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ACC/SCA&I EXPERT CONSENSUS DOCUMENT

American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards

A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents
Endorsed by the American Heart Association and the Diagnostic and Interventional Catheterization Committee of the Council on Clinical Cardiology of the AHA

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PREAMBLE

This document has been developed as a Clinical Expert Consensus Document (CECD), combining the resources of the American College of Cardiology (ACC) and the Society for Cardiac Angiography and Interventions (SCA&I). It is intended to provide a perspective on the current state of cardiac catheterization and the laboratories in which these procedures are performed. Clinical Expert Consensus Documents are intended to inform practitioners, payers, and other interested parties of the opinion of the ACC concerning evolving areas of clinical practice and/or technologies that are widely available or new to the practice community. Topics chosen for coverage by expert consensus documents are so designed because the evidence base, experience with technology and/or clinical practice are not considered sufficiently well developed to be evaluated by the formal ACC/American Heart Association (AHA) Practice Guidelines process. Often the topic is the subject of considerable ongoing investigation. Thus, the reader should view the CECD as the best attempt of the ACC to inform and guide clinical practice in areas where rigorous evidence may not yet be available or the evidence to date is not widely accepted. Where feasible, CECDs include indications or contraindications. Some topics covered by CECDs will be addressed subsequently by the ACC/AHA Practice Guidelines Committee.

The Task Force on CECDs 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 real or potential conflicts of interest to inform the writing effort.

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EXECUTIVE SUMMARY

A. The Cardiac Catheterization Laboratory Environment

Cardiac catheterizations are currently performed safely in hospitals with and without cardiac surgical backup. The latest information from the SCA&I lists >2,100 cardiac catheterization laboratories in the U.S. (including Puerto Rico and the Virgin Islands) (1). Of these, 72% provided on-site cardiac surgery (including 85% of those performing coronary intervention). Fifty-eight laboratories were located in nonhospital settings.

In a hospital with cardiac surgery, essentially all patients with cardiovascular disease can undergo invasive studies safely. Full support services include not only cardiovascular surgery but also vascular surgery, nephrology and dialysis, neurology, hematology, and specialized imaging services (e.g., computed tomography, magnetic resonance imaging, and ultrasound). See Table 7 for assessment of proficiency criteria for individual operators and cardiac catheterization laboratories.

In the hospital setting without cardiac surgery capability, many patients can undergo cardiac procedures safely. Exclusions for cardiac catheterization in this setting include patients with acute coronary syndromes, severe congestive heart failure, pulmonary edema due to acute ischemia, a high likelihood of severe multivessel or left main disease based on noninvasive testing, and severe left ventricular dysfunction associated with valvular disease. Certain elective therapeutic interventional procedures such as percutaneous coronary interventions (PCIs) and valvuloplasty should still be performed in facilities that provide cardiac surgical support. The ACC Competence Statement on Recommendations for the Assessment and Maintenance of Proficiency in Coronary Interventional Procedures and the ACC/AHA Guidelines for PCI Procedures (2,3) have addressed the issue of primary angioplasty for acute myocardial infarction in hospitals without cardiac surgery capability. Recent data suggest a lower mortality rate among patients undergoing primary angioplasty in higher-volume centers (4). Hospitals that perform primary angioplasty but are without on-site cardiac surgery capability must have a proven plan for rapid access (within 1 h) to a cardiac surgical operating room in a nearby facility with appropriate hemodynamic support ca-

pability for such a transfer. The procedure should be limited to patients with ST-segment elevation MI or new LBBB on ECG, and done in a timely fashion (balloon inflation within 90 ± 30 min of admission) by persons skilled in the procedure (≥75 PCIs performed/year) and only in facilities performing a minimum of 36 primary PCIs/year. In accordance with the soon-to-be-published ACC/AHA guidelines for PCI (3), this committee does not endorse the performance of elective PCI in a facility without cardiac surgery capability.

