomy prior to interventions. The reality is that most laboratories provide image storage for only 7 years, even in the pediatric cardiac catheterization environment. The progressively low cost of digital image storage is making these minimum storage guidelines rather obsolete, as indefinite storage is now readily available.

### 3.4.5. Equipment Maintenance and Management

Equipment maintenance and management remain crucial issues from a catheterization laboratory QA/QI standpoint and specific guidelines are, therefore, provided. Each aspect of the radiographic system should be able to meet these performance expectations (126). The same is true for the physiological recorders and other specific devices used in the laboratories.

The modern diagnostic and interventional catheterization laboratory uses many sophisticated radiological, electronic, and computer-based systems, each of which requires a program of rigorous maintenance and troubleshooting. The x-ray imaging system, a crucial component of every laboratory, must be carefully assessed at frequent intervals to detect early signs of deterioration in performance. Unfortunately, this aspect of quality control is the first to be sacrificed in an era of cost constraints.

A program of periodic assessment of system performance and image quality has been recommended by SCAI (127). Additional programs, which address issues specific to digital imaging systems, are under evaluation (127). A representative outline of the performance characteristics needed to assess radiographic cardiac imaging systems is presented in Table 16.

Note that at present, the only federally mandated parameter for fluoroscopic systems is the maximum "table-top" exposure rate (see Section 9). The concept of minimum image performance standards must await universal acceptance of a suitable test instrument for cardiac fluoroscopy. Currently, there is considerable heterogeneity across laboratories in selective measurements of image quality (123,128). Such heterogeneity precludes specific recommendations with respect to what is considered "acceptable" performance. Current-generation imaging systems must be capable, at minimum, of providing images of sufficient diagnostic quality to enable decision making with respect to intervention and provide sufficient spatial and contrast resolution for the conduct of contemporary coronary intervention.

**Table 16. Performance Characteristics of Radiographic Imaging Systems**

| Category | Example |
|---|---|
| System measure | Image quality |
| | Dynamic range |
| | Modulation transfer function |
| Component measures (not inclusive) | Fluoroscopy and cine spatial resolution |
| | Fluoroscopy field of view size accuracy |
| | Collimator tracking and alignment |
| | Low contrast resolution |
| | Record fluoroscopic mode and automatic exposure control under standard conditions and at maximum output |
| | Calibration of integrated radiation dose meters |

Interventional procedures occur in environments of high information density. In the past, physiological recorders were used only for the acquisition and recording of analog signals. They are now required to serve as front ends for the increasingly complex gathering of data. These recorders have essentially been transformed into desktop personal computers capable of acquiring, storing, and transmitting data to other sites. Given the critical importance of these data for numerous administrative purposes (billing, QA, report generation), flawless transmission without data loss must take place at all times (117). Backup systems and low-cost storage media are essential (125).

The need for patient safety-related precautions is paramount (129). The operational efficiency of infrequently-used equipment (e.g., defibrillators and external pacemakers) must be assessed routinely, and the appropriate logs must be kept. Electrical isolation and grounding systems must be regularly assessed (122). The number of ancillary devices used in coronary intervention (Doppler and pressure-tipped sensor wires and ultrasound catheters) now requires that electrical safety precautions that were adequate in the past need to be revisited at periodic intervals (122).

## 3.5. Minimum Caseload Volumes

The cardiac catheterization laboratory previously referenced was primarily an arena for the diagnosis and treatment of coronary artery disease. However, in the last decade, there has been not only an expansion of the anatomic indications for PCIs, but also an expansion of percutaneous interventions to most other vascular beds, as well as the development of a new branch of interventional cardiology involving the treatment of numerous forms of structural heart disease.

Determining who should perform procedures based on volume remains controversial and difficult to adjudicate. The goal is to have successful procedures done on appropriate patients. There are clinical, angiographic, operator, and institutional characteristics that have been shown to influence procedural success. Operator characteristics include cognitive skills, technical skills, experience (including the latest total cases and lifetime total cases), and training (including fellowship, cardiology and interventional board certification, and CME).

Utilizing minimum case volumes for credentialing focuses on only 1 of many factors that may play a role. Case volumes are often used as a surrogate for quality on the presumption that a high volume enhances the operator skills. It is presumed that skill maintenance is also greater for both the operator and the institution if procedural volumes are high. The documented relationships between activity level and outcome are statistical associations, but they may be of limited clinical significance. The heterogeneity within hospital volume groups found by Epstein et al. (143) suggests that activity level is an incomplete surrogate for quality. High-volume operators and institutions are not necessarily of high quality, and low-volume operators and institutions are not by definition poor-quality operators. There is limited statistical power to judge the outcome results of low volume operators. Establishing appropriate oversight and QA programs is more important than volume measures alone. All major complications in any laboratory should be reviewed by the QA committee at least every 6 months, and individual operator complication rates exceeding national benchmarks for 2 contiguous 6-month periods should be reviewed by the QA director (76). Ideally an ongoing subset of cases performed by all operators should be reviewed yearly. To help facilitate the knowledge transfer that is important in continuous quality improvement, participation in catheterization laboratory conferences and a minimum of 12 hours of CME per year should be a required component for operators in the cardiac catheterization laboratory.

Simulation training offers an additional method of improving cognitive and technical skills that is increasingly being used to increase clinical competencies, including endovascular procedures (144). Simulation training is a tool that may be used for maintenance of certification in the Interventional Cardiology Board prerequisite and may be particularly useful for low-volume operators and for low-volume procedures. Simulation training of rarely performed and/or complex procedures and new protocols may be of value.

### 3.5.1. Operator Volumes

#### 3.5.1.1. OPERATORS PERFORMING DIAGNOSTIC PROCEDURES

Because of the low risk of diagnostic cardiac catheterization, it is difficult to arrive at any consensus as to what would constitute a minimum caseload. There are no data supporting the prior recommendation of at least 150 diagnostic cases per year (1). Previously, this has been simply convention. The minimum laboratory diagnostic caseload may vary widely depending on arbitrary requirements such as the presence of the CON process or state department of health regulations. It falls upon the director of the laboratory to ensure that all cardiac catheterization studies are appropriately indicated, performed, and interpreted (76). A maximum number of procedures that an operator should be

performing is also controversial, an area where there are essentially no data. This emphasizes the dependence on the QA process to monitor physician and laboratory behavior appropriately.

#### 3.5.1.2. OPERATORS PERFORMING INTERVENTIONAL CORONARY PROCEDURES

An annual interventional caseload of 75 procedures per year has been used for a considerable time as a standard for ensuring quality. Numerous analyses have addressed the relationship between individual operator caseload and procedural complications. Many of these studies have found an inverse relationship between volume and outcome (78,145,146) whereas others have found no relationship (147–149). Hospital volume affects the operator volume–outcome relationship (150,151). Malenka et al. (152) suggested that differences between high- and low-volume operators are minimized at a high-volume hospital. Moscucci et al. (153) examined the operator volume issue in the stent era and found no relationship between operator volume and in-hospital mortality, though the relationship between volume and any MACCE as measured by major cardiovascular event rates (death, CABG, cardiovascular accident or transient ischemic attack, MI, and repeat in-hospital PCI) was demonstrable. Although there does appear to be a statistical relationship between annual operator volume and MACCE rates, analysis of a linear plot examining these 2 variables reveals a scattergram, though the trend toward higher complication rates at lower volumes is observable (Fig. 3). In this figure, the majority of operators with procedural volumes <75 cases per year perform with excellent outcomes, whereas there are clearly operators >75 cases per year that have higher MACCE rates than expected. The value of using an annual threshold of 75 cases per year is limited when considering each individual operator.

In a report from the Cardiac Advisory Committee of New York State (58), the case volume range was dramatic, ranging from a very small number of cases (presumably only done when the physician was on call) over a 3-year period all the way up to a maximum of 3,722. No comment is made regarding any possible relationship between volumes and adverse outcomes. The report provides individual volumes for the 3-year period from 2004 through 2006, but the data are presented for each laboratory. Those that perform procedures at multiple laboratories are also noted. With those caveats, obviously creating the potential for substantial error, if it is assumed that 225 cases per 3 years should be the minimum for each operator during the 3-year period, then up to 57.9% of the listed physicians in the New York State Report (Table 3 of their report) did not meet the minimum criteria. In Table 4 of the report, 17.5% of operators performing procedures at multiple hospitals did not perform 225 procedures over the 3-year period. Even if these numbers are inaccurate by a wide margin, it does point out that there are many competent operators who do not perform the minimum of 75 PCI procedures per year.

SCAI has noted that the AHA report on the number of PCIs has been revised downward by about half, due to double counting. In the AHA Heart Disease and Stroke Update published in December 2010, the number of inpatient PCIs in 2007 is actually about 0.6 million rather than the 1.3 million in their publication (154).

As outlined earlier, performance of all interventionalists regardless of the volume of procedures performed should be assessed by a standing QA committee. There should be in place a review process to provide evidence to the appropriate oversight committee (usually the credentials committee in association with the director of the cardiac catheterization laboratory) that operators with <75 PCI procedures per year are having a random subset of their cases (at least 15%) critically reviewed each year. This should be in addition to the guidelines for the QA process for all operators as outlined earlier. The QA committee is encouraged to require within their bylaws that each operator obtain some level of PCI education every 2 years. This additional education should be mandatory for the lowest (<75 PCI per year) volume operators.

Volume requirements are of a magnitude of importance, as well as controversy, that a document specifically addressing clinical competence for cardiac interventional proce-

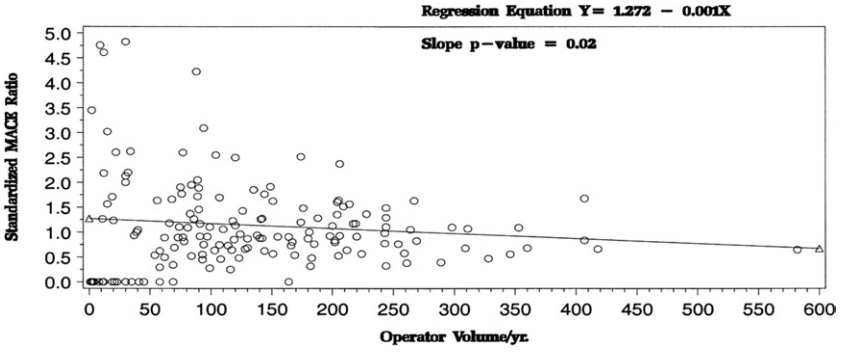


**Figure 3. Linear Plot of Standardized MACE Ratios (Observed/Predicted Rates) Versus Annual Operator Volume**

There remains only a general, but statistically important relationship with higher major adverse cardiovascular events (MACE) in operators doing fewer procedures. Reprinted from Moscucci et al. (153).

dures was developed in 1998, updated in 2007, and the issue is currently being revised. The results of that writing committee are embargoed at the time of this document's publication. The "2011 ACCF/AHA/SCAI Guideline on Percutaneous Coronary Intervention" also include the same volume requirements as herein stated, and it favors the observational evidence of a volume–outcome relationship in PCI at both the institutional and operator level (155). However, the guideline also acknowledges that the volume–outcome relationship is complicated and may be inconsistent across low-volume institutions or operators and that new data in primary PCI suggest that operator experience may modify the volume–outcome relationship at the institutional level (156,157). The ACCF/AHA/SCAI Writing Committee to Update the 2007 Clinical Competence Statement on Cardiac Interventional Procedures will review current data and environmental trends and recommend how we can best assess competence for both individual operators and institutions for PCI in the current era.

#### 3.5.1.3. PRIMARY PCI OPERATORS

PCI for AMI (primary angioplasty) is the application of PCI to, as a group, the sickest patient population undergoing PCI. Additionally, the constraints of D2B time of <90 minutes confer additional pressures on the operator and system. Current recommendations suggest that primary PCI be performed only by higher-volume operators experienced in both elective PCI and primary PCI for STEMI. The current guidelines recommend the operator perform >75 elective PCI procedures per year and about 1 primary PCI per month (11 per year) (6,158). The reality is that this requirement is not being followed in many institutions, would likely eliminate a large number of primary PCI operators, and is likely to prevent many institutions from providing 24/7 interventional calls due to a limited number of qualifying physicians. The data concerning volume–outcome relationship for primary PCI are particularly difficult to categorize because of the relatively small volume of STEMI patients per operator per year.

Vakili and Brown (159), analyzing primary PCI procedures for STEMI, could find no relationship between physician total PCI volume and mortality. The authors also reported an association between an operator's primary PCI activity level and the outcome of primary PCI for STEMI that was independent of the operator's experience in elective PCI (160). Hannan et al. (150) analyzed the New York State angioplasty registry data, found an increased in-hospital mortality at institutions with lower volumes of primary PCI, whereas Politi et al. (161) showed no relationship between operator volume and mortality or MACCE at a high-volume PCI institution. Other studies have also shown no relationship between institutional volume of primary PCI and in-hospital mortality. It is therefore recommended that all primary PCI procedures be subject to review by a designated QA committee, regardless of the operator volume. Operators who wish to perform primary PCI must participate in these reviews if they wish to continue to perform primary PCI. Each facility's QA process must determine whether the results are acceptable for both the institution and the operators involved.

**3.5.1.3.1.** PCI OPERATORS IN THE FACILITY WITHOUT CARDIOVASCULAR SURGICAL SUPPORT. Data from the ACC-NCDR, the largest and most comprehensive assessment of PCI centers with and without onsite cardiovascular surgery, reveal that there are more patients presenting to lower-volume centers without cardiovascular surgery with ACS than to full-service facilities (36). In comparison to sites with onsite cardiovascular surgical back-up, sites without onsite cardiovascular surgery have similar rates of procedural success, morbidity, need for emergency surgery, and risk-adjusted mortality for all patients. Centers without onsite cardiovascular surgery have significantly shorter reperfusion times (2.1 ± 5.1 versus 2.6 ± 8.4 h). Seventy-nine percent of these sites without cardiovascular surgery provide both elective and primary PCI. Eighty-one percent of interventional operators work at both offsite and onsite surgery facilities; only 17% operate exclusively at offsite centers. No differences have been reported in outcomes (36).

Compared with full-service PCI centers, offsite PCI programs are predominantly located in nonurban areas, have lower annual PCI volume, treat a higher percentage of patients who present with subsets of AMI, and have better door-to-reperfusion for primary PCI. These same sites have, for the most part, similar observed procedural success rates, morbidity, emergency cardiac surgery rates, and mortality in cases that required emergency surgery as full-service facilities. The risk-adjusted mortality rates in offsite PCI facilities are comparable to those of PCI centers that had cardiac surgery onsite, regardless of whether PCI is performed as primary therapy for STEMI or in a nonprimary setting. These issues have been previously addressed in this document (see Section 2.4.3.).

An SCAI expert consensus document (14) emphasizes that though offsite surgical backup can be performed with acceptable outcomes and risks, the development of such programs should be based on the health needs of a local area, not on desires for personal or institutional financial gain, prestige, market share, or other similar motives. They recommend that operators performing PCI without onsite surgery should perform ≥100 total PCIs per year, including ≥18 primary PCIs per year. They also recommend that initial operators at a facility without onsite cardiovascular surgical backup should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Operators in such facilities must demonstrate complication rates and outcomes equivalent or superior to national benchmarks and must evaluate their outcomes against established benchmarks.

There are obviously many operators performing primary PCI in facilities without cardiovascular surgical backup who do not meet these stringent guidelines, and these sugges-

tions have not been enforceable. The role of PCI without onsite cardiovascular surgical backup continues to evolve as a strategy for the delivery of care in patients with MI. Systems of care within a community should generally direct STEMI patients to facilities that are able to achieve a D2B time of <90 minutes and have a laboratory available on a 24 hours a day, 7 days a week basis. As pointed out earlier, the committee cannot recommend elective PCI programs without cardiovascular surgical backup that only provide primary PCI coverage during daytime and weekday hours.

It is the consensus of this committee that operators able to achieve successful primary PCI within the established guidelines may perform these procedures if there is a medically obvious advantage to the patient and the community. The decision must not be based on financial or prestige gain to the disadvantage of patient care. It should only be made available where there are written and enforceable guidelines from a full-service facility willing to accept patients should complications arise. Partnership with an experienced tertiary care hospital with a PCI program supported by cardiovascular surgery is mandatory. The organization of a primary PCI program and the patients eligible for primary PCI procedures in sites without onsite cardiovascular surgery have been discussed earlier and the highlights are outlined in Tables 2, 3, 4, 5, 6, and 7.

### 3.5.2. Institutional Minimum Caseloads

#### 3.5.2.1. DIAGNOSTIC CATHETERIZATION INSTITUTIONAL VOLUME

The minimum diagnostic caseload for the entire laboratory facility varies widely from state to state, often depending on the presence of the CON process or other frequently arbitrary requirements. It falls upon the director of the laboratory to ensure that all studies in the cardiac catheterization laboratory are of the highest quality. In general, high-volume laboratories have consistently been shown to have fewer complications than low-volume facilities, although quality cannot be presumed by analysis of the total laboratory volume alone. Minimum laboratory diagnostic volumes are generally about 600 cases per year for financial viability, and that figure is often used as a cutoff minimum value with no strong data to support that it is the minimum number for highest quality. In some states, a minimum volume of 200 diagnostic cases per year has been found acceptable. All of these minimum volume numbers appear arbitrary to the writing committee, and there is concern that very low-volume laboratories may be poorly equipped or poorly maintained because of cost constraints. Just as in PCI programs, facilities performing only diagnostic cardiac catheterization must have an ongoing QA program that functions to ensure that the procedures being done are appropriate and that there are no quality issues with the procedure, the reporting system, or the decision making based on the procedural results.

#### 3.5.2.2. INTERVENTIONAL CORONARY CATHETERIZATION INSTITUTIONAL VOLUME

In many states, the State Board of Health or the CON process will stipulate a minimum institutional PCI volume. McGrath et al. (145) examined institutional volume and outcome relationships. They noted an increased 30-day mortality rate of 4.29% for low-volume PCI programs performing <80 Medicare-reimbursed procedures per year versus high-volume programs that performed >160 Medicare procedures per year (3.15%). It should be noted that higher-volume facilities generally have the capacity to provide more extensive supplies and specialized equipment for PCI procedures, an immeasurable advantage in complex interventions and during unanticipated in-lab complications.

Kimmel et al. (78) using data from SCAI, found an inverse relationship between the number of PCI procedures a hospital performed and the rate of major complications. These results were risk stratified and independent of the patient-risk profile. There were significantly fewer complications in institutions that performed at least 400 PCIs yearly.

Jollis et al. (146) similarly found that low-volume hospitals were associated with higher rates of emergency coronary artery bypass surgery and death after PCI. Improved outcomes were identified at a threshold of 75 Medicare PCIs per physician and 200 Medicare PCIs per hospital. Using a 50% ratio of Medicare patients, the threshold value was estimated to be 150 to 200 PCIs per cardiologist and 400 to 600 PCIs per institution.

Epstein et al. (143), using an administrative dataset, analyzed risk-adjusted mortality in 362,748 admissions to 1,000 U.S. hospitals between 1997 and 2000, during which a PCI was performed. They found a consistent trend of decreasing risk-adjusted mortality with increasing hospital volume. The differences among groups were small, though. There was considerable heterogeneity within groups, suggesting that hospital volume was not the sole determinant of outcome. There are other studies that support the relationship of complication rate to institutional procedural volume (80,162,163). However, some investigators have pointed out that despite data that low procedure volume is poorly related to outcomes (164), many of these studies are small in number and underpowered (165). The National Health Service in the United Kingdom recently published the MACCE for each U.K. facility with data from 2007 and 2008 (Fig. 4) and found no linear relationship between MACCE and institutional volume (166), though improved outcomes were suggested when the institutional volume was >400 cases per year. These data form the basis for the recommendations of the Joint Working Group of PCI of the British Cardiovascular Society (167).

Based on data accumulated in the current stent era, a general volume–outcome relationship appears to exist. For example, Brown and coworkers (168) evaluated the out-

comes of PCI at all hospitals in California in 1997. Mortality and emergency CABG rates for PCI in which a stent was used was 1.5% and 1.2%, respectively, in hospitals performing <400 procedures per year compared with 1.1% and 0.8% in hospitals performing >400 procedures per year (110). Taken as a whole, an institution should be considered low volume if <400 PCI procedures are performed each year. The 2011 ACCF/AHA/SCAI guidelines consider a low laboratory volume of PCIs to be from 200 to 400 per year (158).

For both institutional and individual volume assessments, ongoing 2-year volumes should be measured then averaged to arrive at annual statistics. It is recommended that lower-volume institutions (<400 per year) must hold conferences with a more experienced partnering institution, with all staff expected to attend on a regular basis. Weekly cardiac catheterization laboratory conferences should be a mandatory aspect of the quality control and inspection program. It is also recommended that any institution that falls >2 standard deviations outside the risk-adjusted national benchmarks in mortality or emergency same-stay CABG during 2 of 3 contiguous 6-month periods have an external audit looking for opportunities to improve quality of care. The appropriateness of continuing to perform PCI procedures in an institution with low volume and unsatisfactory outcomes should be directly addressed from a medical standpoint and not from a financial or marketing standpoint.

### 3.5.3. Training

The cardiac catheterization laboratory represents a platform for training in invasive cardiovascular procedures. The goal of training programs is to teach the cognitive knowledge as well as the technical skills used in invasive cardiology. This includes indications and contraindications for the procedures, pre- and postprocedure care, management of complications, and the analysis and interpretation of hemodynamic and angiographic data. The trainee's professional goals determine the knowledge and skill set to be acquired during their time in the catheterization laboratory (169). The ACCF COCATS requirements differentiate among 3 levels of training based on distinct career goals (169). Level 1 training is designed for noninvasive cardiologists, whose invasive activities will be confined to critical care unit procedures. The goal of their catheterization laboratory experience is to learn the indications for procedures as well as how to interpret the data obtained in the laboratory. Level 2 training is for invasive cardiologists who will practice diagnostic, but not interventional, cardiac catheterization. Level 3 training is for interventional cardiologists who plan to perform both diagnostic and interventional cardiac catheterization (169).

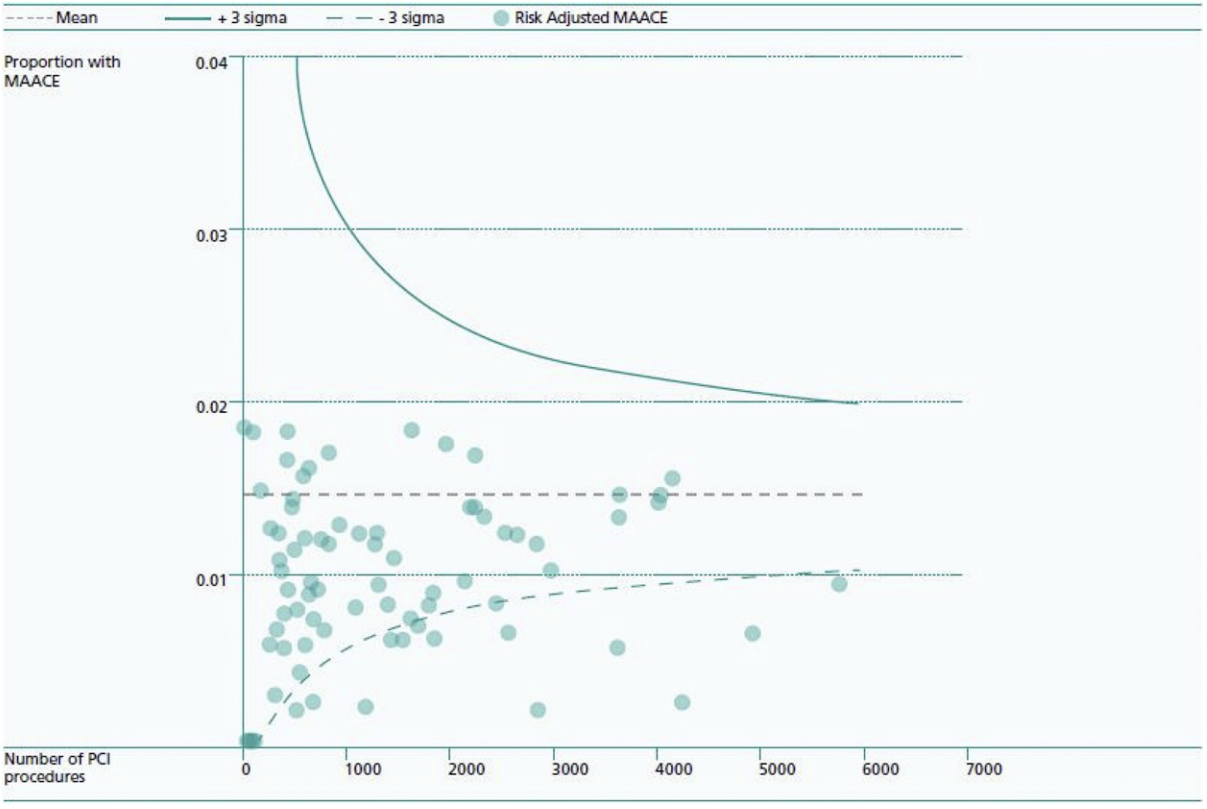


**Figure 4. Relationship Between MACCE and Institutional Volume**

No clear relationship is observable in this assessment of data from a national audit of PCI procedures in the United Kingdom (2007 and 2008). Reprinted from NHS Information Centre for Health and Social Care (166). MACCE = major adverse cardiac and cardiovascular events.

**Table 17. Summary of Training Requirements in Diagnostic and Interventional Cardiac Catheterization**

| Area | Level of Training | Minimum Number of Procedures | Cumulative Duration of Training (Months) |
|---|---|---|---|
| Diagnostic catheterization | 1 | 100 | 4 |
| | 2 | 200 (300 total) | 8 |
| Interventional catheterization | 3 | 250 | 20 |

Modified from Jacobs et al. (169).

#### 3.5.3.1. DIAGNOSTIC CARDIAC CATHETERIZATION AND PCI

A minimum of 4 months experience with at least 100 diagnostic catheterizations is required for Level 1 training, with 8 months experience and at least 200 additional cardiac catheterizations required for Level 2 (Table 17).

In contrast to diagnostic cardiac catheterization, training in PCI requires enrollment in an additional fellowship year in interventional cardiology in an Accreditation Council for Graduate Medical Education (ACGME)-accredited program (169). The trainee should participate in a minimum of 250 coronary interventional procedures during this year. In addition, the trainee should be proficient with the use of associated PCI procedures, such as IVUS and fractional flow reserve. Newer procedures, such as optical coherence tomography, may also find a role, and adequate training in such procedures should be anticipated. Completion of such a program leads to eligibility to sit for the American Board of Internal Medicine interventional cardiology examination. The goal should be that board certification is accomplished for everyone completing an accredited training program who wishes to actively participate in a coronary interventional practice. During fellowship training, all diagnostic and interventional cases should be performed under the direct supervision of a faculty member. Details of the cognitive knowledge and technical skills required for all 3 levels are outlined in the ACCF COCATS 3 training statement. Participation in cardiac catheterization conferences and exposure to cardiac catheterization research must be part of the training of all cardiology fellows.

#### 3.5.3.2. PERIPHERAL VASCULAR PROCEDURES

At present, catheter-based peripheral vascular interventions are performed by subspecialists with diverse formal training including interventional radiology, interventional cardiology, and vascular surgery. Although guidelines of each subspecialty society include endovascular procedures within their training curricula, there is a lack of uniformity regarding the amount of patient exposure required and the precise mechanisms for evaluation of the experience (101,170).

Specific knowledge required for safe and effective performance of peripheral interventions includes the pathophysiology, clinical manifestations, as well as the evaluation and treatment of diseases for a variety of vascular territories. The training requires knowledge of peripheral arterial disease, renal artery stenosis, extracranial cerebrovascular disease, vascular aneurysms and arterial dissections, mesenteric ischemia, and both arterial and venous thromboembolism (101). The ACCF COCATS 3 training statement suggests that for vascular medicine and peripheral catheter-based intervention, training be a minimum of 12 months for both Level 2 (vascular medicine specialist) and Level 3 (peripheral vascular intervention) competence (100). Level 3 peripheral vascular training may be undertaken concurrently with advanced training for coronary interventions, but it must include a minimum of 100 diagnostic peripheral angiograms and 50 noncardiac peripheral vascular interventional cases evenly distributed among the different vascular beds (100).

The fellowship training requirements for performing peripheral vascular interventions are detailed in Table 18. Simulation training has been shown to improve performance of carotid angiography (171). Lower–volume established operators may also benefit from including simulation training as part of their CME.

The ACCF/ACP/SCAI/SVM/SVS Writing Committee on Clinical Competence on Peripheral Vascular Disease suggests that in order to achieve a balanced experience required for competence, the trainee's experience should include no fewer than 20 diagnostic and 10 interventional

**Table 18. Formal Training to Achieve Competence in Peripheral Vascular Catheter-Based Interventions**

**Training requirements for cardiovascular physicians**

- **Duration of training*—12 months**
- **Diagnostic coronary angiograms†—300 cases (200 as the supervised primary operator)**
- **Diagnostic peripheral angiograms—100 cases (50 as supervised primary operator)**
- **Peripheral interventional cases†—50 cases (25 as supervised primary operator)**

**Training requirements for interventional radiologists**

- **Duration of training‡—12 months**
- **Diagnostic peripheral angiograms—100 cases (50 as supervised primary operator)**
- **Peripheral interventional cases†—50 cases (25 as supervised primary operator)**

**Training requirements for vascular surgeons**

- **Duration of training—12 months§**
- **Diagnostic peripheral angiograms‖—100 cases (50 as supervised primary operator)**
- **Peripheral interventional cases¶—50 cases (25 as supervised primary operator)**
- **Aortic aneurysm endografts—10 cases (5 as supervised primary operator)**

This table is consistent with current Residency Review Committee requirements. *After completing 24 months of core cardiovascular training and 8 months of cardiac catheterization. †Coronary catheterization procedures should be completed prior to interventional training. ‡After completing general radiology training. §In addition to 12 months of core vascular surgery training. ‖In addition to experience gained during open surgical procedures. ¶The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included.

individually supervised cases in each of the major vascular territories, including aortoiliac and brachiocephalic, abdominal visceral, renal, and infrainguinal (101). The 12-month training period is in addition to the 24 months required for clinical core cardiology training and at least 8 months acquiring experience in diagnostic cardiac catheterization in an ACGME-accredited fellowship program. It is recommended that the trainee perform a minimum of 300 diagnostic coronary procedures, including 200 procedures with supervised primary responsibility prior to beginning interventional training. The trainee should also participate in a minimum of 100 diagnostic peripheral angiograms and 50 noncardiac peripheral vascular interventional cases during the interventional training period. At least 50 of the diagnostic angiograms and 25 of the interventional cases should be as supervised primary operator. The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis that utilizes percutaneous thrombolysis or thrombectomy should be included.

#### 3.5.3.3. STRUCTURAL HEART DISEASE

The inherent problems in setting threshold volumes in structural intervention is that the procedures—as compared to coronary artery interventions—are more diverse, of higher complexity, of lower frequency, and often require a multidisciplinary approach. Many of these procedures require multiple imaging modalities during the procedure (fluoroscopy and echocardiographic imaging). In addition, most of these procedures are in evolution in terms of indications, procedural issues, devices, and outcomes (172). The current guidelines on congenital heart disease do not offer volume guidelines (173). SCAI is actively addressing this issue and has recently published initial guidelines regarding training (174) as well as a survey of physicians to gain a better understanding of how best to establish competence (175).

Percutaneous noncoronary cardiac interventions for structural heart disease, including ASD and PFO closure, alcohol septal ablation therapy, and valvuloplasty represent growing and important components of the field of interventional cardiology. In addition, newer methods are being investigated for percutaneously approaching closure of other congenital vascular defects and connections as well as repairing or replacing cardiac valvular abnormalities. Although it is recommended that trainees in interventional cardiology programs get exposure to these procedures (169,176), at present, there are few official guidelines for training in each of these interventions. Guidelines for alcohol ablation for hypertrophic cardiomyopathy suggest a minimum of 20 procedures is required for proficiency. The "ACCF/AHA/SCAI 2007 Update of the Clinical Competence Statement on Cardiac Interventional Procedures" provides a review of the additional knowledge skills and training that are necessary for gaining competence in structural heart interventions (6). Due to the small number of these procedures performed, and the specialized knowledge and skills required, it is recommended that both training and practice activity be concentrated among a limited number of operators to allow for adequate expertise to be obtained (169).

For PFO and ASD closure or for the use of alcohol septal ablation in the treatment of the outflow tract gradient in hypertrophic cardiomyopathy, a minimum of 10 procedures each during training is recommended for trainees whose goal is to perform these procedures independently. Alcohol septal ablation should be offered only in those institutions that can employ a multidisciplinary program for pre- and postprocedural evaluation, careful case selection, and assessment of clinical outcomes. If available, partnership with a pediatric interventionalist should be considered when performing septal closure with the available percutaneous devices. In almost all situations the proper performance of interventions in structural heart disease requires a multidisciplinary team of cardiologists, cardiothoracic surgeons, vascular specialists, noninvasive imaging specialists, and radiologists.

Percutaneous aortic and mitral valvuloplasties are among the most complex and challenging interventional procedures. The importance of an operator learning curve has been well described for both of these interventions (177–179). Therefore, it has been recommended that 5 to 10 cases be performed with an experienced colleague, before performing balloon valvuloplasty independently (6). The significance of a learning curve is even more applicable for novel techniques such as percutaneous mitral valve repair, the closure of prosthetic paravalvular regurgitation, or transcatheter valve replacement. At the time of this document, most of these latter procedures remain primarily within clinical trials (177). In order for laboratories to become competent in the performance of structural heart procedures, the supervising or performing operator should be fully credentialed by the local facility in the procedure. Initially, this may require offsite training, simulation training, a visiting proctor, or a combination of these approaches. These procedures should only be done in a full-service hospital facility (Table 2). The operator responsible for the performance of the procedure in the catheterization laboratory should educate and supervise the staff in acquiring the necessary skills for the particular procedure. Since these are essentially always lower-volume procedures, there should be a small number of dedicated staff members and operators trained to perform structural heart procedures. For adult cardiologists performing these studies, a close working relationship with pediatric invasive cardiologists is also critical to ensure optimal performance in addressing percutaneous approaches to adults with congenital heart disease.

## 4. Procedural Issues in the Cardiac Catheterization Laboratory

### 4.1. Safety in Patients With Communicable Diseases

Screening for blood-borne pathogens is not routinely performed before referral to the cardiac catheterization laboratory. Therefore, it should be assumed that every patient has the potential to transmit an infectious agent. This reinforces the need to apply Universal Precautions in the cardiac catheterization laboratory. However, some patients referred for cardiac catheterization laboratory will be known to carry the HIV or the hepatitis virus (180). Heightened protective care should be taken in any case in which a communicable disease such as hepatitis or HIV positivity is present. Every cardiac catheterization laboratory should have an approved additional sterile technique protocol for known highly infectious cases. This protocol should include the use of surgical caps and masks as well as eye protection. Double gloving has been shown to reduce the chances of a puncture and to better clean an inadvertent needle that has punctured the gloves. In a study by Gerberding et al. (181), 17.5% of gloves developed a perforation during surgery. Wearing 2 pairs of gloves reduced the chances of a puncture hole in the inner glove by 60%. Though this practice has not proven to prevent transmission of hepatitis or HIV, it seems prudent to use this technique when the operator is working with high-risk patients. In case of blood-borne pathogen exposure to personnel, the catheterization laboratory should have in place ready access to hospital occupational health resources to rapidly address the risk of exposure to the staff along with the appropriate treatment, if indicated. For example, timely assessment and treatment of HIV-exposed personnel can reduce the risk of HIV-seroconversion. In addition to the usual surgical gown, disposable shoe covers for the cardiologist and all technicians and nurses in the room should be considered. Protective eyewear should be worn by all in-room personnel to prevent accidental blood exposure to the operator's eyes. The careful disposal of all needles, catheters, sheaths, tubing, and other instruments, as well as fluids that come in contact with the infected patient, is obviously important. Disposal of protective gear and all contaminated equipment at the end of the procedure as well as proper disinfection for nondisposable equipment is also important, especially for blood-borne pathogens that are communicable by contact (e.g., methicillin-resistant *Staphylococcus aureus*).

Vaccination for hepatitis B virus should be strongly considered, if not mandatory, for all operators and other personnel who work in the cardiac catheterization laboratory (182).

### 4.2. Patient Preparation

Many laboratories use a checklist to ensure that all relevant data are available prior to a procedure. Although this can be individualized, the checklist should at least include the patient name and hospital number, birth date, the procedure being planned, the status of the consent form signing, the core physical exam features, the indications for the procedure, the American Society of Anesthesiologists classification, the planned site of entry, medications and any allergies, pertinent laboratory findings (including creatinine clearance), and proposed contrast media limit.

Prior to any procedure, appropriate informed consent must be obtained. Discussing the risks and benefits of the procedure, as well as the alternatives to the procedure, must be done. Each facility must have an approved consent form that includes risks of the procedure in terms the patient can understand. For most coronary procedures, the potential need for ad hoc PCI should be included along with the adherent additional risks reviewed. All elective PCI procedures must mention the possible need for surgical intervention. The written informed consent may be obtained by trained secondary operators or physician extenders, but the major concerns should be reiterated when the primary operator discusses the procedure with the patient. Risks of PCI should be explained at the same time as the diagnostic catheterization risks, if the case has the possibility of requiring PCI immediately following the diagnostic procedure.

Educating each patient about the procedure and explaining in detail what they should expect allays patients' anxiety and ensures patients are fully informed. Additional procedures that the patient has not consented to must not be performed unless a life-threatening emergency develops. Written informed consent should be obtained in all elective cases, and ideally in emergency cases. However, in cases that are emergent, it is recognized that written informed consent may not be feasible. In these cases, local standards for documentation of necessity should apply, and documentation should be clearly written in the patient's record.

Prior to the start of the procedure, calling a time-out assures that the appropriate procedure is being performed on the correct patient. This is now a Joint Commission on Accreditation of Healthcare Organizations requirement. The time-out period must occur before the patient is sedated at the start of the procedure. The time-out participants include the attending physician, any trainees or other participating secondary operators, and the procedural staff. The patient should participate if awake to confirm the information. A member of the procedural staff or the attending physician should initiate the time-out period. The elements of the time-out must include, but are not limited to the following: 1) correct patient name; 2) correct procedure being performed; 3) consent signed; 4) confirmation of any allergies; 5) any antibiotic administration; 6) correct site and side is being used; 7) confirmation of pre-wash performed, if indicated, and/or double prep, if necessary; and 8) availability of any special equipment and/or imaging studies that will be used during the procedure.

### 4.2.1. Minimum Laboratory Data in Preparation for the Procedure

Within 2 to 4 weeks prior to any cardiac catheterization procedure, a hemoglobin, platelet count, electrolyte panel, and creatinine should be obtained on all patients. If the patient arrives and has had any significant clinical change or recent contrast exposure since the laboratory tests were obtained, the studies should be repeated on the day of the procedure and prior to the catheterization.

Unless the patient has a known liver disease or a hematologic condition that might affect hemostasis or is on antithrombin therapy, the consensus of the committee is that the routine acquisition of a protime/INR procedure is optional and no longer necessary before the cardiac catheterization in most cases.

In addition, the committee feels that the patient's need for overnight NPO is not always in the best interest of patient hemodynamics, and only a minimum NPO period of 3 hours is sufficient, unless conscious sedation will clearly be required. If conscious sedation is required, the NPO period is suggested to be at least 4 hours. The American Society of Anesthesiologists last published NPO guidelines in 1999, at which time they suggested 2 hours of fasting after clear liquids and 6 hours after a light meal (183). Adequate hydration remains an overlooked but is an important preparatory feature.

Women of child-bearing age should have a urine beta-HCG level or a serum beta-HCG checked within 2 weeks prior to the procedure to exclude pregnancy. During the initial 2 weeks of gestation, the embryo has little risk from ionizing radiation unless a large dose is received (>100 mGy). At that exposure, there is a higher likelihood of fetal death or failure of the blastocyst to implant. The uterus provides considerable protection. Since only a few cells make up the embryo during that period, embryo cells that survive are progenitors of many other cells and exhibit no ill effects from the radiation exposure (206a). The data thus appear to justify the 2-week margin before any woman of child-bearing age receives ionizing radiation.

The presence of a nickel allergy has also been a concern for patients in whom a nickel-containing device may be implanted. It is estimated that about 15% of the population has a skin nickel allergy (184). Nitinol is a nickel/titanium alloy used in self-expanding devices. One report suggests nickel allergy may result in an increase in migraine headaches after ASD or PFO closure with large occluder devices made from nitinol (185). Another report suggested the use of the Helex device rather than the Amplatzer to prevent any nickel allergic reactions (186). The Helex device minimizes the nitinol exposure as its circumferential support is enclosed in an ePTFE membrane. Coronary stents are made of stainless steel, which is biologically inert but may contain as much as 5% nickel. Although there are anecdotal data regarding early stent closure in nickel-allergic patients, there are no data to support routine skin testing for nickel allergy before the use of either occluder devices, or of coronary or vascular stents at the present time.

### 4.2.2. Patients Receiving Antiplatelet and Antithrombin Agents

Aspirin is not stopped or held prior to cardiac catheterization, and if patients have not been taking aspirin, it should be started prior to the procedure. Many patients are loaded with or started on thienopyridines prior to cardiac catheterization if there is a high likelihood of PCI and low likelihood of CABG. Ticlopidine is generally no longer used (except in the rare clopidogrel-allergic patient), and newer antiplatelet agents are becoming increasingly available and may be substituted when medically indicated.

Patients taking warfarin should be instructed to stop taking it at least 3 days prior to the catheterization, and their INR should be checked prior to the procedure. An acceptable INR to perform femoral artery cardiac catheterization procedure is <1.8.; an INR of <2.2 is acceptable for radial access. These thresholds are rather arbitrary and based on scant data. Of note, a new study of fully anticoagulated patients undergoing PCI from either the radial or femoral access site suggests a major advantage to the use of radial access regarding periprocedural bleeding (187). Overuse of parenteral vitamin K may make it difficult to re-establish an antithrombin effect following the procedure, therefore allowing the patient's INR to drift downward after stopping the medication is preferred. In high-risk groups, especially those with mechanical heart valves, a bridging protocol is generally followed (188).

Patients receiving heparin, low-molecular-weight heparin, or glycoprotein IIb/IIIa inhibitors undergo cardiac catheterization safely with only a minimum increase of bleeding risk, particularly in the setting of an ACS. A longer time to hemostasis may be required postprocedure, and the combination of aspirin, heparin, and other antiplatelet agents increases the risk of bleeding. Newer non-heparin anticoagulants may require a change in practice regarding the timing of performing cardiac catheterizations and subsequent angioplasty procedures. Following activated clotting times (ACTs) for patients on IV heparin has been the standard for years. With newer low-molecular-weight heparins, factor Xa inhibitors, and direct thrombin inhibitors (e.g., bivalirudin [Angiomax]), ACTs are often not appropriate. Knowledge of the time when the last dose of the low-molecular-weight heparin or factor Xa inhibitor will dictate further anticoagulant therapy during PCI procedures, risk of bleeding, and the timing of sheath removal. The half-life of bivalirudin is short, 25 minutes in patients with normal renal function.

Dabigatran etexilate (188a) is a small nonpeptide molecule that reversibly inhibits both free and clot-bound thrombin (factor IIa) and has been approved for stroke prevention in patients with atrial fibrillation. At the time of this writing, it is being actively investigated for other indica-

tions. It has a predicable pharmacokinetic profile that allows for a routine dosing regimen without need for routine coagulation monitoring. Peak effect occurs in 2 to 4 hours after administration. Its estimated half-life is 15 hours with normal renal function. Testing for its effect provides a qualitative and not quantitative measure. It does not alter the INR. The activated partial thromboplastin time (aPTT), although not sensitive to the effects, can provide negative predictive value; an aPTT <30 seconds suggests no effect, whereas the median peak aPTT level is about 2 times control. The thrombin time for direct thrombin inhibition is sensitive, though it is still most useful to exclude an anticoagulant effect as other anticoagulant agents can affect its value. The ecarin clotting time has a linear relationship with dabigatran levels, but at present, it is not widely available. Drug levels are affected by renal function. Based on the pharmacokinetics, in patients with normal renal function (eGFR >50 mL/min), discontinuation of 2 doses results in a decrease in the plasma level to about 25% of baseline, and discontinuation of 4 doses will decrease the level to about 5% to 10%. Some reversal of the effects can be achieved by the use of recombinant activated factor VII and prothrombin complex concentrates. It can also be removed with dialysis. About 60% is removed after 2 to 3 hours of dialysis. From a practical standpoint, the drug should be stopped 24 hours (2 doses) prior to cardiac catheterization if the eGFR is >50 mL/min and for 48 hours if the eGFR is 30 mL/min to 50 mL/min. The drug should not be used in patients with eGFR <30 mL/min. The anticoagulant effect in patients with such chronic kidney disease (eGFR <30 mL/min) may persist for 2 to 5 days (189).

Rivaroxaban, a factor Xa inhibitor that is structurally similar to the antibiotic linezolid, has now been approved by the Food and Drug Administration (FDA) as a once-a-day alternative to warfarin. Apixaban, a factor IIa inhibitor similar to dabigatran, is likely to be available soon. A review summarizes their potential advantages and uses (190).

### 4.2.3. Chronic Kidney Disease/Renal Insufficiency

Though there is some controversy regarding the classification of patients with CKD, groups can be divided by glomerular filtration rate (GFR) into 5 categories (based on the Modification in Diet in Renal Disease [MDRD] GFR calculation method). The stages are outlined in Table 19.

**Table 19. Progressive Stages in Renal Dysfunction Utilizing the GFR via the MDRD Method**

| Stage | Severity | GFR (mL/min/1.73 $m^2$) |
|---|---|---|
| I | Slight | <90 |
| II | Mild | 60 to 89 |
| III | Moderate | 30 to 59 |
| IV | Severe | 15 to 29 |
| V | Severe and established | <15 |

Reprinted with permission from Levey et al. (191).
GFR = glomerular filtration rate; and MDRD = Modification of Diet in Renal Disease.

The occurrence of contrast-induced nephropathy (CIN) correlates directly with the severity of chronic kidney disease, contrast volume, and the combination of chronic kidney disease and diabetes mellitus. CIN carries a poor prognosis, particularly if patients become dialysis dependent; however, the occurrence of CIN varies widely depending on the definition used (192). Two definitions (an incremental increase in creatinine >0.5 mg/dL and >25% rise in serum creatinine) are now accepted as a measure of CIN occurrence (193). A multitude of studies have been performed using different iodinated contrast agents, gadolinium, and various modalities to try and prevent contrast nephropathy.

#### 4.2.3.1. ATTEMPTS TO REDUCE THE RISK OF CONTRAST NEPHROPATHY

The cause of nephropathy following radiographic contrast is unknown. There are data that suggest both renal vasoconstriction and direct (possibly free-radical injury) play a role. Some reduction of contrast nephropathy can be accomplished by minimizing contrast volume (194). Iso-osmolar or low-osmolar contrast agents are preferred. One report suggests the volume threshold can be estimated by using the ratio of contrast volume to creatinine clearance. Nephrotoxicity is more likely when the contrast volume/creatinine clearance ratio exceeds 3.7:1 (195).

Biplane coronary angiography should be utilized to reduce the contrast load if the equipment is available. Avoiding unnecessary "test" or "puff" injections, eliminating ventriculography and aortography, and taking the least number of angiograms can limit contrast volume. Careful fluoroscopy setup to reduce panning and use of a higher frame rate may also reduce the volume of each contrast injection per image acquisition. Performing ad hoc interventions and combined coronary and peripheral procedures should be carefully reviewed. There should be a low threshold to have the patient return for a repeat procedure to avoid large volumes of contrast during a single procedure. A discussion of maximum contrast limits should be part of the initial "time-out" before the procedure. N-acetylcysteine has been extensively studied, but the latest randomized data from the Acetylcysteine for Contrast-Induced Nephropathy trial evaluated the effectiveness using large doses of acetylcysteine in 2,308 patients before and after the use of contrast media, and the authors found no evidence for prevention of CIN (196). Its use is no longer recommended. Vitamin C has also been used with some favorable effect to reduce free-radical injury, as has sodium bicarbonate. None have been consistently useful, though, and none proven in any large randomized trial. Fenoldapam and theophylline, agents used to reduce the vasoconstrictive component, have not been found effective (192), and the use of gadolinium is not recommended for coronary angiography but has been used in renal and peripheral angiography (197).

Prehydration and posthydration with normal saline or sodium bicarbonate has been the gold standard for reducing the incidence of contrast nephropathy and the only modality

that has consistently been shown to be of some value. This is generally easy to accomplish in an inpatient setting; however, it is more difficult in an outpatient setting. The use of sodium bicarbonate infusion 1 hour prior to and 6 hours after angiography has been shown to decrease contrast nephropathy in some studies and might have an advantage compared to normal saline hydration, though the advantage is very modest (198).

Continuous veno-venous hemofiltration and hemodialysis have been tested and the benefits remain unclear. It may be considered in the very high-risk patients (199). There are also data suggesting an advantage with the use of statins (200) and the use of iso-osmolar contrast (201). However, the latest data do not suggest an advantage of iso-osmolar contrast over low-osmolar agents (202). Guidelines to reduce contrast nephrotoxicity have been developed by SCAI (203) and the Contrast Nephropathy Working Group that met in 2006 (204). At this juncture, the only recommendations the writing committee suggests are outlined in Table 20. These are consistent with the "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention" as well (158).

### 4.2.4. Other Contrast Media Reactions

Identifying patients at risk for a reaction to iodinated contrast remains a cornerstone of the preprocedure history. Besides the nephrotoxicity issues noted above, contrast media reactions include 1) acute hypersensitivity (anaphylactoid reactions—non-IgE mediated); 2) delayed hypersensitivity (IgE mediated and often resulting in rash or fever up to 48 hours after the procedure); 3) acute hemodynamic or electrophysiological consequences during the procedure (now less common with low-osmolar and iso-osmolar contrast); 4) possible hypercoagulation (e.g., stressing the importance of minimizing the contrast media–blood interface in syringes); and 5) hyperthyroidism (the only real side effect due to the iodine in the contrast media—seen usually in elderly patients with history of thyroid nodules).

A previous anaphylactoid reaction and a history of atopic conditions such as asthma are the most significant risk factors for acute hypersensitivity reactions (205). It should be recognized that contrast reactions can be idiosyncratic so that a history of any past reaction (regardless of subsequent reactions) should be treated. Patients with other food or medication allergies, those of an advanced age, and women are at higher risk. It has never been shown that patients with a history of shellfish allergy have a higher risk of a reaction to radiocontrast media and, in fact, the allergen is actually in the tropomysin protein and appears unrelated to iodine. Pre-medication is recommended for those with a strong atopic history and for patients with a known prior allergy to contrast. It appears that anaphylactoid reactions are much more common when contrast is administered in the venous rather than the arterial circulation, so these types of potentially life-threatening reactions are much more common with computed tomography (CT) angiography or IV pyelography use than during cardiac angiography. Premedication regimens with H2 blockers and steroids are recommended for the highest-risk atopic patients, particularly those with known prior reaction. Current options include giving 50 mg oral prednisone 13 hours, 7 hours, and 1 hour prior to the procedure or 200 mg IV hydrocortisone 2 hours before the cardiac catheterization with or without H2 blockers (205). Anaphylaxis results in profound vasodilation, bronchospasm, and circulatory collapse. Treatment not only includes epinephrine but requires circulatory support with large doses of IV fluids and other inotropic agents.

The importance of recognizing delayed hypersensitivity due to contrast is important to avoid stopping appropriate medications, such as clopidogrel, on the assumption the transient fever and rash may be due to a new medication started after the procedure rather than simply due to the contrast media.

### 4.2.5. Diabetes Mellitus

Patients with diabetes mellitus require precautions to prevent hypoglycemia. Insulin doses the night before are generally cut in half, and in the morning oral hypoglycemic and insulin are held. These patients should be scheduled early in the morning to avoid prolonged fasting. Blood glucose levels should be checked upon arrival in the precatheterization staging area and treated accordingly. Patients with normal renal function taking metformin are instructed to not take the metformin the day of the procedure and not to restart it for at least 48 hours afterwards and until an assurance of no contrast-related nephropathy (206). The danger of metformin and contrast media is the clinical syndrome of severe and persistent lactic acidosis. This syndrome invariably occurs in patients with renal insufficiency, and metformin should not be used in this group anyway. Because diabetes mellitus itself is an independent

**Table 20. Suggested Protocol to Reduce the Incidence of Contrast-Associated Nephropathy Following Cardiac Catheterization**

| |
|---|
| 1. Identify risks |
| a. Highest risk—eGFR <60 mL/min/1.73 $m^2$ |
| b. Diabetes |
| 2. Manage medications |
| a. Hold nephrotoxic drugs (e.g., NSAIDS) |
| 3. Manage intravascular volume |
| a. Hydrate with either normal saline or sodium bicarbonate (either acceptable) |
| b. Hydrate with 1.0 to 1.5 mL/kg/min for 3 to 12 hours before and 6 to 12 hours post |
| 4. Radiographic contrast |
| a. Minimize contrast volume |
| b. Use either low-osmolar or iso-osmolar contrast |
| 5. Follow-up data: obtain 48-hour creatinine |

eGFR = estimated glomerular filtration rate; NSAIDS = nonsteroidal anti-inflammatory drugs.

risk factor for contrast nephropathy, the current recommendations are to stop the metformin the day of the procedure and not resume (usually 48 hours) until a normal creatinine level has been documented (see Table 20).

#### 4.2.6. Sedatives and Relaxants

Conscious sedation is most commonly used for the majority of procedures performed in the catheterization laboratory. Appropriate sedation is imperative and ensures patient comfort. Pre-medication with oral diphenhydramine and diazepam is common. IV sedative hypnotics and analgesic regimens vary. A combination of midazolam and fentanyl citrate is very popular. IV morphine, diphenhydramine, and hydromorphone hydrochloride are also used. Conscious sedation protocols must be strictly adhered to and excessive sedation should be avoided. All patients should have baseline blood pressure (BP), oxygen saturation, and heart rate and rhythm documented. These vital signs must be monitored closely throughout the procedure and in recovery. Reversal agents should be readily accessible in the laboratory.

General anesthesia is often used if transesophageal echocardiography is required for a procedure. Many patients undergoing valvuloplasty, percutaneous aortic or mitral valve procedures, and ASD and PFO closures are managed, with the assistance of an anesthesiologist, under general anesthesia.

#### 4.2.7. Heparin-Induced Antibodies

Great precautions must be taken in patients with known antibodies to heparin. Heparinized flush is not to be used in the manifold system. Therefore, great care must be taken between catheter exchanges with wiping wires thoroughly, and extra attention to flushing the sheaths and catheters must be performed. If patients require anticoagulation, then direct thrombin inhibitors are used.

#### 4.2.8. Pregnant Patients

Radiation exposure should be avoided as much as possible in pregnant patients. The concept of ALARA (As Low As Reasonably Achievable) in regard to radiation dose should always be followed. Despite the fact that direct x-ray targeting during the procedure mostly affects the upper torso, Compton scattering within the body results in indirect x-ray exposure to the developing fetus. Efforts to minimize x-ray dose should also include using low fluoroscopy settings or in-laboratory echocardiography rather than cineangiography, limiting total exposure time, using reduced framing rates, using the minimum number of contrast injections, and avoiding angulated or magnified views when possible. A lead apron between the x-ray tube and abdomen is recommended. The fetus is less vulnerable during the first 2 weeks of gestation but becomes especially vulnerable during the duration of the first trimester (206a).

### 4.3. Access Site (Femoral, Radial, Brachial)

The most common site for percutaneous arterial access for both diagnostic and interventional cardiac procedures is the common femoral artery. Localization of the appropriate access insertion using the radiographic femoral head as a marker has been popular and found helpful. The sheath entry should be located within the femoral artery at the medial third of the femoral head (207). The radial artery approach is gaining more and more popularity, especially for obese patients and outpatients. The use of the radial approach in the United States remains much lower than many other countries, despite fewer bleeding complications using the radial approach compared with the femoral artery approach in the elderly and those undergoing PCI for ACS (208). Brachial access is rarely used. Brachial cut-downs are, at this point, of historical interest only. Femoral cut-downs for large abdominal aortic aneurysm stent grafts or for percutaneous aortic valve replacement are still required at times. In cases where greater wound exposure is necessary, such as in pacemaker implantation or femoral cut-downs, a full surgical sterile technique should be used. A vascular sheath should be used to minimize vascular trauma, especially when multiple catheter changes are anticipated. Each percutaneous vascular site (femoral, brachial, radial, subclavian, or internal jugular) requires that the operator have specialized training. Although some aspects of percutaneous vascular access are similar for all sites, certain issues (e.g., compression and/or administration of heparin or intravascular verapamil or nitroglycerin) are unique to each site. If venous access is required, in most cases it should be performed using the femoral vein or the internal jugular vein. The use of ultrasound to localize and facilitate cannulation, particularly of the internal jugular and subclavian veins has become routine in many institutions. Multiple venous catheters can be safely inserted in the same femoral vein; multiple arterial catheters require separate arterial access sites. In radial artery access cases, it is routine and acceptable to obtain venous access via the femoral vein. Strict sterile procedures should be followed at each site.

### 4.4. During the Procedure

#### 4.4.1. Medications

Adequate hydration, appropriate for the patient's underlying condition, is important before the procedure. Drugs, such as long-acting phosphodiesterase inhibitors (e.g., tadalafil) should be held in case nitrates would be needed. Chlorhexadine is now the preferred prep solution over the use of betadine.

Multiple medications can be administered during the catheterization procedure. These are related to sedation, procedural performance, and BP or heart rate changes. Anticoagulants, antiplatelet adjuncts, and emergency-related medications may also be used. Vasoactive medications for either high or low BP may be required depending on the clinical situation. The selection of the appropriate agent should be based on the

individual patient, clinical setting, and etiology of the abnormal hemodynamic state. Hypertension is common, in part because of the heightened adrenergic tone from anxiety, as well as from the underlying condition. Treating high BP during a procedure (after adequate sedation) can be accomplished with IV boluses of hydralazine, labetalol, nicardipine, or metoprolol. Nitroprusside and nitroglycerin continuous infusions may also be of benefit. Caution should be exercised in patients with certain conditions, such as severe pulmonary hypertension or critical aortic stenosis. Hypotension must be diagnosed and managed aggressively, and management is critically dependent on the etiology. Vagal episodes are characterized by an inappropriately low heart rate in association with hypotension, whereas other causes of hypotension are generally associated with a high compensatory heart rate. IV fluid boluses with normal saline are often first-line therapy for hypotension from any cause. Patients are commonly dehydrated from having food and drink withheld for many hours prior to the procedure. If volume resuscitation is unsuccessful, dopamine, norepinephrine, and phenylephrine infusions can be started to maintain adequate BP. Specific conditions that need to be considered and treated include vagal reaction, hemorrhage, allergic reaction (anaphylaxis), cardiac tamponade, or cardiogenic shock.

During both diagnostic angiography and percutaneous coronary interventions, a variety of vasodilator agents may be required. These agents include intracoronary nitroglycerin, nitroprusside, verapamil, nicardapine, adenosine, and other vasodilators. There is a significant variation regarding the use of intracoronary vasodilators among hospitals. Cardiac catheterization labs should have standard medication doses and procedures regarding the use of these medications so that all personnel are familiar with the most commonly used and requested vasodilators in their region.

### 4.4.2. Sterile Techniques

Infection is rare after invasive cardiovascular procedures. The Occupational Safety and Health Administration recommends that preparation of all patients include the removal of hair from the site (electric clippers are preferred over typical razor-blade shaving to avoid skin abrasion), application of antiseptic to the skin, and the use of sterile drapes. Sterile covers for the image intensifier and protective operator shielding should be placed when these are used over or next to the sterile field. Systemic antibiotics are not required, although some operators use them with large-vessel noncoronary stents or other devices that will be left in the body. A generally sterile environment should be maintained during the procedure. Disposal of all materials should also follow local safety and infection control guidelines.

Although the strict sterile techniques used in the operating room are not necessary for most cardiac catheterization laboratory procedures, operators should use appropriate hand washing and wear a sterile gown and gloves. Personnel should wear hospital-based scrub attire. Occupational and Health Safety Guidelines (180) and Usual Precaution Guidelines suggest that masks, an eye shield, and protective caps should be worn during cardiac catheterization. These protect from accidental blood exposure to the operator as well as help preserve the sterile access field. Strict adherence to aseptic techniques are mandatory when devices are being implanted, such as those used in the treatment of structural heart disease.

### 4.4.3. Technical Issues

#### 4.4.3.1. CORONARY ANGIOGRAPHY

The safe injection of a contrast agent into coronary arteries is predicated on the coaxial placement of the coronary catheter in the coronary ostium and the correct positioning of the tip of the catheter in the coronary artery. Assurance of an air-free connection between the contrast manifold port or syringe and the catheter must be established. To avoid red blood cell clumping and potential thrombus formation, the syringes should be flushed clear of blood. Careful replenishment of contrast in the injection syringe and the maintenance of an air-free environment is the responsibility of the operating cardiologist. Most invasive cardiologists inject the coronary arteries manually themselves or use support personnel to perform the injection. Specialized mechanical injectors can be used with appropriate equipment and training. Coronary injections should include a tiny test dose of contrast once the catheter tip is in position. This ensures that the catheter is not subintimal or under a plaque that might result in an extensive coronary artery dissection if a full injection of contrast were administered. Monitoring catheter tip pressure is obligatory. A "flush" injection into the respective coronary sinus may help define ostial coronary disease.

It remains the responsibility of the individual invasive cardiologist to ascertain whether nonphysician personnel or power injectors are capable of administering contrast into the coronary arteries. Physician extenders should never be primary operators. They can be secondary operators but should always be viewed as extensions of the primary operator's hands, with the responsibility for safety ultimately residing with the invasive cardiologist.

In the majority of cases, the use of single-plane x-ray imaging is satisfactory, recognizing that most laboratories do not have biplane capabilities. It is desirable for laboratories contemplating angiographic evaluation of patients with congenital heart disease, however, to have biplane capabilities. A biplane option also is useful to keep contrast volume at a minimum in patients with renal failure. In the case of left ventriculography in patients with coronary artery disease, an appropriate view should be selected to gain the most information regarding LV function. This may include a left anterior oblique view if left circumflex disease is discovered, and there is interest in observing lateral ventricular wall motion. The use of noninvasive modalities to assess wall motion and ejection fraction prior to the cathe-

terization procedure has reduced the frequency with which LV angiography is now required.

The use of multiple orthogonal views of the coronary arteries is of obvious importance, as coronary lesions are defined by "worst view." The invasive cardiologist must be certain that appropriate information is obtained and recorded in order to make an accurate diagnosis and to determine suitability for PCI or CABG. Each segment of the coronary artery should be seen in at least 2 orthogonal views. Although it may be helpful and expeditious to have routine views performed on each coronary study, additional views should be obtained if the anatomy is not clearly presented or there are overlapping structures. The knowledge and application of additional views is the hallmark of excellence for angiographers.

In the case of right-heart and pulmonary angiography, it is important that the appropriate views be obtained to demonstrate the anatomy being interrogated. Because most cardiac catheterization laboratories have only a maximal 9-inch image intensifier, multiple images of the lung are usually required to interrogate the entire lung fields. If the aorta is to be investigated, cine aortography can be performed in the catheterization laboratory to ascertain the size of the aorta (in cases of aortic stenosis with anticipated aortic valve replacement) and to visualize the arch vessels. If detailed examination of the lung and aorta and arch vessels is required, it is often better to use a system with a larger-size image intensifier field of view designed for that purpose. It should be recognized that angiography in the catheterization laboratory is limited by 2-dimensional imaging, hence complete evaluation of the aorta and pulmonary arteries (PAs) may be difficult, and the potential use of alternative imaging modalities (i.e., CT or magnetic resonance imaging [MRI]) should be considered if clinically important.

#### 4.4.3.2. VENTRICULOGRAPHY AND VASCULAR ANGIOGRAPHY

Power injectors are recommended for optimal opacification and visualization during ventriculography and large vessel angiography, such as aortography. Hand injection can be performed for selective subclavian, carotid, or renal angiography. Using a pigtail catheter appropriately placed in the mid–left ventricle usually avoids or minimizes inducing premature ventricular contractions or ventricular tachycardia. End-hole catheters should generally not be used for ventriculography power injections because of the risk of perforation or an intramyocardial contrast injection. At times, visualization of the pulmonary veins can be obtained by wedge angiograms (the injection of contrast into a pulmonary wedged balloon catheter then release of the balloon to observe the pulmonary veins during the washout period).

#### 4.4.3.3. PRESSURE MEASUREMENT

During a routine left heart and coronary arterial catheterization, a preprocedural and postprocedural aortic pressure tracing, as well as the recording of the LV systolic and end-diastolic pressure should be obtained. Some laboratories find it useful to repeat the LV pressure after the left ventriculogram to report the LV end-diastolic pressure after contrast, although the clinical value of this exercise is questionable. During right-heart catheterization, the acquisition of right atrial (RA), right ventricular (RV), PA, and PA wedge tracings is routine, and sufficiently long strips of phasic recordings should be obtained to account for respiratory variation. Obtaining the end-expiratory pressure helps reduce the respiratory variation, although some patients are unable to hold their breath without performing a Valsalva maneuver, and thus the pressures are influenced by the resultant high intrathoracic pressure generated. The mean pressure in atrial and pulmonary chambers should be obtained over 10 beats to allow for correction of respiratory changes. A 10-beat average should also be reported in patients having atrial fibrillation.

If pullback pressures are used to measure valvular gradients, the patient should be in as steady a state as possible to diminish the likelihood of any respiratory variation between pressure measurements from 1 chamber to another. Simultaneous pressures to gauge gradients across valvular lesions are preferred to pullback pressures when feasible. Care should be taken if the femoral artery pressure is used as a substitute for aortic pressure in younger patients, as normally the femoral pressure is higher than the central aortic. If femoral pressure is to be used as the aortic pressure surrogate, documentation should be obtained that the pressures between the 2 sites are similar. Newer dual lumen catheters should generally be used for the measurement of aortic or pulmonic gradients.

On occasion, the pulmonary capillary wedge pressure will also not correspond well with the LA pressure (especially after mitral valve replacement), and a transseptal puncture with simultaneous measurement of the LA and LV pressure may be required for an accurate transmitral gradient. With the improvement in noninvasive assessment of valvular gradients, it is not uncommon that cardiac catheterization hemodynamics focus only on the pulmonary pressure, outputs and coronary anatomy and the valvular gradients are not directly assessed. Pressure wires are of small enough caliber that they can be used to cross even mechanical prosthetic valves safely.

**4.4.3.3.1.** HEMODYNAMICS. The importance of high-quality pressure measurements has unfortunately been deemphasized in most laboratory facilities. The availability of numerous types of hemodynamic equipment precludes detailed description here. Appropriate filtering of the pressure signal is important for adequate interpretation of individual waveforms. Careful balancing and zeroing of the system at the level of the mid-atria are necessary for each procedure. Often, simultaneous pressures are important, and frequently higher-speed recordings (100 mm/s) are needed to obtain adequate data for waveform analysis. It is the responsibility of the laboratory director to ensure that the equipment available produces the information desired. Detailed knowl-

edge of each laboratory's transducers and recorders should be part of the orientation and a requirement for credentialing of invasive cardiologists in a particular catheterization laboratory. It is each invasive cardiologist's responsibility to direct the acquisition of appropriate pressures so that key hemodynamic data are obtained and not overlooked. Invasive cardiologists using the laboratory should review the quality of the pressure recordings obtained, and any deficiency should be corrected.

Accurate hemodynamic measurements aid in sorting out constrictive pericarditis from restrictive cardiomyopathy. In either instance, it is important that simultaneous measures of both LV and RV pressure during respiration are recorded to assess for ventricular interdependence (209). In patients with dyspnea, both a superior vena cava and PA oxygen saturation may be useful to exclude an unanticipated left-to-right shunt.

4.4.3.3.2. INTRACORONARY HEMODYNAMICS. Measuring the pressure gradient across a lesion in a coronary vessel may provide information regarding the hemodynamic significance of that lesion (210). Multiple studies have confirmed the use of pressure wires to assess pressure gradients across an intermediate angiographic stenosis (211–213). This information can now be used to guide whether or not stents should be placed (214,215). These studies have shown excellent outcomes in patients who have had insignificant gradients who did not have stents placed (216). The fractional flow reserve (FFR) is measured after the pressure sensor tip wire is placed distal to the lesion in question. Adenosine is administered intravenously or intracoronary to dilate the microvascular coronary circulation. An FFR measurement of $>0.75$ was initially used as the standard cut off to defer stent placement. The latest studies suggest an FFR $>0.80$ can be used with excellent long-term outcomes (212,213).

#### 4.4.3.4. CARDIAC OUTPUT AND VASCULAR RESISTANCE MEASUREMENTS

Cardiac output measurements commonly used in the cardiac catheterization laboratory include the use of indicator dilution methods (typically thermodilution), the Fick method (use of pulmonary and arterial blood oxygen saturations and oxygen consumption), angiographic methods, and impedance estimates. Indocyanine green dye is no longer used as the indicator. As a consequence, most cardiac catheterization laboratories rely on either thermodilution methods or the Fick method for determination of cardiac outputs. Thermodilution methods use a thermistor on the end of a right-heart catheter. As a proximally injected bolus of saline traverses past the thermistor, the temperature change results in a curve similar to that observed with dye dilution methodology. Analysis of this curve allows determination of cardiac output by a variety of methods. Accurate measurement requires a concentrated bolus of saline. Thus, tricuspid or pulmonary insufficiency may significantly alter the results obtained. Fick cardiac outputs require measurement of oxygen saturation, hemoglobin, and oxygen consumption. Oxygen consumption is the most difficult variable to obtain. Most laboratories use an assumed value from an established reference table or an established formula. Direct measurement of oxygen consumption provides a more accurate assessment using a variety of instruments, but the unstable nature of some of these devices and the expense and time involved have discouraged direct oxygen consumption measurements in most catheterization laboratories. Angiographic cardiac output using area-length assumptions or Simpson's rule provides LV volumetric data useful for estimating valvular stenosis severity in the presence of valvular regurgitation (assuming only 1 left-sided valve demonstrates regurgitation). The regurgitant fraction can also be derived. Angiographic methods suffer from vagaries in the accuracy of shape assumptions and from the determination of the requisite correction factors needed because of x-ray divergence. Whatever method is used for determining cardiac output should be well understood by all personnel. Each cardiac output method has limitations and errors that can be minimized with careful attention to the inherent vagaries of each technique. Similar data are often obtained now from noninvasive methods.

Vascular resistance calculations require knowledge of the mean pressure before and after the resistance of interest and a measure of the flow through the area. Thus, for pulmonary vascular resistance, the pulmonary blood flow and the mean PA and the mean pulmonary capillary wedge pressure (or LA pressure if no pulmonary venous disease) must be recorded.

#### 4.4.3.5. SHUNT MEASUREMENT

Important information regarding physiology of congenital heart disease is gathered from measurements of intracardiac shunts. Both right-to-left and left-to-right shunts must be able to be quantitated during the catheterization. Because of the need to determine intracardiac shunting, oxygen saturation samples are drawn from many sites rather than simply from the PA for mixed venous oxygen level and from the systemic artery for arterial oxygen level. The availability of oxygen saturation measurements and arterial blood gas determinations within the catheterization laboratory is useful for the efficient performance of the typical congenital cardiac catheterization. The availability of blood gas measurements also allows for the inclusion of dissolved oxygen in the determination of oxygen content.

### 4.4.4. Other Diagnostic and Therapeutic Procedures in the Cardiac Catheterization Laboratory

#### 4.4.4.1. PULMONARY VASODILATORS IN THE EVALUATION OF PULMONARY HYPERTENSION

The World Health Organization classifies pulmonary hypertension into 4 categories (217). Pulmonary arterial hypertension, or "idiopathic" pulmonary hypertension, is associated with a normal pulmonary capillary wedge pressure and elevated pulmonary vascular resistance. The normal pulmonary pressure is generally considered to be 25/10 mm

Hg with a mean of 15 mm Hg (range from 12 to 16 mm Hg). Pulmonary hypertension is considered present when the mean PA pressure is >25 mm Hg at rest or >30 mm Hg with exercise. The pathophysiology of pulmonary hypertension involves a reduction of flow through the lungs due to pulmonary vascular remodeling and vasoconstriction. Remodeling involves endothelial, smooth muscle, and fibroblast cell types, as well as inflammatory cells and platelets (218). Vasospasm plays a greater role early in the disease, and its presence can be assessed in the cardiac catheterization laboratory using 100% oxygen, adenosine, and epoprostenol and inhaled nitric oxide (usually 40 to 80 ppm). A 10 mm Hg fall in mean PA pressure and a final mean PA pressure of <40 mm Hg is considered a positive vasodilator response. Therapy for pulmonary arterial hypertension is then dependent upon the response to these vasoactive agents (219). In general, responders are treated with calcium channel blockers and phosphodiesterase inhibitors whereas nonresponders are considered candidates for endothelial-receptor blockers and prostacyclin analogs. The clinical functional class also plays a role in the aggressiveness of therapy (219).

Response to vasodilators has also been used to decide on surgical suitability for patients with congenital heart disease or transplantation. In those instances, the change in the resistance in the pulmonary circulation (Rp) over the systemic resistance (Rs) is often used, with high risk associated with an Rp/Rs ratio >0.7. One study shows the achievement of an Rp/Rs ratio of <0.33 and a 20% decrease in the ratio with vasodilators allowed for safe surgical intervention (220).

Of note, in pediatric catheterization laboratories, the pulmonary vascular resistance is calculated using the cardiac index rather than the cardiac output alone. Despite this correction making sense, the practice has unfortunately never been adopted in the adult cardiac catheterization laboratory.

#### 4.4.4.2. VASODILATOR OR INOTROPIC STRESS TESTING IN AORTIC STENOSIS

Patients with aortic stenosis (AS) and depressed ejection fraction may have low valvular gradients despite significant AS by aortic valve area (<1.0 $cm^2$). Whether to replace the aortic valve in this situation is often a difficult clinical question. When data from noninvasive studies using dobutamine are not available or are equivocal, the use of either dobutamine or nitroprusside during cardiac catheterization to assess the response of the aortic valve area, gradient, and stroke volume has been used to help decide whether the stenosis is an actual or a pseudo-stenosis due to low output. An increase in the aortic valve area and a little increase in the aortic valve gradient suggest the primary problem is myocardial and not valvular stenosis. Graded doses of dobutamine (5 mg/kg/min, 10 mg/kg/min, 20 mg/kg/min) to test whether there is "contractile reserve"—a >20% increase in stroke volume—have been used to separate those who are candidates for surgical intervention from those who are believed to be too high risk (221). Nitroprusside may be used to improve cardiac output in patients with atrial fibrillation to help prevent the rapid ventricular response often seen with the administration of dobutamine. Patients in atrial fibrillation with a wide variability in the ventricular response are best studied with RV pacing greater than baseline to control the heart rate before and after the infusion. There are data that suggest the use of brain naturietic peptide (BNP) may influence whether the results truly separate the operable candidate out from the inoperable candidate, with poor outcomes regardless of the result in those with BNP levels >550 pg/mL (222). In addition, using contemporary surgical methods, some have demonstrated excellent surgical results despite failure to demonstrate any contractile reserve in this patient population (223). The threshold for therapy in these difficult patients may also be changing with the availability of the percutaneous aortic valve replacement procedure.

#### 4.4.4.3. TRANSSEPTAL CATHETERIZATION

Transseptal catheterization is performed from the femoral artery by placing a long, pointed, sheathed introducer with a hollow Brockenbrough needle first into the superior vena cava then rotating into the foramen ovale. The stiff system is "locked" into the foramen ovale and pressure applied to the foramen ovale. In about a third of cases, the system will push open the septum primum in the foramen ovale. If the system does not cross, then the needle is extended just past the introducer tip and the interatrial septum is punctured. A change in the waveform reflecting LA pressure should be evident before advancing the catheter and sheath. Once LA pressure is obtained, the needle is withdrawn and a guidewire inserted into the LA. The sheath and transducer are advanced into the LA and once inside, the introducer is withdrawn and the sheath remains. Catheters can then be inserted through the sheath into the LA. Transseptal catheterization to obtain LA pressures is primarily used in the adult catheterization laboratory during the performance of balloon mitral valvuloplasty or mitral repair using the eValve mitral clip. It is required to perform stenting of pulmonary vein stenosis or in the EP laboratory during atrial fibrillation ablation. Hemodynamically, the LA/LV pressure gradient may be different from the pulmonary capillary wedge/LV pressure gradient, especially in patients with mitral valve replacement, and it is useful to document the difference. Entry into the LA allows entry into the LV when crossing the aortic valve retrograde is not feasible or desirable and LV pressure is necessary. Percutaneous aortic valvuloplasty or valve replacement can be performed in this manner. In congenital heart disease, at times the only access to the pulmonary arterial pressure is retrograde through the pulmonary veins and both hemodynamics and pulmonary angiography can be performed via a reverse wedge in most patients when this is the case. The procedure is also required for the placement of an LA appendage occluder. Complications related to transseptal puncture include perforation of

the RA or LA with subsequent pericardial effusion or tamponade, pain perception by the patient while crossing the septum, vagal stimulation, or inadvertent entry into the ascending aorta. Care must be taken to avoid air entry into the LA or thrombus formation. Recently, the addition of intracardiac echocardiography/Doppler methods can be used to help guide the transseptal procedure.

#### 4.4.4.4. LV PUNCTURE

There is essentially no longer any indication for percutaneous LV puncture to assess the LV pressure. Echocardiography/Doppler methods and MRI are adequate to evaluate combined mitral disease and a mechanical aortic prosthesis. Fine pressure wires have also been used to cross even bileaflet mechanical aortic valves or the Starr-Edwards aortic prosthesis with little risk. Surgical LV puncture may be used for the placement of the percutaneous aortic valve and to stabilize guidewires when attempting to plug paravalvular leaks in a hybrid room situation.

## 4.5. Therapeutic Interventions for Hemodynamic Compromise

### 4.5.1. Improving Cardiac Output

#### 4.5.1.1. INTRA-AORTIC BALLOON PUMP

The intra-aortic balloon pump (IABP) improves cardiac output, improves myocardial perfusion and reduces myocardial demand by maintaining diastolic pressure and reducing afterload. This is because maintaining diastolic pressure improves coronary and systemic perfusion, whereas the afterload reduction reduces myocardial demand. It is particularly useful in situations of hypotension due to low cardiac output and in patients with refractory unstable angina. The intra-aortic balloon pump is a thin synthetic balloon positioned within the descending thoracic aortic about 2 cm below the normal takeoff of the left subclavian artery. It is inflated with helium during ventricular diastole and deflated during ventricular systole. Cyclic obstruction of the aorta in this manner increases diastolic aortic pressure and helps maintain coronary perfusion (primarily an early diastolic phenomenon, especially in the left coronary). Systolic deflation of the balloon unobstructs the aorta, and cardiac ejection occurs against a markedly lower aortic impedance and peripheral vascular resistance, improving stroke volume. The physiology is ineffective if significant aortic regurgitation, excessive tachycardia or other arrhythmias are present. The latest meta-analysis of the use of IABP therapy in STEMI suggests, however, that there was no impact on mortality (224) despite short-term hemodynamic improvement.

Balloon placement is not feasible unless the aortoiliac vessel lumens are large enough (>7 mm) to accommodate the device. Aortic dissection and extreme tortuosity may not allow for the IABP placement. Because the device is placed in the femoral artery and aorta, it could obstruct flow to the limbs, and lead to limb ischemia and even a compartment syndrome. Renal failure can occur if placed too low in the aorta over the ostia of the renal arteries. Other possible complications include cerebral embolism during insertion, infection, dissection, or perforation of the aorta or iliac artery, and hemorrhage into the mediastinum. The balloon may fail to deflate or may rupture, requiring surgical removal. Showering of aortic atherosclerosis particles can lead to leg ischemia from cholesterol embolization or from thrombi originating on the balloon's surface—this is especially a risk during balloon removal. Mechanical failure of the balloon may require vascular surgery for removal.

#### 4.5.1.2. OTHER CATHETER DEVICES TO IMPROVE CARDIAC OUTPUT

Several newer percutaneous devices have become available to augment cardiac output during high-risk cardiac catheterization. These include the Impella device (Abiomed, Inc., Danvers, MA) and the TandemHeart (Cardiac Assist, Pittsburg, PA). Both have been used in a variety of situations. The Impella device is a 12-F rotary micropump catheter able to produce continuous flow up to 2.5 L/min. It is placed across the aortic valve and augments LV output directly into the aorta. The TandemHeart is placed into the LA via a transseptal puncture using a 21-F venous catheter. It pulls oxygenated blood from the LA and returns it to the femoral artery via a 15-F catheter. It is capable of continuous flows up to 5 L/min. Early studies comparing the results with that of an IABP suggest that the acute hemodynamics are superior, but there is no difference in early survival (225). ECMO can also be used to provide both cardiac and respiratory support via either veno-veno or veno-arterial cannulation. The role of all these types of devices to augment cardiac function during cardiac catheterization remains to be further defined.

## 4.6. Pericardiocentesis

The performance of pericardiocentesis is a critical skill that every invasive cardiologist should acquire. Although the methods may vary, the importance of being able to remove pericardial fluid in a patient who is experiencing tamponade physiology is critical, especially when the fluid has resulted from a complication of a catheterization procedure. All invasive cardiologists should be able to recognize the hemodynamics associated with cardiac tamponade, including equalization of the end-diastolic RA, RV, and LV pressures, and usually an associated paradoxical pulse (a fall in the pulse pressure and systolic central BP with inspiration). Emergency echocardiography is critical to define the effusion and assess for RA collapse and RV diastolic collapse. Most acute pericardial effusions are not large, and the use of echo-guided aspiration is generally preferred. A defined sterile pericardiocentesis package should be part of any cardiac catheterization laboratory so that there is no scrambling for the items required to perform an emergency tap of the pericardium. The director of the cardiac catheterization laboratory should define what equipment is in the package and ensure it is available at all times within the laboratory area. All operators should be familiar with the contents of this package for any

given institution and should understand how to use the equipment if the need arises.

### 4.7. Coronary Artery Catheter Imaging Devices

A variety of diagnostic and some therapeutic catheters are now either available or are being tested for use within the coronaries during cardiac catheterization. IVUS devices have the longest track record, and a consensus document from the ACCF still provides important information on the proper use of these tools (226). Both mechanical and phased-array catheters are available. IVUS studies have provided information regarding the unreliability of angiography to define lesion severity. IVUS studies also provide valuable information at times on plaque composition and remodeling, stenosis severity (especially in left main disease), the satisfactory deployment of intracoronary stents, and in cardiac transplant vasculopathy. It has also been a valuable tool to assess plaque burden over time in some clinical trials, to identify thrombus, and to help assess bifurcation lesions. The use of IVUS catheters in any laboratory setting is undoubtedly dependent on the skills and the enthusiasm of the operators for these procedures. Its use is not without a small risk; an early European registry found a 1.1% complication rate due to spasm, dissection, or wire entrapment (227). Competence in using these devices holds sway over any established guidelines, and all of these devices have a learning curve, not only in their placement, but more importantly in the interpretation of the images and then appropriately altering therapy based on the results.

Newer coronary imaging devices are being investigated including such devices as forward looking IVUS, plaque imaging with virtual histology, and tissue ingrowth assessment using optical coherence tomography, for instance. The proper use of all of these novel devices requires the ongoing QI program to be involved so that proper technique is followed and all complications are reviewed and discussed. If the device is still under investigation, it is vital that all local policies regarding investigational devices be followed, and appropriate oversight by the institutional review board at the facility be established.

#### 4.7.1. Intracardiac Ultrasound and Doppler

Intracardiac echo cardiography/Doppler is now being used to visualize the atrial septum during transseptal catheterization to facilitate left-sided EP ablation studies, mitral valvuloplasty, appendage occluder implantations, and ASD or PFO occlude positioning. The devices have also been used in complex myocardial biopsy procedures. Doppler methods help define flow and are of particular value in balloon sizing of ASD defects to detect when total occlusion has occurred. There are no data specifically addressing the incidence of complications related to these devices, but the complication rate is acknowledged to be low. Known complications include cardiac tamponade from perforation, thrombus formation in the sheath, and air emboli. In the face of no established guideline, competence assessment is left to the QI process with oversight by the director of the cardiac catheterization laboratory. Similar to all the procedural methods that are used in only a small number of patients, there is a learning curve, and there needs to be a careful review of any complications associated with the use of intracardiac ultrasound.

## 5. Postprocedural Issues

### 5.1. Vascular Hemostasis

The most frequent complication of coronary angiography and coronary interventions occurs at the vascular access site. Although careful vascular entry is essential in reducing such complications, vascular hemostasis obtained after the procedure is a crucial component of the procedure. Methods to achieve hemostasis include manual compression, mechanical compression, percutaneous vascular suture, and staples or clips, vascular plugs, and topical hemostatic pads.

#### 5.1.1. Routine

In cases of femoral puncture, where a vascular closure device is not used, it should be routine to assess the ACT value before access-site compression following interventional procedures whenever heparin has been used. Once the ACT has returned to near normal (<180 s), sheaths can be removed and manual pressure or mechanical pressure clamps applied. If lytic agents have been used, prolonged vascular compression may be necessary. The size of the sheath roughly determines the length most patients should be confined to bed after manual compression. A minimum of 1 to 2 hours after the procedure for 4- to 5-F sheaths, whereas 2 to 4 hours for 6- to 8-F sheaths is common practice. The use of the radial or brachial artery approach obviates the need for prolonged bed rest, but hemostasis must still be achieved by manual or device pressure. All patients should have the puncture site auscultated before discharge and, if a mass is palpated and/or a new bruit audible, then a vascular ultrasound should be obtained to exclude a vascular pseudoaneurysm or fistula that may need repair. Most pseudoaneurysms are now closed with percutaneous thrombin.

#### 5.1.2. Use of Vascular Closure Devices

The last decade has seen revolutionary changes in the development of vascular closure devices. Local femoral angiography is generally performed to assess puncture site, size of common femoral artery, and extent of atherosclerosis and calcification in order to properly place these devices. Although they do not decrease all complications compared with manual compression, they have become the standard of care in many cardiac catheterization laboratories because of the convenience and economic pressures to reduce length of stay. Whether they are being placed by the invasive cardiologist or a physician extender, adequate education and hands-on training is necessary to become consistently pro-

ficient in utilizing these devices and achieving excellent results and very low complication rates. A bleeding risk model has been developed using data from the ACC-NCDR database. The bleeding risk score assigns points to a variety of variables including STEMI (10 points), cardiogenic shock (8 points), age ≥85 (8 points), sex (6 points), prior CHF (5 points), age 76 to 85 (5 points), no prior PCI (4 points), NYHA (New York Heart Association) functional class IV (4 points), NSTEMI (3 points), peripheral vascular disease (2 points), and age 66 to 75 (2 points). The risk of a postprocedural bleed was then 0.7% for those with ≤7 points, 1.8% for those with 8 to 17 points, and 5.1% for those with ≥18 points (136). Using similar data from the ACC-NCDR database to test the association between the use of bleeding avoidance strategies and post-PCI bleeding, Romaguera et al. found some advantage to the use of both bivalirudin and vascular closure devies (213).

The failure of these devices does occur (228), however, and not all reviews suggest a great advantage of the vascular closure devices in low-risk patients (229). Because of the expense of these devices, each laboratory should systematically review whether they are being used in a cost-effective method. In many cases, the radial approach appears to reduce the vascular risk compared with the standard femoral approach, and this may be an appropriate alternative (72). An AHA Scientific Statement on the use of vascular closure devices has been published (230). This committee reviewed those recommendations and endorse the suggestions outlined.

### 5.2. Medications Postprocedure

#### 5.2.1. Pain Control and Sedation

Patients should not require substantial pain control or sedation postprocedure. If patients have access site discomfort, fentanyl hydromorphone hydrochloride, or morphine can be used. If sheath removal will require prolonged manual or mechanical compression pain management will be necessary. Patients who appear to be oversedated or are not regaining appropriate level of consciousness should be given naloxone and/or flumazenil to reverse the effects of any narcotics or benzodiazepines they received during the procedure.

#### 5.2.2. Hypertension

Severe postprocedural hypertension can cause increased vascular site bleeding complications, myocardial ischemia, and with associated diastolic dysfunction, pulmonary edema. Postprocedural hypertension should be managed relatively aggressively. Patients can be given doses of their outpatient medications and/or can be given IV doses of antihypertensives. Hydralazine, labetalol, nicardipine, or metoprolol are commonly used as IV push medications; nitroglycerin infusions can be used as well. In general, the goal BP should be 140/80 mm Hg. More aggressive reduction in BP is not necessary. Hypertension could be a sign of an overdistended bladder; therefore, placement of a temporary Foley catheter if the patient is unable to void may resolve the hypertension. The use of bedside bladder ultrasound devices may be confirmatory.

#### 5.2.3. Vagal Complications and Hypotension

Vagal responses occur most commonly after sheath removal. The pain, from manual or mechanical compression, generally triggers this response. Pre-medication of patients with subcutaneous lidocaine or the use of fentanyl or morphine prior to sheath removal may diminish vagal reactions. The hypotension and bradycardia must be recognized promptly. Rarely, severe vagal complications result in asystole and the need for CPR. Treatment with boluses of normal saline followed by a saline infusion plus the use of atropine 1 mg IV help counteract this complication, since vagal reactions usually include both vasodilatory and a cardiodepressor component. Nurses who care for post-cardiac catheterization patients must be trained to recognize this and treat it promptly and aggressively. Vagal responses can also occur with loss of hemostasis and abrupt hematoma and pseudoaneurysm formation as well as pseudoaneurysm rupture. A retroperitoneal bleed can often be confused with a vagal reaction and must be considered, particularly if patients are complaining of flank pain and are not responding rapidly to treatments. A mass may be perceived, and usually the heart rate is increased (unless the pain has resulted in a vagal component). In many situations, the most rapid and appropriate diagnostic procedure is to return to the cardiac catheterization laboratory for contralateral access and identification of any bleeding site angiographically. Balloon occlusion may then prevent further bleeding until a more definitive procedure can be carried out. Abdominal noncontrast CT is usually definitive in assessing the presence of a retroperitoneal bleed when there is no sense of urgency or hemodynamic compromise.

## 6. Personnel Issues

### 6.1. Personnel

A cardiac catheterization laboratory requires a critical mass of interdisciplinary personnel to allow safe and optimal performance of catheterization-based procedures, including minimum key personnel. Most of the technical staff should be certified by the appropriate certifying body. The laboratory staff should meet ongoing continuing education requirements for current registration and institutional employment. The following is an outline of pertinent personnel requirements, roles, and obligations.

#### 6.1.1. Attending Physician

The attending physician is the physician in charge of the procedure. The attending physician is considered the primary operator for the procedure. He or she must hold a valid medical license and be credentialed by the institution.

He or she must be experienced in all aspects of the performance of the procedure, including procedural indications or contraindications, preprocedural and postprocedural evaluation and care of the patient, and the management of periprocedural complications. If 2 attending physicians participate in the procedure, only 1 may be the attending of record for the purpose of billing. Adjunct attending physicians may be responsible for specific aspects of the procedure, such as the performance of transesophageal echocardiography or general anesthesia, and they may bill appropriately for the additional services provided, if these services are required for the proper performance of the catheterization procedure.

### 6.1.2. Teaching Attending Physician

A teaching attending physician meets the requirements of an attending physician in a program instructing graduate physicians in the performance of the procedure and transmission of information to the trainee physician(s). A teaching attending physician must be present for all critical aspects of the cardiac catheterization procedure, and should be board certified or eligible. Attending physicians directly supervising fellows in the performance of interventional procedures should perform a minimum of 75 interventions per year at the primary training institution and meet all other hospital credentialing requirements for the performance of the procedure.

### 6.1.3. Secondary Operators

Secondary operators are additional "attending" physicians, physician extenders, or cardiovascular trainees who assist the primary attending physician. These physicians may fulfill the some of the requirements for an attending physician, but they are not in charge of the procedure at hand and are not considered the primary operator. Cardiology fellows are secondary operators but may be considered supervised primary operators for the purpose of the ACGME requirements. Secondary operators should not take credit for the case for the purpose of fulfilling minimum performance volume physician requirements or for billing.

### 6.1.4. Laboratory Director

The laboratory director should be a physician with the experience and leadership qualities needed to monitor and control the laboratory environment. The director is charged with the responsibility for policy development, quality control, and fiscal administration. Depending on the type of laboratory and type of patients studied, the director may be either an adult cardiologist or a pediatric cardiologist and may have special interests such as in interventional cardiology or electrophysiology. The director should be an attending physician who is board certified and thoroughly trained in cardiac radiographic imaging and radiation protection. The director must be proficient in performing procedures specific to the laboratory and supportive to the needs of the operating physicians. Ideally, the director should be knowledgeable of all the major procedures being performed in the catheterization laboratory; however, with emerging technologies and the evolution of subspecialty areas (e.g., labs that offer a large range of interventional, peripheral, and EP services), the director may necessarily collaborate with other attending physicians for management regarding specialized procedures. He or she must have the necessary skills to address emergent complications.

It is the director's responsibility to ensure the laboratory has the equipment necessary to competently perform the catheterization or interventional procedures, as well as the tools and personnel required to address complications should they occur. The director's qualifications should include at least 5 years of cardiac catheterization experience and possess recognized skill in the laboratory. He or she should be board certified in interventional cardiology if interventional procedures are performed in the laboratory, though exceptions may occur in special instances with approval of the facility leadership and the credentials committee at the specific institution. Directors that have not had time to accumulate 500 PCI cases should have a QA system in place, as noted previously, wherein a random number of cases are reviewed by a large-volume PCI center. This should be on a continuing basis until the minimum 500 PCI cases have been satisfactorily achieved and competence established.

For centers with cardiovascular, interventional, or EP fellowship training programs, the catheterization laboratory director must work in collaboration with the training program director (if different) to assure the proper training and supervision of the trainees. The interventional program director must also be board certified in interventional cardiology. This assures that the laboratory provides an environment conducive to teaching the requisite knowledge and skill sets, and that teaching attending physicians meet the volume and professional standards necessary to qualify them as educators.

The director is responsible for a wide range of personnel management. The director shall set criteria for granting privileges to physicians and then review and make recommendations about applications for those privileges. The director must periodically review physicians' performance, make recommendations for renewal of laboratory privileges, review performance of trainees and nonprofessional staff, and provide necessary training to personnel. The director shall establish and monitor quality control, including morbidity and mortality, and program and policy development, including incorporation of guidelines and defining monitoring plans for guideline compliance. He or she must be an active proponent of a CQI and QA program for the laboratory, as established earlier in this document.

In addition, the director should have the responsibility of advocating and ensuring adequate healthcare resources (devices, equipment, and supportive personnel) for the catheterization laboratory. Necessary emergency equipment must be available in the lab. Other important equipment might

include new devices, x-ray or imaging equipment, information technology resources, integrated imaging resources, nurse or technical specialists, diagnostic technology, point of care testing, patient transport resources, or other healthcare resources.

The director must work in collaboration with the institution (including occupational and radiation safety) and with a qualified medical or health physicist to ensure personnel safety and compliance regarding the use of x-ray–generating equipment, including compliance with local regulations and laws. This includes advocating for adequate radiation safety training and protective equipment for catheterization laboratory personnel, patient and personnel monitoring for radiation exposure, and a system to address occupational exposures and injury.

The duties and responsibilities of the director are thus multiple and wide-ranging and demand strong management skills. The role should be appropriately compensated by the hospital, group, or health system in charge of the laboratory as these responsibilities are always in addition to other clinical duties. Adequate time should be provided along with adequate financial compensation.

Other responsibilities include oversight of patient scheduling, referral services, postprocedure reporting and tracking of quality measures (including complications), establishing quality improvement programs, procurement and maintenance of equipment and supplies, budget preparation and monitoring, organization of regular conferences for laboratory personnel, and regular reports on laboratory activity. The director shall maintain communication and cooperation among laboratory staff, clinicians, and the hospital administration to ensure that the patient is best served. The director must designate a substitute who will act in his or her absence.

### 6.1.5. Operating Physicians

All physicians credentialed to operate in the catheterization laboratory must have proper training and meet all credentialing requirements for the facility. This includes those classified as the attending physician and those functioning as teaching attending or secondary operators. This training may be in adult or pediatric cardiology. Clinical training in any of these fields should fulfill requirements for that specialty board and preferably from an ACGME-certified program. The physician should be deemed competent to perform the procedures by the program director of his or her training institution. A laboratory physician should be a fully accredited member of the hospital staff and ideally be specialty certified or have completed formal training in the area he or she practices. An operating physician who provides only laboratory service without being a full member of the hospital staff should not be the attending of record. The physician must also be trained in general emergency and critical care, which includes a minimum of current advanced cardiac life support certification. This should also include training and competence in emergency scenarios that commonly occur in the specific procedural setting (diagnostic or interventional). Operating physicians must also be trained in patient and staff radiation safety, and meet the institutional standards for the operation of fluoroscopic/x-ray equipment that pertains to the procedures performed. Finally, the physician should meet the institutional requirements for the administration of conscious sedation. Operating physicians must participate in the laboratory's QA program, including peer review. Physicians performing electrophysiological procedures should have completed formal training or be certified in electrophysiology. The performance of complex electrophysiological procedures, such as atrial fibrillation ablation, requires additional training and experience, and the credentials committee must certify anyone contemplating these procedures is adequately trained.

#### 6.1.5.1. CARDIOVASCULAR TRAINEE (FELLOW)

The primary role of the cardiovascular trainee is to obtain the cognitive knowledge and technical skills necessary to competently perform cardiac catheterization procedures. This includes the indications, contraindications, and limitations of the procedures; pre- and postprocedure patient care; analysis, interpretation, and reporting of hemodynamic and angiographic data; and management of complications related to procedure performance (111). Combined with the core training that occurs within a cardiovascular training program, trainees obtain the critical skills necessary to become qualified attending physicians. Trainees may perform all functions of the procedure as the primary operator would, but only under the direct supervision of a credentialed attending physician who assumes responsibility for the procedure. In this capacity, the use of house staff not directly engaged in a formal cardiovascular training program is inappropriate. Outlines for current volume recommendations for the various levels of training are addressed in Tables 17 and 18.

### 6.1.6. Use of Physician Extenders (Physician's Assistants and Nurse Practitioners)

Increasingly, "physician extenders" (e.g., physician's assistants and nurse practitioners) are being used clinically as patient care assistants in the provision of medical services within the field of cardiology. In regard to cardiac catheterization and intervention, trained and credentialed physician extenders may perform preprocedural evaluation and postprocedural follow-up of cardiac catheterization patients. In some medical centers, specially trained and qualified physician extenders may have an expanded role to assist the physician with the invasive or interventional procedure itself (231).

It should be recognized that extenders can never be primary operators and should work only under the direction of an attending cardiologist. The physician extender should be proficient in both the technical and cognitive aspects of cardiac catheterization, including 1) preprocedural evalua-

tion; 2) indications; 3) cardiac physiology and pathophysiology; 4) emergency cardiac care; 5) radiation safety; and 6) application of diagnostic catheterization data regarding the procedure.

The primary operating physician must be in the catheterization suite during the procedure when secondary operators are performing the procedure and direct the physician extender as well as provide all clinical decision making. Specially trained nurses/nurse practitioners may assist attending physicians in much the same role as physician's assistants in the performance of procedures. They may be able to assist in place of cardiovascular trainees, but they require even greater supervision during all aspects of the procedure.

### 6.1.7. Nursing Personnel

The type and number of nursing personnel required in the catheterization laboratory depend on the laboratory caseload and types of procedures performed. This support group may include nurse practitioners, registered nurses, licensed vocational or practical nurses, or nursing assistants. In most laboratories, the laboratory supervisor is a registered nurse. This nurse must be familiar with the overall function of the laboratory, have strong management skills, help set the tone of patient surroundings, and influence the efficiency and safety of procedures. The nurse supervisor may also directly participate in observation and nursing care of the patient during catheterization and should be ready to respond to any emergency. The nursing supervisor should be in charge of the preprocedure and postprocedure holding areas. Although variation exists among institutions, in general, the nurse supervisor should ensure that institutional guidelines for patient monitoring, drug administration, and protocols for patient care (including protocols for handling potential complications) are established, and that all catheterization laboratory nurses are properly trained) for the level of patient care that they deliver. The nurse manager, in collaboration with the hospital pharmacy and other clinical managers, should work to ensure appropriate medications are immediately available for administration in the catheterization laboratory, particularly those needed in emergency situations. In laboratories in which nursing personnel administer conscious sedation (under physician direction but in the absence of an anesthesiologist), the training, qualifications, and safety of conscious sedation should be in accordance with hospital policy, with compliance monitoring by the nurse supervisor.

The background of a catheterization laboratory nurse preferably includes critical-care experience, knowledge of cardiovascular medications, the ability to start an IV infusion and administer drugs, and experience in sterile techniques. Ideally, there should be some formal training, though certification programs have yet to be a prerequisite. The committee would endorse a movement toward such certification measures. Experience with vascular catheter instrumentation, especially with identification, cleaning, sterilization, and storage, is helpful and should be part of training. Knowledge of vascular catheter materials and the proper catheter size, appropriate guidewire, and adapters is also valuable. Some familiarity with the manipulation of manifolds, injection of contrast, and changing of guidewires and catheters is important. The catheterization laboratory nurse must have a thorough understanding of the flushing of catheters and syringes to prevent clots or air emboli. The nurse in the catheterization laboratory must also have essential skills to monitor the patient's vital status, including BP, heart rate, oxygenation, general neurological function, and pain. For nurses administering conscious sedation, institutional training and guidelines for patient monitoring and drug administration protocols must be followed. A nurse with the primary responsibility of the patient should be able to assist in acute cardiac care, including resuscitation and related therapeutic efforts.

A licensed practical nurse with the proper background and experience may have duties similar to those of the registered nurse. However, a licensed practical nurse should not supervise laboratory nursing. In some laboratories, an appropriately trained nursing assistant may be responsible for some duties. The nursing assistant may be a cardiopulmonary technician who is familiar with procedures in associated disciplines and is thereby able to function in the dual capacity of cardiopulmonary technician and nursing assistant.

Nursing personnel (registered nurse or licensed practical nurse), when properly trained, can manage blood samples, perform point-of-care testing (such as ACTs), and perform blood gas measurements and saturations. In addition, team training on simulators, especially for rarely done or more complex procedures, may help ensure an understanding of the optimal techniques and management issues.

### 6.1.8. Non-Nursing Personnel

Several kinds of technical knowledge are required in the cardiac catheterization laboratory, and a single person may not possess all the different types of technical expertise. At least 1 technologist, preferably a certified radiological technologist, should be skilled in radiographic and angiographic imaging principles and techniques. This technologist should be experienced in the proper performance of x-ray generators, cine pulse systems, image intensification, pressure injection systems, video systems, cine and digital imaging and storage, and radiation safety principles. He or she, in cooperation with electronic and radiological service engineers, should be responsible for routine care and maintenance of the radiological equipment. A basic ability to troubleshoot this equipment is advantageous. This technologist, in cooperation with a qualified medical physicist, should monitor radiation safety techniques for both patients and laboratory personnel. Immediate availability of a radiological engineer in the event of equipment failure is highly desirable. The technologist, with the service engineers and

qualified medical physicist should ensure optimal image quality while limiting radiation exposure to staff and patients. This technologist may also assist with the data storage and report generation system.

Each laboratory should also be reviewed and managed by a qualified medical physicist in order to provide appropriate teaching, to ensure optimal monitoring equipment is being used and to assist with the actual monitoring of radiation exposure to patients and laboratory personnel. A program of radiation safety should be in place in every cardiac catheterization laboratory.

Laboratory technologists should be skilled in managing blood samples, and performing blood gas measurements and calculations. They should be qualified to monitor and record electrocardiographic and hemodynamic data and have enough skill and experience in interpreting these data to report significant changes immediately to the physician responsible for the patient. During any single procedure, the monitoring technician or nurse must have no responsibility other than monitoring and observing patient status. It is encouraged that during each procedure at least 1 technologist (and/or physician) should be skilled in radiographic and angiographic imaging techniques. In facilities performing interventions, other equipment related to imaging, diagnosis, and treatment is generally available. This ancillary equipment necessitates at least 1 available technologist within the laboratory to be proficient in the equipment use, maintenance, and general troubleshooting. These technologies may include the use of digital subtraction angiography, intracoronary ultrasound, FFR or Doppler coronary velocity, intracardiac echocardiography, optical coherence tomography, atherectomy, rotational atherectomy, angioscopy, intra-aortic balloon counterpulsation, and percutaneous mechanical cardiopulmonary support devices. In addition, an increasing number of laboratories, particularly those performing EP procedures, are integrating noninvasive imaging directly into the catheterization lab suite for use during the invasive procedure. The technologist should be familiar with these multimodality integrative technologies so as to be able to help troubleshoot when issues arise.

For technologists participating directly in patient care, skills are necessary in patient preparation and for assistance in acute cardiac care, including resuscitation and related therapeutic efforts. Technologists at diagnostic and interventional labs should be trained in the sterile techniques as well as emergency procedure (basic and preferably advanced cardiac life support) and in the use of onsite equipment, such as intra-aortic balloon counterpulsation and temporary transvenous pacemakers, defibrillators, and mechanical cardiopulmonary resuscitative vests if these are available. Technologists often directly assist the primary operator with the procedure.

A technician with expert computer skills is a very valuable addition to the team to assist with the handling of image transfer methods and archival storage devices, image compression, and to maintain the digital libraries. Because of the complexity of digital archival storage and database management many catheterization laboratories will also require dedicated information technology support.

On occasion, additional administrative personnel may assist in the optimal functioning of the cardiac catheterization laboratory. Such personnel may include a dedicated case manager, scheduler, inventory manager and related staff, compliance monitor, and database or administrative staff for CQI and QA. In addition, some laboratories have dedicated employees that apply groin compression devices and report follow-up groin and other complications.

### 6.2. Staffing Patterns

A credentialed attending cardiovascular physician must be present in the laboratory during each procedure and must be responsible for the outcome as the primary operator. To maintain effective and safe laboratory operation, each basic support function should be performed by adequately trained personnel who constantly maintain their skills and credentials. There should be adequate cross-training among laboratory staff so that personnel can rotate responsibilities and provide 24-hour coverage of essential team functions.

Complex studies, especially those of children and acutely unstable patients, require personnel with special training. In complex cases and procedures, the presence of a second physician may be needed for optimal care. The requirements for a full-service facility are listed in Table 2.

### 6.3. Cardiopulmonary Resuscitation

All members of the catheterization team (physicians, nurses, and technologists) should complete a basic course in CPR. Certification in advance cardiac life support is also strongly urged, especially for all members that are part of the actual procedure. Recertification is to be expected every 2 years.

## 7. The Hybrid Cardiac Catheterization Laboratory

### 7.1. Overview and Patient Selection

The hybrid cardiac catheterization/operating room represents an integrated procedural suite that combines the tools and equipment available in a catheterization suite with anesthesia facilities and sterility of a fully equipped operating room. A key feature is that the suite meets all the standards of an operating room as well as all the standards of a catheterization laboratory. Although the hybrid suite is designed to meet the needs of an increasingly complex patient population, it also serves as a platform for collaborative work between subspecialists. In some hybrid suites, operators can perform cardiovascular procedures ranging from the most straightforward PCI to aortic arch reconstruction. As a result, different teams across different subspecialties can benefit from the hybrid suite.

Hybrid catheterization laboratories require fixed imaging equipment that has greater resolution and better image storage capacity compared with mobile C-arms previously used in some operating rooms. Higher-quality imaging is required for many new techniques such as hybrid coronary stenting and CABG and percutaneous aortic valve placement.

Hybrid suites must also meet the strict environmental standards of state-of-the-art open operation rooms to reduce the risk of wound infection associated with surgical cut-down for vascular access, large prosthetic devices (e.g., valves and stent grafts), and open cardiac surgical procedures. These standards include a closed environment, traffic control specifications, specific HVAC requirements, the availability of vacuum equipment, and structural designs to promote a sterile environment. Because many will be placed in the traditional cardiac catheterization suites, special attention to converting a portion or all of the catheterization area into a sterile environment is often required.

Procedures best suited for the hybrid laboratory include those where surgical vascular access is required for large endovascular devices that are deployed using high resolution imaging (e.g., percutaneous aortic valves or aortic stent grafts), where conversion to open surgery may be required if endovascular procedures are unsuccessful (e.g., aortic stent grafts), or for hybrid treatments such as PCI with minimally invasive valve or CABG (Table 21).

**Table 21. Examples of Procedures for a Hybrid Catheterization Laboratory**

| |
|---|
| Surgical vascular access required for large endovascular devices |
| Percutaneous aortic valves |
| Thoracic and abdominal aortic stent grafts |
| Large-bore percutaneous ventricular assist devices |
| Conversion to an open surgical operation may be required |
| Percutaneous aortic valves (apical approach or bailout) |
| Thoracic and abdominal aortic stent grafts |
| Percutaneous ventricular septal defect closure |
| Hybrid treatments |
| Combined percutaneous coronary intervention and minimally invasive or open coronary bypass grafting |
| Combined percutaneous coronary intervention and minimally invasive cardiac valve surgery |
| Combined iliac stenting and distal bypass grafting |
| Endomyocardial/epicardial atrial fibrillation ablation |
| Apical access to assist in percutaneous closure of paravalvular leaks |
| Electrophysiology device placement |
| Implantable defibrillators |
| Temporary rhythm recorders (e.g., loop recorders) |
| Removal of pacemaker leads |
| Emergency procedures |
| Extracorporeal membrane oxygenation |
| Emergent thoracotomy |

Modified with permission from Hirsch (232).

## 7.2. Special Considerations

### 7.2.1. Staffing

The hybrid laboratory must serve as both a surgical suite and cardiac catheterization laboratory facility. The operation can only be done properly if there is a team approach, with each team member contributing differing expertise. As a generality, a specific team of nurses, technicians, and clinical staff familiar with the room and the goals of the procedure being performed is necessary for optimal care. These staff should be selected and trained for use in this room rather than rotating individuals unfamiliar with the stringent sterile requirements and diverse nature of the procedures to be performed. As each institution will use the hybrid room for different procedures, a definitive staffing pattern is facility- and procedure-dependent. Laboratory staff must understand there can be no compromising either the surgical procedure or the cardiac catheterization if the laboratory is to be used safely and effectively.

### 7.2.2. Location

The location of the hybrid suite is related to the availability of space and to the training and experience of those who will primarily use the facility. Some are located in the cardiac catheterization (232) or interventional suites, while others are upgraded operating rooms (233,234). Ideally, the hybrid suite would be located in a single cardiovascular procedural area, where standard catheterization laboratories are in the same general area as open heart surgical suites, so that the people (cardiologists, surgeons, catheterization technicians, operating room technicians, perfusionists) and equipment (catheters, stents, cardiopulmonary bypass, perfusionist equipment, surgical equipment) are readily available for all conventional catheterization laboratories, operating rooms, or hybrid suites.

Hybrid suites are designed to maximize sterility and conform to operating room guidelines that may differ state to state. These include laboratories located off a clean core or semirestricted corridor where staff are required to wear scrubs, hats, and masks. Scrub alcoves are located outside the hybrid laboratory with a window into the laboratory to observe patient and staff movement. A separate control room with wide windows permits technicians to observe the procedure and assist running the x-ray equipment without jeopardizing the sterility of the hybrid room. Alternatively, a monitor station can be used within the hybrid suite. Audio and video monitoring assists communication between operators and other staff (see Section 7.2.8).

Although design standards for hybrid catheterization laboratories are evolving, operating room standards serve as a guide for hybrid suites. Veterans Affairs standards suggest cardiac surgical operating rooms be a minimum of 65 $m^2$ (700 $ft^2$), with an upper limit for special purpose operating rooms being 75 $m^2$ (800 $ft^2$) (235). Given the extra space requirements for x-ray imaging, anesthesia equipment, the additional staff and equipment compared with con-

ventional cardiac catheterization laboratories and operating rooms, 70 $m^2$ (750 $ft^2$) may be a reasonable minimum guideline for the hybrid suite. We believe that 90 $m^2$ (1,000 $ft^2$) will provide the needed space for safe performance of hybrid procedures.

### 7.2.3. Room and Floor Design

Walls and flooring should generally follow seamless designs prevalent in operating rooms to avoid joins and cracks that may trap blood and other body fluids that can form a nidus for bacterial growth.

The hybrid laboratory requires x-ray shielding on walls and doors and a structure that is able to support the weight of the x-ray equipment. Floor trenching is required to run equipment infrastructure such as cable and conduit from the control room and the table to the C-arm.

Power outlets should include a range of high-voltage outputs (e.g., for laser catheters and cardiopulmonary bypass), regular-voltage outputs, and emergency (backup) power outlets. These should be distributed on the walls, from pull-down columns, and under the table (235).

Each room should have wall-mounted video monitors connected to the appropriate PACS server to call up CT, MRI, and other x-ray reference images. Because hybrid procedures usually require constant reference to multiple imaging modalities (e.g., angiography, ultrasound, FFR) as well as hemodynamic monitoring (e.g., indirect and direct arterial pressure, heart rate, electrocardiogram, oxygen saturations), these should be displayed simultaneously on multiple monitors or a large flat screen mounted on a movable ceiling-mounted boom adjacent to the table.

### 7.2.4. Ceiling Lighting and Design

In general, dim lighting is used in catheterization procedures to help view the images on the monitors. However, surgical operations use bright lighting that includes fixed ceiling fluorescent lights and movable ceiling mounted surgical lights. Therefore, the hybrid room needs a range of flexible lighting options to accommodate the needs of x-ray guidance and the operative stages of a procedure.

Many new hybrid suites use a ceiling-mounted (rather than floor-mounted) C-arm gantry. Ceiling mounted C-arms can be moved further away from the table during surgical procedures and are arguably easier to clean as they are less likely to have crevices where blood or bacteria can accumulate. However, ceiling mounted C-arms have tracks that protrude over the table, and track placement must not interfere with lighting or with laminar airflow. The C-arm needs to move in and out of the operating field and allow angulations (cranial–caudal and oblique angles) without interfering with anesthesia needs. Some operators prefer floor-mounted C-arms despite these issues.

In general, the mounts for the surgical lights are not directly over the table as this zone is preserved for the supply air outlet. However, these need to avoid the ceiling track of the C-arm and not interfere with angulations of the C-arm. Fifty percent of fluorescent lighting should be on emergency power with battery backup (235). Dimmable recessed lighting is distributed around the ceiling over the table for the x-ray procedure.

### 7.2.5. Anesthesia Requirements

General anesthesia requires greater space at the head of the table for staff and equipment compared with conventional cardiac catheterization laboratories. This area should have dedicated medical gas supplies (vacuum, medical air, nitrogen, nitrous oxide, oxygen, and waste gas lines)... similar to an operating room, and space for the transesophageal echocardiography. Inventive solutions include incorporating these equipment into movable ceiling booms so that they may be moved in and out of place as needed (232). Monitoring cables and other equipment should be radiolucent if at all possible.

### 7.2.6. HVAC Standards

HVAC should meet operating room standards for the number of air exchanges per hour, laminar air flow over the operating table, positive air pressure, and optimal temperature and humidity (235). The hybrid laboratory should have thermostat and humidistats for recording temperature and humidity.

### 7.2.7. Table Requirements

The surgical table needs to meet the individual requirements of interventional cardiologists, surgeons, and their teams. Surgeons need a fully motorized table and tabletop. In special circumstances (such as performing an aortic valve replacement), often the best position is to have the patient "sitting up," in reverse Trendelenburg, with the head up to 30° from the horizontal. The interventional cardiologist requires a radiolucent table with a full range of motion and a floating tabletop to allow fast movements during angiography. Both requirements are satisfied by a nonmetallic, carbon-fiber surgical table, with floating table-top and lateral and vertical tilt (234). Most tables designed for hybrid suites include in their specifications adequate weight tolerance (e.g., over 450 lb), longitudinal and lateral displacement, height displacement (e.g., 28 to 48 inches [685 to 1180 cm]), lateral tilt (e.g., 20° or more), and Trendelenburg and reverse Trendelenburg tilt (20° or more). The table can be positioned horizontal or diagonal in the room, depending on the size of the hybrid suite and the location of ancillary equipment.

### 7.2.8. Audio Video Inputs and Outputs

As procedures in a hybrid laboratory may involve many operators, audio and video monitoring may help to orientate anesthesia staff, staff in an adjacent control room, or those outside the sterile field. It may also provide an opportunity to educate staff and students without them entering the sterile zone around the table. Multiple video cameras that

are remotely operated with zoom function may be mounted on a wall, the x-ray monitors, or the surgical light handle. Key operators may choose to wear microphones and headsets to request equipment or to inform or receive requests from other team members (232).

### 7.3. Representative Procedures Suitable to the Hybrid Room Environment

Table 21 outlines some of the types of procedures that may benefit from the use of a hybrid cardiac catheterization laboratory.

## 8. Ethical Concerns

A physician's primary obligation is to act in the best interest of his or her patient. Associated with this is the obligation to "do not harm," and respect patient autonomy (236–238). The respect for autonomy mandates that patients be given appropriate and uncoerced choices about their health and potential medical care and requires that physicians provide accurate and unbiased information about the patient's medical condition, and disclose all potential avenues of care. The physician is responsible for obtaining satisfactory informed consent, and delineating the potential risks, benefits, and alternatives of the agreed-upon diagnostic and/or therapeutic strategy (236). The physician is responsible for documentation of the indication for the procedure and to document review of appropriate data (e.g., noninvasive tests). In addition, the physician must be transparent concerning any and all potential ethical or financial conflicts concerning therapies or devices employed in the patient's care.

Changing practice patterns in medicine, including the increased pressure for productivity from practice and hospitals due to declining reimbursement, and other nonmonetary factors (academic promotion, etc.) have altered the relationships among physicians, patients, and payers, creating potential conflict of interest in maintaining the patient's best interest (237,239,240).

Physicians may now serve simultaneously as physician, inventor, and investigator of new therapies for vascular intervention. Similar issues exist with respect to the conduct of clinical research, in which the patient may be encouraged to participate in clinical protocols that may lead to little personal benefit (and potential risks), by physicians who may have a direct or indirect financial interest in their participation (112,239,241). This practice cannot be condoned.

### 8.1. Operator Assistant's Fees, Sharing of Fees, Fee Splitting, and Fee Fixing

There has been close scrutiny by third party payers and the federal government of the ethical (and financial) relationships between the referring physicians and the interventional cardiologist. Although some procedures may be optimal with the participation of 2 operators (e.g., percutaneous mitral repair, percutaneous aortic valve replacement, complex coronary procedures, or pediatric intervention), it is only ethical and legal for a cardiologist to charge an operator assistant's fee when he or she has directly participated in the procedure and was necessary for the performance of the procedure. Only 1 may be the primary attending physician as noted earlier. Furthermore, offering or providing a shared fee with another physician for the performance of cardiac catheterization is unethical and illegal.

It is also not ethical for a cardiologist to receive an admission fee, referral fee, or other "kickback" or commission for admitting or referring a patient to a hospital or cardiac catheterization facility (242). This principle applies not only to fees, commissions, and compensation received from other physicians and hospitals, but also to those received from manufacturers of catheters, medications, instruments, devices, or supplies that may be used in the catheterization laboratory. Great care must be exerted to avoid procedural incentives, as more and more cardiologists become employees of healthcare systems and hospitals, and incentives for increased productivity may be construed as violating the principles behind the Stark laws. Furthermore, such collusion may be illegal when such arrangements involve Medicare funds and are construed as inducement for referral. Collusion with other cardiologists in an attempt to fix fees for catheterization services may also violate antitrust laws.

### 8.2. Unnecessary Services

Duplication of services with additional charges or performance of unnecessary procedures or add-on procedures (right-heart catheterization, temporary pacemaker insertion) without specific indications and documentation of those indications is unethical and potentially illegal. A charge to over-read data by a physician who has not performed the procedure is also an unnecessary duplication of services and fees (241).

The overuse of tests as a means to protect providers from medical malpractice is an issue that needs further examination. Any unnecessary testing is discouraged and may place the patient at unnecessary risk as well as incurring unnecessary cost.

### 8.3. Self-Referral, Self-Ownership, and Self-Reporting

Physician self-referral is the practice of a physician referring a patient to medical facility in which the physician or an immediate family member has a financial interest. That interest may be in the form of ownership, investment, or like compensation (237,239,243–246). In response to the suggestion that self-referral unnecessarily increases the cost of medicine by overutilization of services, the Stark Laws were introduced. Stark I was introduced into law in 1989 (Omnibus Budget Reconciliation Act of 1989) (246a) and prohibited self-referrals of services of Medicare beneficiaries

except where provide by specific exceptions. This was expanded to include Medicaid beneficiaries in 1993 and extended in 2007 (246b).

Critics of physician-owned facilities, whether hospital or laboratory, consider them a source for overutilization and unnecessary increase in the cost of medicine, whereas backers of physician-owned facilities point out that individual procedures are cheaper, and there is a significant convenience for the patient.

A provision in the recently enacted health reform law (Patient Protection and Affordable Care Act of 2010) now places major limits on physician ownership of hospitals (246c). New doctor-owned facilities that are not certified as Medicare participants by December 31, 2010, no longer will be allowed into the program. Existing physician-owned facilities are currently being reconsidered and debated and may face restrictions on expansion.

### 8.4. Informed Consent

Informed consent is a legal procedure to ensure that a patient knows all of the benefits and risks involved in a treatment. The elements of informed consent include informing the client of the nature of the treatment, possible alternative treatments, and the potential risks and benefits of the treatment. The patient should be informed of the experience of the primary operator responsible for the procedure. In order for informed consent to be considered valid, the patient must be competent and the consent should be given voluntarily. In the absence of a patient's ability to understand or give informed consent, a person holding power of attorney may act as a surrogate.

Patient autonomy mandates that informed consent be obtained before performance of any invasive diagnostic or therapeutic cardiovascular procedure. Informed consent is an "ongoing process," and the education can be presented by any of the personnel involved in the procedure and may involve the use of written or video material, as well as traditional oral explanation. Although, there may be multiple people involved in obtaining informed consent, the physician is responsible for presenting him/herself to the patient and family and for the consent process. Informed consent must include an accurate description of the procedures, benefits, risks, and potential complications. Although not every eventuality can be predicted, it is adequate to present the common and usual risk and complications. The risks and complications must be presented accurately and must not be understated. They must be presented at a communication level that the patient and family can understand. If a physician extender (e.g., physician's assistant or nurse practitioner) or cardiology trainee is to perform any part of a procedure, this should be stated. If an "ad hoc" PCI procedure is anticipated immediately after a diagnostic procedure, then consent for this should be done prior to any sedation for the diagnostic procedure.

Informed consent must be obtained in a nonpressured environment when possible, but in situations (such as primary PCI for AMI) it is recognized that the environment may not allow a leisurely description, but nonetheless must be complete. Written informed consent should be obtained and documented in the medical record before the procedure.

Frequently, interventional procedures are performed as ad hoc procedures where the intervention immediately follows the diagnostic procedure. Ad hoc angioplasty has several inherent advantages; it expedites patient care, avoids a second invasive procedure with its associated risks and recognized morbidity, and reduces total x-ray exposure and therefore cost. However, it is associated with a larger volume of procedural contrast and ideally requires interventional pretreatment. A staged procedure allows ample time to review the angiogram; plan the procedural strategy; discuss the risks, benefits, and alternatives with the patient and family; and give informed consent based on the anatomy. Previous documents (110) have endorsed the recommendations from the SCAI (247) that ad hoc PCI be individualized and not be the standard or required strategy for all patients. Whenever there is a medical advantage to staging the procedures, this should be strongly considered. The convenience and cost advantage of ad hoc procedures, however, has made this practice commonplace and perfectly appropriate for most situations. The European Society of Cardiology has emphasized the importance of engaging the patient in any decision regarding an interventional procedure and making sure the patient has the final decision when there are several therapeutic options with no clear evidence for a particular strategy over another (248).

### 8.5. Ethics of "Teaching"

Although teaching hospitals have been essential to medical training for decades, patients admitted to a "teaching" hospital have a right to be aware of the level of training of the various physicians and related personnel involved in their care. It is ethical for the cardiologist to delegate the performance of certain aspects of the procedures to assistants, such as physician's assistants or fellows, providing that this is done transparently with the patient's consent and under the attending physician's supervision. Fellows or physician's assistants, if qualified, can also perform certain components of the invasive procedures, provided that they are supervised at all times by the attending cardiologist. It is not ethical to delegate the entire responsibility of invasive procedures to anyone not appropriately experienced and properly trained in the performance of the procedure. The attending physician must be responsible for all major decision making and must physically be present during all the critical points in the procedure.

### 8.6. Clinical Research Studies During Diagnostic and Interventional Cardiac Catheterization

An increasing number of teaching and community hospitals participate in clinical research protocols. Local institutional review boards now require a higher standard of disclosure for research studies than that required for clinical practice.

Accordingly, extra time should be taken with patients asked to participate in clinical research to ensure that all questions have been addressed. Research studies should not increase the risk of major complications disproportionally to the possible benefit when combined with diagnostic catheterization and interventional procedures. The investigative procedure should be performed after the essential information has been obtained if possible, but only if the patient's condition is stable and the diagnostic procedure has been performed in a timely fashion. Research procedures performed during the catheterization must be reviewed and approved by an institutional review committee.

Safeguards for ensuring that patients are appropriately enrolled in clinical research trials are as follows: that the clinical investigator has thoroughly reviewed the protocol for its scientific validity; the patient has met all the inclusion criteria and none of the exclusion criteria; the patient has been fully informed about the risks, benefits, and alternative therapies; and the clinical investigator follows the clinical protocol without unjustified deviation. In fact, most clinical investigators are ethical individuals whose motivations are to further scientific knowledge. Strict adherence to the clinical protocol is the best assurance that conflicts of interest will be minimized.

Although many challenges face cardiologists today, high ethical standards, including maintenance of proficiency, avoidance of real or perceived financial conflict of interest, disclosure of potential conflicts, and, most important, maintaining the patient's best interest as primary, remain of paramount importance. Only with attention to these issues will our profession continue to be viewed by the public (and our patients) as trustworthy and deserving of their respect.

### 8.7. Physician– and Physician Group–Industry Relations

Physicians and industry have a common interest in advancing medical knowledge. Nonetheless, the primary goal of the physician is to promote the patient's best interests, whereas promotion of profitability is a goal of industry. Although partnerships between physicians and industry can result in impressive medical advances, they also create opportunities for bias and can result in unfavorable public perceptions even if unintended. Accepting industry hospitality and gifts, even drug samples, can compromise judgment about medical information and subsequent decisions about patient care. It is unacceptable for physicians to receive gifts from industry. Physician–industry conflicts of interest can arise from other financial ties between physicians and industry, whether to outside companies or self-owned businesses. Such ties include honorariums for speaking or writing about a company's product, payment for participating in clinic-based research, and referrals to medical resources. All of these relationships have the potential to influence a physician's attitudes and practices (249). Excessive fees for speaking on behalf of industry or for participation in advisory boards are to be avoided. Most institutions have in place well-defined conflict of interest statements where gifts and income of even a modest amount from outside the respective institution are reported, and then reviewed by disinterested parties (usually a conflict of interest committee). These can then be judged whether appropriate. It is the responsibility of each physician to honestly and completely report such gratuities, honoraria, or income to these governing bodies.

Similarly, providers of medical education to interested groups of medical personnel have a duty to present objective and balanced information and should not accept any funds that are tied to industry-shaped programming. Medical educators have the sole responsibility to evaluate and control the planning, content, and delivery of education. They should disclose industry sponsorship to medical education participants and should adopt explicit organizational policies about acceptable and unacceptable interactions with industry (250).

### 8.8. Hospital Employment of Physicians

With wholesale changes in the U.S. healthcare system occurring currently, many cardiologists are being targeted to become employees in an effort to control costs. Physicians should never compromise patient care nor perform unnecessary procedures to satisfy a corporate or hospital "expectation." All decisions regarding the delivery of care should be focused on providing better patient results and not corporate profits.

## 9. X-Ray Imaging

Significant qualitative and quantitative changes in x-ray systems have transpired since the previous ACCF/SCAI consensus document on Catheterization Laboratory Standards published in 2001 (2). The qualitative changes reflect the migration to digital image acquisition, processing, and archiving, whereas the quantitative changes reflect the extent of market "penetration" of these digital systems. Consequently, the following discussion will be limited to significant advances in the field since the 2001 publication. Details of analog and digital imaging chains can be found in previous ACCF/AHA documents (1,251), past proceedings of the SCAI Melvin P. Judkins Imaging Symposia, NCRP Report 168 (252), as well as classic textbooks on the subject (253,254).

Continuing improvements in gantry design, ergonomics, and room layout belie the fundamental use of this equipment in the contemporary cardiac catheterization laboratory—the performance of potentially high-dose, fluoroscopically guided interventions. In 2000, the International Electrotechnical Commission published an interventional standards document in which a number of key technical and performance criteria were delineated (255). These standards were updated in 2010 (255). These standards are the basis of many of the FDA legally enforceable regulations (256).

Importantly, manufacturers of x-ray units built after this date, and designated for the purpose of high-dose, fluoroscopically guided interventions, must demonstrate compliance with these criteria. Additional criteria were added by the FDA in 2005 for all such units manufactured after that date (257). A number of these criteria are discussed below, but it is important to point out that some portions of these standards are not applicable to simple mobile gantry systems. Any x-ray unit used for high-dose, fluoroscopically guided cardiovascular interventions should be compliant with the IEC interventional standard.

## 9.1. Equipment and the "Imaging Chain"

### 9.1.1. Image Formation

The advent of digital x-ray systems has fundamentally transformed the process of image formation and, consequently, image quality (Table 22). Although "analog" and "digital" systems share a common means for generating x-rays using high-output, micro circuitry-driven generators and similar x-ray tube technologies, it is the "detector" that has fundamentally changed the way in which images are formed and processed. "Flat-panel" detectors (and their inherent charge-coupled device technology) have not only physically replaced the image intensifier and television camera in traditional analog imaging chains, but have improved the overall efficiency of the process of image formation. Although a detailed description of the physical design and electronic configuration of these detectors is beyond the scope of this document, the translation of information contained within the pattern of x-rays exiting the subject to that contained within an electrical (digital) video signal created by the flat panel detector is a major improvement over the sequential conversions (and consequent loss of information) of x-ray energy to light energy (image intensifier) and light to electrical/video signals (TV "pick-up" tubes, video scanners). Such improved process performance with flat-panel systems is measurable and expressed as greater detective quantum efficiency, or DQE (258). Flat panel detectors have enhanced image uniformity, uniform brightness, and dynamic range when compared with the image intensifier. However, there are scant objective, comparative data on other measurable parameters of digital fluoroscopic "image quality" (e.g., high-contrast spatial resolution and low-dose, low-contrast resolution) between flat panel systems and traditional image intensifier–based systems (259). The use of the National Electrical Manufacturers Association fluoroscopic phantom (260), although developed for image-intensifier–based technology, is a significant advance in this area and may allow for such cross-system comparisons. Importantly, despite initial aspirations to the contrary, the consequences of these improved performance characteristics have not been consistently shown to result in reduced x-ray dose (258).

Just as an understanding of the generation of x-rays is fundamental to the process of image formation, so is an understanding of the control of the dose-rate (strength) of the x-ray beam. The importance of dose-rate control for both image quality and patient and staff safety is discussed elsewhere in this document. However, an understanding of the characteristics of the x-ray beam, and its modification, is critical from a catheterization laboratory standards viewpoint. Although none of these factors is uniquely different in flat panel systems, they may be overlooked owing to the other (perhaps forgiving) features of flat panel detectors (e.g., greater dynamic range and improved contrast). In addition, in most flat panel systems, image, or quantum, noise may be reduced with special recursive filtering and image processing algorithms, resulting in a more attractive visual image display.

The main "beam factors" that affect image formation, and patient dose, are beam penetrating power (hardness), scatter, and signal-to-noise ratio. The current generation of x-ray tubes and generators are designed for the high-performance, high-power requirements of interventional cardiology. High heat load capacity x-ray tubes in combination with the filtering of "soft" (low-frequency) x-rays from the beam prior to patient entrance enhance the "hardness" of the beam in order to reduce patient dose and improve overall image quality. The amount of scattered radiation—the result of Compton interactions within the patient—is directly related to the primary dose. Scattered radiation not only degrades image quality and reduces contrast, but is the main source of staff exposure as well as patient exposure outside of the primary field. It is difficult to overheat state-of-the-art x-ray tubes.

In traditional "analog" catheterization laboratories with a classic image intensifier, the level of light intensity at the

**Table 22. Summary of Major Changes in the Contemporary Catheterization Laboratory Imaging Chain Over the Last Decade**

**X-ray generator:** electronic control/high-frequency/high-output; automatic dose control; pulse and continuous modes of operation with a large selection of "stations" corresponding to different procedure types, as well as multiple dose/exposure settings for each procedure.

**X-ray tube:** high-heat capacity tubes with more efficient anode cooling mechanism; more effective collimation (automatic); more effective spectral filtration ("beam hardening"); use of wedge filters.

**Flat panel detector**: improved "dynamic range"; improved uniformity of image/brightness; improved contrast; improved detective quantum efficiency.

**Image processing:** recursive filtering; edge enhancement/"smoothing" algorithms.

**Image display:** in-room liquid crystal display flat panel monitors; improved dynamic range.

**Dose monitoring**: dose-area product monitoring/display/reporting (suggested); interventional reference point cumulative dose monitoring/display (FDA mandated since 2006).

**Dose management**: virtual collimation permitting collimator settings without fluoroscopy, fluoroscopic last-image-hold; retrospective storage of fluoroscopy data.

output phosphor was fed back to the generator in order to maintain a preset, calibrated level of intensity on the phosphor (automatic brightness control, or ABC). In "digital" catheterization laboratories with flat panel detectors, the flat panel–produced digital video signal is fed back to the generator in order to maintain the preset, calibrated voltage output from the detector (automatic dose-rate/exposure control, or ADC). Variability in patient body habitus or angled gantry configurations will be sensed by the generator/x ray tube unit as conditions requiring greater beam penetrating power (increasing kVp and/or increasing mA) and subsequently increased dose-rate.

Unavoidable variability in the construction of the detector itself may result in an inherently "noisier" image, particularly at the lower dose rates employed during fluoroscopy, thereby necessitating a higher dose- rate of x-ray. While the higher dose-rate may result in an "improved image," the need for total dose monitoring under such conditions should be obvious. Thus, U.S. federal and international standards for dose monitoring and dose limits are important additions to catheterization laboratory safety and performance standards. Operators need to be aware of the dose-monitoring capabilities of newer x-ray systems as this information can be used to minimize patient radiation exposure.

#### 9.1.2. Digital Storage and Display

The increase in information content and flux that occurs with digital imaging requires a commensurate increase in storage capacity and system "bandwidth" to facilitate "online" and postacquisition review and archiving of studies. "In-room" central processing units with storage capacity in the terabyte range are not unusual nor are archiving systems with multiterabyte capacity. The fundamental requirement for online, immediate review of portions of a coronary interventional procedure mandate fast Ethernet-transmission speeds for the acquired images at mega-pixel resolution that are then "processed," "filtered," and presented for review. The importance of high-resolution, in-room, table-side monitors cannot be overstated. Although the latter are often incorporated into the entire "package" of a newly purchased x-ray system, "retrofitting," "upgrading," and "refurbishing" of extant in-room monitors are still frequently encountered and may be primarily responsible for less-than-expected improvement in fluoroscopic image quality. Careful attention must be paid to the calibration, resolution (contrast and spatial), and dynamic range of these monitors, including those installed as part of a new system.

#### 9.1.3. Quantitative Measures

Although multicapability "software" packages and modules are now universally available with the purchase of a new x-ray system, the full extent of use of such capabilities is unknown. In contrast to the near-universal use of administrative and logistical (scheduling, billing, coding, etc.) software modules—all provided in one form or another with the purchase of a new catheterization laboratory—the quality-assured, routine use of quantitative ventriculographic, hemodynamic, and/or coronary angiographic software is less widespread. Even less frequent is onsite validation of the information provided by such user-interfaced software. This is particularly important in instances of "lesions of borderline significance" and likely contributes to the still widespread practice of ad hoc PCI (99). Similar issues abound with incorrectly obtained hemodynamic information "processed" with such software, the consequences of which may lead to erroneous conclusions regarding condition severity (261). The importance of "acceptance testing" or onsite validation of such software cannot be overemphasized, and physician diligence and clinical judgment is always critical for the proper interpretation of these data.

### 9.2. Radiation

#### 9.2.1. Biological Risks

The biological risks of x-radiation have been discussed in great detail in The NCRP Report 168 and in standard texts (262) in addition to recently updated reports and expert consensus documents (251,263–267). X-rays produce cellular injury primarily by causing fractures in the DNA backbone. X-ray radiation risks can be broadly categorized as 1) deterministic—that for which a "dose–injury" relationship exists and for which a threshold dose has been determined and 2) stochastic—that for which the probability of injury is related to dose and for which no threshold dose has been defined ("linear–no-threshold" hypothesis). The former relates most importantly to the risk of skin injury and possibly cataract formation whereas the latter relates to the long-term risks of radiation-related cancer. When enough cells of a particular organ (such as the skin) are injured so that its function is impaired, that defines a deterministic risk, and the dose when that occurs is the threshold dose. In contrast, a stochastic injury occurs when there is injury to the DNA backbone that does not properly heal itself, and the result is not cell death but a mutation leading to either a cancer or a genetic abnormality. A single x-ray photon may cause this change and is not directly dose related, though the risk of acquiring such injury increases with dose. Risks to the germ plasm, and offspring of the x-radiated subject are stochastic in nature albeit substantially lower than the risk of cancer development to the subject. Although the clinical manifestation of deterministic injury is seen in characteristic skin lesions (268–270), there is, at present, no validated or reliable "biomarker" for stochastic risk. Risks to the irradiated fetus can be considered deterministic (a defined threshold dose), although periods of highest vulnerability to radiation-related effects are time dependent and confined to the first trimester. Doses to the fetus of >100 mGy may result in mortality or failure to implant during the first couple weeks, but it is unlikely a fetus would receive this amount from cardiac catheteriza-

tion. Surviving fetuses during this initial period of exposure have few lasting effects due to the fact that the embryo is composed of only a few cells that will eventually differentiate into multiple organs (206a). The stochastic risk of cancer induction in a fetus is considered similar to that of a newborn.

### 9.2.2. Measuring Radiation Exposure and Radiation Dosimetry

Monitoring of personnel in the cardiac catheterization laboratory is important to detect potentially unsafe working practices and to remediate them whenever possible. It is the individual's legal and ethical responsibility to wear radiation badges to monitor their exposure to ionizing radiation. If specific individual records reveal unusual dose exposure, a review of the individual practice is warranted (252) and corrective action should be undertaken.

The International Commission on Radiation Protection recommends 2 monitoring badges, 1 under the radiation protection garment (between the waist and chest) and 1 on the collar (271). The NCRP accepts a single outside collar monitor, though prefers the 2 monitor suggestion (272). The SCAI suggests a single monitoring device worn on the collar is acceptable. If a worker declares she is pregnant, a fetal monitor under the lead apron is required at waist level (273).

Table 23 provides the standard terminology and definitions for catheterization laboratory–based considerations of radiation exposure.

Further, and more detailed, explications of the terminology employed can be found in authoritative review articles on the subject (271). Importantly, although "exposure" to x-radiation can be directly measured, the dose to internal organs cannot be directly measured and must be estimated. Thus, the measure of risk is imprecise, subject- and procedure-dependent, and ultimately, obtained from epidemiologically derived associations of such estimated absorbed doses with long-term, clinically manifest disease. A detailed discussion of this subject is beyond the scope of this document, but the interested reader is referred to the latest publication of the BEIR VII report (264).

Of most relevance to the catheterization laboratory environment is the derivation, and meaning of, the effective dose (ED), as it is the latter that encompasses the stochastic risk associated with ionizing radiation. ED, a quantity derived from the weighted sum of Monte Carlo–derived estimates of individual organ doses, should more properly be viewed as a metric of radiation safety and used for interprocedural comparisons rather than a unique "dose" of radiation to a given individual (275). Given the above-noted complexity in the assessment of ED, an approximation of the stochastic risk associated a given x-ray procedure can be estimated by multiplying the DAP—the product of the air kerma at any point along the center axis of the x-ray beam and the beam cross-sectional area at that point—and an anatomically based and empirically derived conversion factor reflecting the conversion from DAP (Gy-cm$^2$) to ED (Sv) (276). The DAP is derived from a transmission chamber fitted to the output of the x-ray tube. It represents total x-ray energy directed toward the patient. The accumulated reference point air kerma when combined with gantry position and patient geometry provides a rough idea about how much x-ray dose the patient's skin received. The association between the risk of radiation-related cancer mortality and exposure is derived mainly from the atomic bomb survivor experience where exposure was whole-body (in contrast to localized, as in invasive procedures), averaged over a population of varying ages and gender (hence the need to specify age- and sex-specific risks of cancer mortality) and cancer-related deaths in individuals with exposures below 100 mGy. However, this latter dose is well above the reported range for EDs associated with most but not all fluoroscopically guided interventional procedures. Furthermore, the risk of radiation-related cancer development and mortality must be placed in perspective with respect to the overall lifetime risk of cancer mortality (~25% overall). Currently, the overall lifetime incremental risk of cancer-related mortality attributable to radiation exposure is estimated at 4% to 5% per Sv (264,277). A dose–response relationship between occupational exposure and posterior lens changes in the eyes has also been suggested recently (278).

**Table 23. Relevant Nomenclature for Radiation Exposure and Dosimetry**

| Term | What Is Being Measured | Unit of Measure | Conversion |
|---|---|---|---|
| Exposure | Ionization produced in air by x-rays | Roentgen, R, or coulomb/kg air | 1 R=2.58 $\times 10^{-4}$ coulomb/kg air |
| Air kerma | The sum of the initial kinetic energies of all the charged particles liberated by uncharged particles | Rad, or gray (Gy) | 100 Rad=1 Gy |
| Absorbed dose | The energy imparted to matter by ionizing radiation per unit mass of irradiated material at the point of interest | Rad, or gray (Gy) | 100 Rad=1 Gy |
| Effective dose | Estimated total body dose | REM or sievert (Sv) | 1 Rad=10 mGy |

#### 9.2.2.1. PATIENT EXPOSURE

There is an extensive literature on patient exposure during coronary angiographic procedures. The majority of this literature was generated in the "pre-flat panel" era, but remains applicable. Overall, estimated patient ED for diagnostic coronary angiographic procedures ranges from 2.3 to 22.7 mSv with a mean of 7 mSv (279,280), whereas EDs for simple coronary interventional procedures range 50% to 100% higher than those for diagnostic studies and, on average, are approximately 15 mSv (281). To put this into some kind of perspective, the average nonmedical background radiation dose in the United States is about 3.0 mSv per year, and the average dose from a routine chest x-ray is about 0.02 to 0.10 mSv. Manufacturer-originated claims have suggested reduced patient exposure with flat panel systems, although these claims are likely confounded by secular trends in enhanced awareness of radiation safety and improved operator technique. The need for vendor-independent, geographically disperse data in this regard is significant.

The increased complexity of interventional procedures—coronary as well as peripheral vascular, valvular, and congenital heart disease—is of increasing relevance in any contemporary consideration of patient exposure. A median ED in the pediatric diagnostic catheterization experience has been reported at 4.6 mSv and that for therapeutic procedures at 6.0 mSv (282). Similarly, estimated EDs for complex electrophysiological procedures have been reported to average 50 mSv in men and 32 mSv in women (283). Limited data in the setting of complex structural heart disease interventions in adults suggest that, on average, ED exceeds that for coronary intervention by 25% to 50% (284).

A more immediate concern with increasingly complex and lengthy high-dose fluoroscopically guided interventional procedures is that of radiation-related skin injury (269,270,285). The awareness and likelihood of skin injury with increasing dose has focused attention on its recognition and prevention. The skin dose metric that is believed to best capture this deterministic risk is the peak skin dose. However, such a determination requires the placement of numerous dosimeters over, or adjacent to, the irradiated area—a cumbersome and infrequently performed routine. Analogous to the use of the DAP as an estimate of stochastic risk, the cumulative dose at the IRP—15 cm below isocenter—has been suggested as an alternative measure of deterministic risk (255). The 15 cm distance from the patient's isocenter is about the distance one would expect the skin to be located. Note that the displayed cumulative value of air kerma is not skin dose. It does provide a starting point for calculating skin dose. Other factors, including beam motion during the procedure, patient–gantry geometry, and backscatter from the patient, affect the amount of radiation received by the skin as well. A clinically useful simplification is to regard cumulative reference point values above 5,000 mGy as the threshold of a substantial dose (252,255). This is an amount that would be quite rarely received during cardiac catheterization but is not uncommon in complex interventions. Tissue skin reaction for various parts of the body is outlined in Table 24. Ideally an estimate of the patient radiation dose should be a part of every clinical report, and if a substantial dose has been delivered, the patient should be appropriately informed prior to discharge.

#### 9.2.2.2. OCCUPATIONAL EXPOSURE

The major source of exposure to catheterization laboratory personnel is scattered radiation from the patient, with the latter strongly dependent on procedural length and complexity, operator technique, and gantry configuration (263,286). The extent of scatter radiation is closely associated with the DAP. In a review of the literature on occupational exposures in cardiac catheterization laboratories over the past 30 years, the authors identified primary operator EDs ranging from 0.02 to 38.0 $\mu$Sv and 0.17 to 31.2 $\mu$Sv, for diagnostic and interventional procedures, respectively (287). Exposure of support personnel working in catheterization laboratories, but not in immediate proximity to the tableside or image detector, receive the lowest exposures (272).

### 9.2.3. Minimizing Radiation Exposure

Professional societal guidelines directed towards radiation safety and the minimization of patient and personnel exposure have been available for 25 years (263,288,289) and have been recently summarized and updated (251). The mechanics of reducing patient exposure require proper use of the equipment itself (e.g., gantry positioning, degree of magnification, detector input dose, x-ray tube output dose rate, collimation and beam filtration; recognition of patient-specific factors; procedure-related factors, length and complexity of procedure, and proper use of control mechanisms).

The mitigation of patient exposure translates directly to mitigating the exposure of operator and staff because scatter radiation increases (decreases) as beam intensity increases (decreases). The driving principle behind reducing occupational exposure is the ALARA principle (290). Attention to "time" (beam on-time or the period in which x-rays are emitted from the x-ray tube), "shielding" (the use of lead-or its equivalent-lined aprons for the torso and waist, as well as thyroid collar and protective eyewear), and "distance" (establishing a safe working distance from the patient as well as image detector, utilizing the "inverse square law") are the most effective means of reducing occupational exposure. Tables 25 and 26 highlight the major means of reducing exposure to patients and staff, respectively.

### 9.2.4. Quality Management and Measurement of Radiation Exposure in the Cardiac Catheterization Laboratory

An effective QA/QI program in the cardiac catheterization laboratory must be centered on patient and staff safety.

**Table 24. Tissue Reactions From Single-Delivery Radiation Dose to Skin of the Neck, Torso, Pelvis, Buttocks, or Arms**

| | | | Approximate Time of Onset of Effects | | | |
|---|---|---|---|---|---|---|
| Band | Single-Site Acute Skin-Dose Range (Gy)* | NCI Skin Reaction Grade† | Prompt | Early | Midterm | Long Term |
| A1 | 0–2 | NA | No observable effects expected | No observable effects expected | No observable effects expected | No observable effects expected |
| A2 | 2–5 | 1 | Transient erythema | Epilation | Recovery from hair loss | No observable results expected |
| B | 5–10 | 1–2 | Transient erythema | Erythema, epilation | Recover; at higher doses, prolonged erythema, permanent partial epilation | Recovery; at higher doses, dermal atrophy or induration |
| C | 10–15 | 2–3 | Transient erythema | Erythema, epilation; possible dry or moist desquamation; recovery from desquamation | Prolonged erythema; permanent epilation | Telangiectasia; dermal atrophy or induration; skin likely to be weak |
| D | >15 | 3–4 | Transient erythema; after very high doses, edema and acute ulceration; long-term surgical intervention likely to be required | Erythema; epilation; moist desquamation | Dermal atrophy; secondary ulceration due to failure of moist desquamation to heal; surgical intervention likely to be required; at higher doses, dermal necrosis, surgical intervention likely to be required | Telangiectasia†; dermal atrophy or induration; possible late skin breakdown; wound might be persistent and progress into deeper lesion; surgical intervention likely to be required |

Note: Applicable to normal range of patient radio-sensitivities in absence of mitigating or aggravating physical or clinical factors. Data do not apply to the skin of the scalp. Dose and time bands are not rigid boundaries. Signs and symptoms are expected to appear earlier as skin dose increases. Prompt is <2 weeks; early, 2 to 8 weeks; midterm, 6 to 52 weeks; long term, >40 weeks. *Skin dose refers to *actual* skin dose (including backscatter). This quantity is not the reference point air kerma described by the Food and Drug Administration (256) or International Electrotechnical Commission (255). Skin dosimetry is unlikely to be more accurate than ±50%. †Refers to radiation-induced telangiectasia associated with area of initial moist desquamation or healing or ulceration may be present earlier. Reprinted with permission from Balter et al. (285).

NA = not applicable; NCI = National Cancer Institute.

Building on a 20-year tradition of such efforts, SCAI published a monograph in 1999 in which seminal and relevant publications addressing the many dimensions of catheterization laboratory standards for the assessment of quality and safety can be found (291). A broader discussion of the assessment of procedural quality and outcomes is found elsewhere in this document. The ongoing assessment of quality and outcomes in the catheterization laboratory, a fundamental aspect of any continuous quality improvement process (292), must include dose monitoring for both patients and personnel. Although personnel exposure always needs to be monitored in the catheterization laboratory (293), there are surprisingly fewer sets of guidance data for patient exposure. Maximum allowable exposure limits for medical radiation workers exposed to various sources of ionizing radiation are explicitly described in Table 27 (272,288).

The FDA has set an upper limit to "tabletop" fluoroscopic exposure rate of 10R/min for systems with automatic exposure control (256); however, there are no regulatory limits on cine exposure rates. The fluoroscopic guideline, however, serves more as an indicator of x-ray generator and overall imaging chain function (294) than a direct measure of skin dose (and, therefore, deterministic risk). As noted earlier, differences exist between the FDA-specified air kerma determination 30 cm in front of the detector versus the IEC-recommended (cumulative) air kerma determination at the IRP 15 cm from middle of the patient to the source along the isocenter line (assuming that equates to where the skin lies). Unfortunately, neither measurement is an accurate indicator of stochastic (earlier) or deterministic (later) risk. However, all catheterization laboratory x-ray systems manufactured after 2005 and sold in the United States are now required to provide real-time information regarding total radiation exposure time (fluoroscopic and acquisition mode) and reference point air kerma; many systems also measure and display DAP. These data provide patients and physicians more meaningful estimates of risk. This information should be included in the procedural report. A summary of these records should be incorporated into the catheterization laboratory's performance improvement process logs. All of this information should be reviewed for internal consistency within the lab and in comparison to published external guidance data (252).

The measurement and management of radiation exposure in the catheterization laboratory environment cannot be divorced from the issues of competence, credentialing, and proficiency. Accordingly, physicians (and staff) must be knowledgeable in matters of radiation physics, radiation biology, and technological developments in x-ray imaging systems and x-ray dose management (251). A rigorous curriculum for the latter should be an integral part of every

**Table 25. Reducing Exposure to Patients**

| |
|---|
| Minimize beam "on-time" |
| Minimize framing rates |
| Minimize total fluoroscopy time |
| Use pulse fluoroscopy whenever possible with frame rates <15 fps |
| Minimize use of "high dose" rate fluoroscopy |
| Minimize number of acquisition runs |
| Minimize use of geometric/electronic "magnification" modes |
| Keep tube current (mA) low |
| Keep tube potential (kVp) as high as possible without washing out image |
| Use collimation to irradiate only the area of interest |
| Use copper and other filters at the x-ray tube output to reduce unnecessary x-ray photons |
| Appropriate use of gantry configuration |
| Optimize the source-to-skin distance |
| Minimize the source-to-detector distance ("air gap") (source-to-image distance) |
| Minimize extreme compound angulations to reduce the x-ray beam path in the patient |
| Use multiple rotational and axial skew configurations |
| Do not work in 1 view exclusively to vary radiation distribution on the skin (if so, minimize need for extreme compound angulation (e.g., left anterior oblique projection) |
| Limit cineangiography acquisition and save fluoroscopic image data in its place when possible. |

interventionalist's training and should comprise an important segment of the certifying examination. The increasingly complex clinical conditions seen in catheterization laboratories today require a more sophisticated understanding of, and approach to, the technical, pharmacological, and radiologic aspects of interventional cardiology. Rigorous training and ongoing assessment of each of these 3 "pillars" is, ultimately, the responsibility of each practitioner. Numerous excellent training and "refresher" curricula are currently available from authoritative sources (295,296) and are recommended readings.

## 10. Special Concerns for the Pediatric Cardiac Catheterization Laboratory

Routine cardiac catheterization of children is performed in most of the 120 children's hospitals in the United States. In general, these hospitals also provide the infrastructure for comprehensive pediatric cardiovascular centers, which support pediatric open-heart surgery, pediatric ECMO, advanced pediatric and neonatal intensive care, as well as noninvasive pediatric cardiology diagnostic services. Basically all facilities that perform cardiac catheterization on children must be full-service facilities as defined earlier.

**Table 26. Reducing Occupational Exposure**

| |
|---|
| Control dose to patient (see Table 27) |
| Implementation of time/shielding/distance |
| Correct positioning of staff relative to gantry |
| Staff education and training |

**Table 27. Maximum Allowable Radiation Limits for Medical Workers**

| | |
|---|---|
| Whole body | 5 REM/y (50 mSv/y) |
| Skin | 50 rad/y (500 mGy/y) |
| Lens of eye | 2 rad/y (20 mGy/y) |
| Fetus (for pregnant worker) | 0.5 rad (5 mGy) for the total pregnancy or 0.05 rad/month (0.5 mGy/month) (estimated by abdominal badge under lead apron |
| Cumulative exposure (lifetime) | 1 REM × age (10 mSv × age) |

In the context of the catheterization laboratory: National and international general recommendations have been reformatted to better distinguish between local dose (measured in rad or mGy) and effective dose (measured in REM or mSv).

Pediatric catheterizations are performed either in dedicated pediatric cardiac catheterization laboratories (PCCLs) or in catheterization laboratories used for both children and adults. Dedicated pediatric laboratories are most often components of free-standing children's hospitals. Joint-use laboratories are most often located in general hospitals that have either a large inpatient pediatric service or a closely affiliated neighboring children's hospital that shares core infrastructure with the general hospital.

Whether children have catheterizations in dedicated or in joint-use laboratories, it is appropriate for both catheterization laboratory environments to adhere to applicable guidelines of all catheterization laboratories outlined earlier in this Statement. Furthermore, additional PCCL guidelines and best practices designed to address the unique challenges and issues related to pediatric patients and to congenital heart disease should be instituted. These additional PCCL guidelines and best practices are the focus this section of the document.

### 10.1. Differences in Goals

The PCCL should function as one of the critical elements within a pediatric cardiovascular center. The goals of the PCCL within a center should be to provide the diagnostic information needed to support medical, interventional, hybrid, and surgical treatments, as well as to provide the full range of interventional and hybrid treatments needed to achieve high-quality outcomes in pediatric patients with congenital and acquired heart diseases (297). Diagnostic catheterizations in children and adults with congenital heart disease are distinct from typical adult catheterizations, because, by definition, they are designed to evaluate structurally abnormal hearts. Catheterizations usually include right (and left) heart catheterization, quantification of cardiac index, multichamber oximetry assessments, calculations of left-to-right and right-to-left shunts, and pulmonary and systemic vascular resistance. Cardiac index may be measured by thermodilution, but because of the presence of shunts, the Fick principle is more commonly employed, and oxygen consumption is usually assumed. Because of dramatic growth-related changes in pediatric body surface area and the need for comparative hemodynamic data, flow and resistance values are usually indexed for body surface area.

Furthermore, in addition to demonstrating all aspects of coronary arteries, pediatric angiographic studies are usually intended to define and display complex intracardiac anatomy as well as pulmonary and systemic vessels. These imaging data may supplement or complement other common imaging modalities such as echocardiography, CT angiography, and MRI. A wide variety of congenital and acquired heart and great-vessel defects and abnormalities are investigated in the PCCL.

Interventional procedures are the primary or a secondary objective in up to three fourths of all catheterizations performed in the PCCL. A substantial number of unique interventional procedures are performed. Most of the individual procedures are performed in relatively small numbers. These procedures include atrial septostomy, valvuloplasty, angioplasty, stent implantation in large vessels, vascular closure (patent ductus arteriosus, other anomalous vessels, and fistulae), device closure of atrial communications and ventricular septal defects, transcatheter valve implantation, endomyocardial biopsy, foreign-body retrieval, pericardiocentesis, and a range of electrophysiological procedures (298,299). Expertise in these procedures is acquired during pediatric cardiology fellowship training and in pediatric cardiology post-fellowship training in the interventional cardiac catheterization laboratory (often during an additional training year) (300).

Hybrid procedures are an important activity in many PCCLs. These procedures are performed jointly or cooperatively by an interventional cardiologist and a cardiac surgeon. They are often performed in infants who have a thoracotomy exposing the surface of the heart. Interventional catheterization procedures are performed with access provided directly through the anterior wall of the right ventricle or the main PA. The most common interventions are Stage I palliation of hypoplastic left heart syndrome (stenting of the patent ductus arteriosus), angioplasty and/or stenting of PAs, and closure of muscular ventricular septal defects (301,302).

### 10.2. Who Should Perform Catheterizations in the Pediatric Cardiac Catheterization Laboratory?

PCCLs, whether dedicated or shared with adult cardiologists, should have a pediatric director. The director should be board certified in pediatric cardiology and should have additional training in pediatric cardiac catheterization and intervention (or qualifying experience). The director should be responsible for all aspects of the administration and function of the PCCL (including backup of other pediatric operators with less training or experience). In addition, QA and QI activities related to pediatric studies should be under the director's guidance.

Other attending physicians who perform cardiac catheterization in children are generally board eligible or board certified by the American Board of Pediatrics, Subspecialty Board of Cardiology. There may be exceptional cases in which a competent physician has gained extensive experience without formal board certification, but these physicians usually have been allowed privileges by a "grandparent" clause. Whether privileges for non–board-eligible physicians may be granted is left to the discretion of the individuals involved and the hospital credentialing process.

The pediatric age range is usually considered to be from birth through 18 (or 21) years of age. It is recommended that pediatric cardiologists perform catheterization on patients under the age of 18 years who require cardiac catheterization for congenital cardiac problems. Adult patients with previously diagnosed (repaired or unrepaired) congenital heart disease or with native congenital heart problems requiring cardiac catheterization should have the procedure performed 1) by a pediatric cardiologist; 2) by an adult cardiologist and a pediatric cardiologist collaborating during the procedure; or 3) by an adult cardiologist with an established special interest and expertise in adult congenital heart disease.

### 10.3. Quality Assurance Issues in the Pediatric Cardiac Catheterization Laboratory

New methodologies have recently been developed and applied to assessing adverse events occurring in the PCCLs (303). Contemporary complication rates for pediatric cardiac catheterizations have been defined in a large, well-structured, and controlled prospective multicenter catheterization laboratory registry study utilizing these methods (304). The median rate of overall adverse events is 16%: 10% for diagnostic cases and 19% for interventional cases—considerably higher than adult laboratories due to the marked difference in the patient population. Moderate severities to catastrophic adverse events are less common, occurring in 1% of endomyocardial biopsies, 5% of diagnostic cases, and 9% of interventional cases. Death occurred in 0.3% of cases. Previous studies reporting adverse events in the PCCL had been uncontrolled, retrospective, single-center studies, and/or reflected practice patterns and technologies from the 1980s and 1990s (305–307). These studies report lower rates of adverse events and are not so reflective of the contemporary era. Further prospective adverse events data in the PCCL are being collected by the IMPACT Registry.

The Bergersen et al. study (304) suggests that catastrophic complications (those resulting in death, rescue ECMO, or emergency surgery) should occur in well under 1% of all cases and in under 1% of interventional cases in a PCCL. Major complications (those requiring admission to the intensive care unit, emergent readmission to the hospital, a major nonsurgical intervention) should occur in $<2\%$ of all cases and in $<4\%$ of interventional cases. Informed consent for PCCL procedures is usually obtained from the patient's parents or guardians. This consent includes the physician's (or his or her designees, such as the cardiovascular fellows) explanation of the risks, benefits, and alternatives related to the procedure, with documentation of the explanation and of the parent/guardian understanding

shown by a signature. In urgent or emergent cases, such as when a transferred patient requires emergency balloon septostomy and the parents are in transit, consent may be obtained by telephone or even assumed and the procedure performed. The committee recognizes that there are consent and assent procedures and guidelines that vary by jurisdiction (hospital, state, county) and defers to those where applicable. Age or other circumstances that afford competence to the patient vary as well. These will determine whether it is acceptable to obtain the patient's "assent" or whether formal consent is required.

### 10.4. Inpatient Versus Outpatient Setting for Procedures

Although outpatient procedures have become common in the PCCL, there is less uniformity in patient and parent suitability for hospital discharge shortly after catheterization than in adult patients. Infants and young children cannot be instructed or expected to remain still without moving their legs for a period after a procedure. Any volume of blood lost into the subcutaneous tissue or retroperitoneum or onto the bandage or bedclothes will have more significance if the patient is smaller. Given the small number of PCCLs, pediatric patients and their families often have to travel farther for treatment than adult catheterization laboratory patients. The pediatric patient may also be farther from appropriate medical attention after returning home. Despite the smaller size of the patient, the sheath sizes used in pediatric cases may be nearly the same size (5-F to 8-F) as those used in adults. For these reasons, it is suggested that overnight observation be anticipated and allowed whenever there is any concern about patient safety. Nonetheless, a set of written criteria should be established for same-day catheterization and discharge by each PCCL. These criteria would account for differences in procedure type, patient age and expected compliance, parent or guardian reliability, travel distance, procedure duration and time-of-day completion, and the cardiac physiology in determining which patients are eligible for discharge on the day of catheterization. These guidelines should establish discharge criteria such as absence of bleeding, presence and adequacy of pulses and perfusion, access to medical evaluation and care after discharge, and parental understanding and ability to observe overnight.

### 10.5. Operator and Laboratory Volumes

Although the committee recognizes that access to services is important, there is also the valid impression that an adequate and maintained level of experience is required for the cardiologist and staff to obtain and preserve proficiency. In its 2002 "Guidelines for Pediatric Cardiovascular Centers," the American Academy of Pediatrics elected to specify outcome benchmarks rather than to recommend minimum operator or PCCL volume (297). However, previous ACCF/SCAI statements have recommended that individual operator minimum annual caseloads to be in the range of 50 to 100 cases per year (1). The committee continues to believe that an individual cardiologist performing catheterization in the PCCL should have a minimum annual case number >50 per year. Furthermore, if a PCCL routinely performs <100 cardiac catheterizations per year, consideration should be given to whether the volume justifies the program. In addition, because the level of skill and expertise required and the complication rates are related to the type of intervention and to patient characteristics, credentialing for therapeutic cardiac catheterization should be procedure specific (308).

A number of considerations must be taken into account when a decision is made regarding the minimum operator or PCCL volumes and credentialing of operators for specific interventional procedures. Although there are ample data regarding adult interventional procedures, there are no data relating number of pediatric procedures to skill or outcomes. It is important that institutional, local, and personal factors be weighed.

Importantly, QA plans must be in effect in all PCCLs to monitor outcomes of pediatric cardiac catheterization. There are some similarities and differences between the strategies required for QA in the PCCL versus the adult cardiac catheterization laboratory. For example, there is not a prior acceptable rate of normal cardiac catheterizations. In patients undergoing cardiac catheterization for hemodynamic reasons or possible intervention, the rate of normal should be zero. Any number of patients may have electrophysiological abnormalities or acquired disease with structurally normal hearts but abnormal physiology, and these would not be considered to be in the "normal" group. The effort to operate within benchmark adverse event rates is the same in all laboratories, although the types and rates of complications in the PCCL are different from those in the adult laboratory. Although intervention procedures are usually planned well in advance, ad hoc procedures might well be required. Such procedures as coil occlusion or vascular plugging of a ductus arteriosus or an aortopulmonary collateral or balloon dilation with or without stent placement may be needed even when not previously planned. Diagnostic quality and accuracy of catheterizations and procedural outcomes should be examined, with each PCCL responsible for earmarking certain indicators and examining them with plans for improvement if warranted by the data.

### 10.6. Procedural Performance Differences Compared With Adult Cardiac Catheterization

#### 10.6.1. Pre-Medication and Baseline Laboratory Data

In many pediatric laboratories, if the patient is in otherwise good health and on no medication, no preliminary laboratory tests are obtained prior to the cardiac catheterization procedure.

The choice, dose, timing, route, and overall use of pre-medication vary widely with age, size, and condition of patient and the experience and training of the operator. There is no "standard" pre-medication. Chloral hydrate,

diphenhydramine, and diazepam are frequently given orally for sedation. Intravenously, midazolam, morphine, fentanyl, hydromorphone hydrochloride, and other medicines can be used with good effect. The advantages of midazolam are that it can be given by continuous infusion and it can be reversed if necessary. Reversal of midazolam with flumazenil (Romazicon) does not usually precipitate the severe discomfort and agitation seen with naloxone (Narcan) narcotic antagonism. Ketamine may be used in small intramuscular or IV bolus doses for rapid-onset anesthesia. This may help during precise intervention when patient movement might be detrimental to procedure success. Meperidine (Demerol) alone or in combination with promethazine is sometimes used intravenously or by the intramuscular route for analgesia and sedation. Chlorpromazine is used less often than previously, because of the availability of and experience with other medicines.

#### 10.6.1.1. VASCULAR ACCESS ISSUES

Techniques for venous and arterial access are similar for children and adults. Most catheterizations are performed using the femoral vein and femoral artery. However, in a significant number of cases the left heart and aorta may be accessed through the venous approach, and retrograde arterial catheterization may not be required. Furthermore, transseptal procedures are commonly performed during diagnostic and/or interventional procedures in patients of a variety of ages (including infants). Properly performed, this approach does not add significantly to the incidence of complications. In general, newborn catheterization should be performed through the umbilical vessels when possible in order to preserve femoral vessels. In addition, because of the frequency of venous catheterizations and indwelling femoral venous lines in neonates and infants, limited or absent venous access from the femoral veins is not uncommon. Therefore, venous access from the internal jugular, subclavian, basilica, and transhepatic approaches are frequent. Alternative arterial approaches are also required in some children because of occluded femoral arteries. In young infants, a hybrid approach with carotid artery cut-down may be used to access the aorta in order to perform balloon valvuloplasty in critical aortic stenosis or for stenting of the patent ductus arteriosus in cyanotic infants. In addition, percutaneous brachial artery access or axillary artery cut-down may be used as alternative approaches in some children if femoral arteries are occluded.

The use of heparin in the flush solutions is routine, but the additional use of bolus-dose heparin depends on the patient's preprocedural ACT, procedure type, and vascular approach. It is common practice, for example, to avoid use of bolus heparin for right heart catheterization or prograde right and left heart catheterization, but heparin bolus is commonly used in retrograde left heart catheterization. At the end of a procedure, an ACT may be checked, and if necessary, the heparin effect reversed with administration of protamine sulfate in much the same manner as for adults. Some laboratories no longer use heparin during the cardiac catheterization procedure. Hemostasis is usually achieved by direct manual pressure followed by placement of an adhesive or elastic tape over a gauze pad on the percutaneous access site. However, percutaneous suture closure of suitable arterial and venous sites has become relatively common among suitable patients in the PCCL.

#### 10.6.1.2. SEDATION AND ANESTHESIA FOR PROCEDURES

Medications used during the procedures in the PCCL are essentially the same as those noted earlier for premedication. Repeated bolus doses of sedatives may be used, and/or a continuous infusion of midazolam or other drug may be instituted. It is necessary that a nurse or physician assess and document the patient's condition after each bolus dose of sedative according to the institution's conscious-sedation guidelines. Systemic arterial oxygen saturation should be continuously monitored by pulse oximetry. General anesthesia is performed by an anesthesiologist or nurse anesthetist under supervision for all or most patients in many PCCLs. Indications for anesthesia include patient considerations and procedure characteristics. For example, a developmentally delayed teenager who is fearful may be unable to be sedated without general anesthesia. Patients who are critically ill or in pain will benefit from anesthesia. Prolonged procedures such as those that require transesophageal echocardiography may be greatly facilitated with general anesthesia. Certain interventional procedures such as aortic or mitral valve dilation, ASD occlusion, and others may be made significantly easier, safer, and more effective when performed with general anesthesia. The use of anesthesia is a judgment made by the attending cardiologist in consultation with the anesthesiologist, just as it is in surgery.

In the current era, the PCCL has become the site for more invasive percutaneous interventions as well as hybrid procedures. The opportunity for catastrophic or critical events is thereby heightened. Therefore the committee believes that the PCCL should have plans for and access to rescue ECMO, in addition to standard resuscitation methods and technologies, in order to provide definitive resuscitation of patients having such events in the laboratory (308).

### 10.6.2. Single-Plane Versus Biplane Angiography

The standard equipment in a PCCL includes biplane radiographic equipment. In general, pediatric and congenital cardiac catheterizations are performed using biplane fluoroscopy and angiography. This is important both for localizing the catheter in space within the heart and great vessels and for reduction in contrast dosage administration. Certain procedures can be routinely performed with single-plane fluoroscopy, including (in many laboratories) electrophysiological study and radiofrequency ablation, some types of ASD occlusion, and others. ASD occlusion is often performed with localization and positioning of the device using transesophageal or intracardiac echocardiography as

well as fluoroscopy. Coronary arteriography in children may be performed with single-plane use, especially if it is assisted or performed by an adult cardiologist for whom performance of single-plane fluoroscopy/angiography might be standard.

### 10.6.3. Hemodynamics

As noted, right and left heart catheterizations are performed in combination in many pediatric and congenital heart catheterization procedures. In addition to the LV systolic and end-diastolic pressures and aortic or arterial pressures normally obtained in the adult cardiac laboratory, right-heart pressures are standard. Pressure waveforms and determinations of oxygen saturations are generally obtained from each chamber of the heart entered and from the PAs or veins, aorta, or systemic veins as indicated during any particular procedure. The routine pressure measurements and recordings necessary are difficult to specify, because they vary widely depending on the anatomy and physiology involved. For example, in a patient with pulmonary valve stenosis, an LV pressure may not be obtained at all, whereas an RV systolic and diastolic pressure recording is mandatory. On the other hand, PA pressure, routinely obtained in a right-heart catheterization, may be ill advised in a patient with severe tetralogy of Fallot. Even an invasive arterial or aortic pressure might not be obtained in the setting of a cardiac transplant repeat biopsy or other limited right-heart procedure. Pressures should be able to be recorded with excellent and reliable fidelity on scales, which range from a full scale of 10 mm Hg to 400 mm Hg. Rapid availability of oxygen saturations and blood gas determination is essential for interpretation of shunt physiology and for patient safety.

### 10.6.4. Angiographic Acquisition Differences

Angiograms are routinely performed with framing rates ranging from 7.5 to 30 fps (60 fps are rarely needed). The frame rate depends on the patient's heart rate and the types of images to be acquired. For example, during balloon dilation, images may be acquired at 15 (or 7.5) fps, whereas a ventriculogram in an infant with a high heart rate may require imaging at 30 fps. A wide variety of catheters, appropriate contrast materials, and injection techniques and parameters are available. Contrast is often injected at a faster rate in the PCCL compared with the adult laboratory, because fine details of the anatomy are sought rather than global function or regional wall motion abnormalities. In selected patients, 30 to 40 mL of contrast may be injected over 1 to 2 seconds, for instance. In addition, in most cases, premature ventricular beats or even ventricular tachycardia are better tolerated in younger patients with no ischemic heart disease. Angiograms should be available for immediate review after acquisition with instant-replay digital playback. Short- and long-term archival of digital data or cineangiograms does not differ from that described in prior sections.

### 10.6.5. Radiation Protection and Pregnant (or Potentially Pregnant) Patients

The same principles of radiation protection applied in the adult cardiac catheterization laboratory apply in the PCCL. In addition, girls and young women of child-bearing age should undergo beta-HCG testing to ensure that they are not pregnant before having a cardiac catheterization. This might be based on history in some cases (e.g., if a patient has an implanted chronic chemical contraceptive or if she has had a bilateral tubal ligation or hysterectomy), but it should otherwise include a serum or urine HCG level obtained within 2 weeks of the procedure. If a pregnant patient must be studied, the abdominal and groin areas should be shielded to help reduce any direct x-ray exposure, acknowledging that most of the fetal exposure is from scatter radiation. Efforts to minimize exposure should include using fluoroscopy or in-laboratory echocardiography rather than cineangiography and include all of the suggestions noted in Tables 25 and 26.

### 10.6.6. Shunt Measurements

Important information regarding physiology of congenital heart disease is gathered from measurements of intracardiac shunts. Both right-to-left and left-to-right shunts must be able to be quantitated during the catheterization. Because of the need to determine intracardiac shunting, oxygen saturation samples are drawn from many sites rather than simply from the PA for mixed venous oxygen level and from the systemic artery for arterial oxygen level. Therefore, the availability of oxygen saturation measurements and arterial blood gas determinations is essential for the efficient performance of the typical congenital cardiac catheterization. The availability of blood gas measurements also allows for the inclusion of dissolved oxygen in the determination of oxygen content.

## 10.7. Laboratory Personnel Issues

The laboratory staff in the PCCL should be specifically trained and experienced in the care of sick infants and children during performance of cardiac catheterization. The responsibilities within the laboratory may necessitate the services of 1 or more registered pediatric-trained nurses, a radiography technician, a certified catheterization technician, or others. It is the responsibility of the director and supervisor of the PCCL to ensure adequate staffing on a case-by-case basis. On-call cases must be considered, and a call schedule available in order to provide adequate staffing and anesthesia support in the PCCL for emergent and urgent pediatric catheterizations at all times. Timeliness of cases must also be part of the on-call planning.

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**Key Words:** ACCF expert consensus document ■ catheter-based coronary interventions ■ quality assurance ■ registries.

## APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2012 ACCF/SCAI EXPERT CONSENSUS DOCUMENT ON CARDIAC CATHETERIZATION LABORATORY STANDARDS UPDATE

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| Committee Member | Employment | Consultant | Speaker | Ownership/Partnership/ Principal | Research | Institutional, Organizational, or Other Financial Benefit | Expert Witness |
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*Recused from writing initial text and voting on document recommendations due to relevant relationships with industry to this document. †Significant relationship.

## APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHERS ENTITIES (RELEVANT)—2012 ACCF/SCAI 2012 CLINICAL EXPERT CONSENSUS DOCUMENT ON CARDIAC CATHETERIZATION LABORATORY STANDARDS UPDATE

| Peer Reviewer | Representation | Consultant | Speaker's Bureau | Ownership/ Partnership/ Principal | Research | Institutional, Organizational, or Other Financial Benefit | Expert Witness |
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| J. Dawn Abbott | Content Reviewer—ACCF Peripheral Vascular Disease Committee | • Medtronic | None | None | None | None | • Third party, interventional cardiology, 2010<br>• Plaintiff, interventional cardiology, 2010 |
| Christopher Allen | Content Reviewer—ACCF Peripheral Vascular Disease Committee | None | None | None | None | None | None |
| Amjad AlMahameed | Organizational Reviewer—SVM | None | None | None | None | None | None |
| Robert J. Applegate | Organizational Reviewer—SCAI | • Abbott<br>• St. Jude Medical | None | None | • Abbott*<br>• St. Jude Medical*<br>• Terumo* | None | None |
| John Baker | Content Reviewer—ACCF Cardiovascular Team Council | None | None | None | None | None | • Third party, case review, 2011 |
| Eric R. Bates | Official Reviewer—ACCF Board of Trustees | • Bristol-Myers Squibb<br>• Daiichi Sankyo<br>• Eli Lilly<br>• Sanofi-aventis | None | None | • Datascope | None | None |

| Peer Reviewer | Representation | Consultant | Speaker's Bureau | Ownership/ Partnership/ Principal | Research | Institutional, Organizational, or Other Financial Benefit | Expert Witness |
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| Deepak L. Bhatt | Official Reviewer—ACCF Task Force on CECD | None | None | None | • Bristol-Myers Squibb*<br>• Medtronic*<br>• Sanofi-aventis* | None | None |
| James Burke | Content Reviewer—ACCF Interventional Scientific Council | None | None | None | None | None | None |
| Michael Y. Chan | Content Reviewer—ACCF Cardiovascular Team Council | None | None | None | None | None | None |
| Willy Chi (Yung-wei Chi) | Organizational Reviewer—SVM | None | None | None | None | None | None |
| Curt Daniels | Content Reviewer—ACCF Adult Congenital & Pediatric Cardiology Council | None | None | None | None | None | None |
| Jose G. Diez | Content Reviewer—ACCF Interventional Scientific Council | • Sanofi-aventis | None | None | None | None | None |
| Stephen G. Ellis | Content Reviewer—ACCF CIP CCS | • Abbott<br>• Boston Scientific<br>• Cordis | None | None | None | None | None |
| Steven R. Fera | Content Reviewer | None | None | None | None | None | None |
| Federico Gentile | Content Reviewer—ACCF Task Force on CECD | None | None | None | None | • NIH* | None |
| Hitinder Gurm | Content Reviewer—ACCF Peripheral Vascular Disease Committee | None | None | None | None | None | • Defendant, need for invasive therapy in patient with CHF, 2011 |
| John W. Hirshfeld, Jr. | Content Reviewer—ACCF Fluroroscopy CCS | • St. Jude Medical | None | None | None | NIH, Data Safety and Monitoring—ATTRACT Trial | • Defendant, catheterization vascular access site complication, 2009 |
| David Holmes | Content Reviewer—ACCF Interventional Scientific Council | None | None | None | None | Atritech | None |
| Fred Kushner | Content Reviewer—ACCF UA/NSTEMI Guidelines | None | None | None | None | None | None |
| Glenn N. Levine | Content Reviewer—ACCF PCI Guideline | None | None | None | None | None | • Defendant, patient nonresponsive after noncardiac surgery, 2010 |

| Peer Reviewer | Representation | Consultant | Speaker's Bureau | Ownership/ Partnership/ Principal | Research | Institutional, Organizational, or Other Financial Benefit | Expert Witness |
|---|---|---|---|---|---|---|---|
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| Lloyd W. Klein | Content Reviewer—SCAI Quality Improvement Committee | None | None | None | None | None | None |
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| James Tcheng | Content Reviewer—ACC-NCDR Board | None | None | None | • NIH* | None | None |
| Robert Vincent | Content Reviewer—ACCF Adult Congenital and Pediatric Cardiology Council | None | None | None | • AGA | None | None |
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| Christopher White | Content Reviewer—ACCF Interventional Scientific Council | None | None | None | • St. Jude | None | None |
| Mathew Williams | Organizational Reviewer—STS | • Abott<br>• Edwards Lifesciences<br>• Medtronic | None | None | None | None | None |

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|---|---|---|---|---|---|---|---|
| Steven J. Yakubov | Organizational Reviewer—SCAI | None | None | None | None | None | • Defendant, adequacy and decision process of a PCI, 2010<br>• Defendant, stress testing evaluation, 2010 |

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∗Significant relationship.

ACCF = American College of Cardiology Foundation; SVM = Society for Vascular Medicine; SCAI = Society for Cardiovascular Angiography and Intervention; CECD = Clinical Expert Consensus Documents; CCS = Clinical Competence and Training Statements; UA/NSTEMI = Unstable Angina/Non–ST-Elevation Myocardial Infarction; PCI = Percutaneous Coronary Intervention; NCDR = National Cardiovascular Data Registry; STS = Society of Thoracic Surgeons.

## APPENDIX 3. ABBREVIATION LIST

ACS = acute coronary syndrome
ACT = activated clotting time
ADC = automatic dose control
ALARA = as low as reasonably achievable
AMI = acute myocardial infarction
aPTT = activated partial thromboplastin time
ASA = American Society of Anesthesiologists
ASE = American Society of Echocardiography
ASNC = American Society of Nuclear Cardiology
Atlantic C-Port-E = Atlantic Cardiovascular Patient Outcomes Research Team
AVA = Aortic Valve Area
BMS = bare-metal stent
BP = blood pressure
CABG = coronary artery bypass grafting
CARESS = Combined Abciximab Reteplase Stent Study in Acute Myocardial Infarction
CHF = congestive heart failure
CIN = contrast-induced nephropathy
CKD = chronic kidney disease
CME = continuing medical education
COCATS = The ACCF Core Cardiology Training Symposium
CON = Certificate of Need
COPD = chronic obstructive pulmonary disease
COURAGE = Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation
C-Port = Cardiovascular Patient Outcomes Research Team
CQI = Continuous Quality Improvement
CT = computed tomography
DAP = dose-area product
DQE = detective quantum efficiency
D2B = door-to-balloon times
ECMO = extracorporeal membrane oxygenation
ED = effective dose
eGFR = estimated glomerular filtration rate
FDA = Food and Drug Administration
fps = frames per second

GFR = glomerular filtration rate
GRACE = Global Registry of Acute Coronary Events
HCG = human chorionic gonadotropin
HIPAA = Health Insurance Portability and Accountability Act
HIV = human immunodeficiency virus
HR = hemodynamic response
IHE = Integrating Health Care Enterprise
IMPACT = Improving Pediatric and Adult Congenital Treatment
IRP = interventional reference point
LA = left atrial
LCD = liquid crystal display
LM = left main
LV = left ventricular
LVEDP = left ventricular end-diastolic pressure
LVEF = left ventricular ejection fraction
MACCE = major adverse cardiac and cerebral events
MACE = major adverse cardiovascular events
MDRD = Modification of Diet in Renal Disease
MI = myocardial infarction
MRI = magnetic resonance imaging
NCDR = National Cardiovascular Data Registry
NCRP = The National Council on Radiation Protection and Measurements
NHLBI = National Heart, Lung, and Blood Institute
NRMI = National Registry of Myocardial Infarction
NSAIDs = nonsteroidal anti-inflammatory drugs
NYHA = New York Heart Association
PA = pulmonary artery
PACS = picture archiving and communication system
PCCL = pediatric cardiac catheterization laboratory
PCI = percutaneous coronary intervention
PFO = patent foramen ovale
QA = quality assurance
QI = quality improvement
RA = right atrial
RACE = Reperfusion of Acute Myocardial Infarction in Carolina Emergency Departments
RAID = redundant array of independent disks
RCT = randomized controlled trial
RV = right ventricular
STEMI = ST-elevation myocardial infarction
SVG = saphenous vein graft
SYNTAX = Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery
TRANSFER-AMI = Trial of Routine Angioplasty and Stenting After Fibrinolysis to Enhance Reperfusion in Acute Myocardial Infarction

# 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

American College of Cardiology Foundation Task Force on Expert Consensus Documents, Society of Thoracic Surgeons, Society for Vascular Medicine, Thomas M. Bashore, MD, FACC,, Stephen Balter, Ana Barac, John G. Byrne, Jeffrey J. Cavendish, Charles E. Chambers, James Bernard Hermiller, Jr, Scott Kinlay, Joel S. Landzberg, Warren K. Laskey, Charles R. McKay, Julie M. Miller, David J. Moliterno, John W.M. Moore, Sandra M. Oliver-McNeil, Jeffrey J. Popma, and Carl L. Tommaso

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