Patients are also being studied in freestanding laboratories (i.e., those that are not physically attached to the hospital). By definition a freestanding laboratory is one where quick transportation of a patient to a hospital by gurney is not possible. These patients clearly must be in stable condition and at the lowest risk for complications. It is vitally important to have mechanisms for backup and bailout in place to provide assistance should patients become unstable in this setting. Although a tertiary hospital serves as an appropriate means for providing proper oversight of a freestanding laboratory, recognized credentialing bodies approved by the local community may be able to provide appropriate oversight to ensure that all issues related to quality assurance (QA) are monitored and addressed. Interventional procedures of any kind should not be performed in a freestanding facility.

B. Same-Day and Outpatient Cardiac Catheterization

With the decline in risk associated with cardiac catheterization, the performance of invasive procedures in the ambulatory setting has become more popular. However, prehospitalization may still be important in patients receiving anticoagulation therapy or in those with renal failure, diabetes, or a contrast allergy. Early discharge after the procedure may also be inappropriate for certain patients, including those with a procedure-related complication or hemodynamic instability. In addition, some patients are best observed overnight if severe disease is discovered (e.g., significant left main coronary artery disease or severe aortic stenosis) or in the presence of significant comorbid diseases that increase the risk of late complications. A general scheme is presented to help determine who should be excluded from early discharge after cardiac catheterization.

C. QA Issues

Quality assurance starts with an assessment of clinical proficiency among the operators in the cardiac catheterization laboratory. This is surely one of the most difficult elements to assess, but issues of cognitive knowledge, procedural skill, clinical judgment, and procedural outcomes are all important. QA extends to the performance of the laboratory as a whole. A continuous quality-improvement (QI) program should also be included in the laboratory's overall design.

One measure of outcome is the number of "normal" diagnostic cardiac catheterizations performed. "Normal" in this regard refers to no disease or insignificant (<50% diameter narrowing) coronary stenoses in patients studied primarily for the identification of coronary artery lesions. It is recognized that there is a difference between coronary arteries that are completely normal and those that have insignificant luminal stenoses. It is further recognized that coronary disease is a dynamic process and that endothelial dysfunction may contribute to certain clinical syndromes. In some laboratories "normal" coronary arteries may be especially prevalent because the patient mix includes a variety of disease states where coronary disease is not the major concern such as cardiomyopathy and valvular disease. The rate of "normals" identified as either insignificant or no obvious luminal narrowing should be in the range of 20% to 27% if proper screening and baseline decision making is operative prior to the catheterization.

Outcomes related to complications for diagnostic catheterization should be very low–<1%. Diagnostic accuracy and adequacy are obviously important parameters as well, though they are rarely tracked. In the interventional cardiac catheterization laboratory the acceptable complication rates are more difficult to gauge, since measures of assessing high-risk patients have not been standardized. Major complications, (i.e., death, acute myocardial infarction, and emergency bypass surgery) from interventional procedures should be <3%.

The minimum number of studies needed to confirm adequate skills in cardiac diagnostic catheterization procedures has never been validated. Given the low risk of diagnostic catheterization, the QI system should be operative and should hold precedence over any arbitrary figures proposed in this setting. The Committee could find no data to support the prior recommendation for a minimum caseload of 150 catheterizations performed by an individual per year. A minimum interventional caseload is 75 cases/year per operator and ideally 400 cases/year for the laboratory. Because of the direct correlation between both laboratory and physician volume and outcomes, a low-volume operator (<75 cases/year) should only work in a high-volume laboratory (>600 cases/year), and even then with mentoring. Low-volume operators in any other setting should not perform interventional procedures. The minimum caseload for operators performing pediatric catheterizations has not been established by data, although a caseload of 50/year has been suggested for individual operators. Pediatric cardiac catheterization laboratories often share space with adult procedural facilities. The pediatric catheterization laboratory should perform at least 75 procedures/year.

Equipment maintenance and management remain an issue, and certain guidelines are provided. Each aspect of the radiographic system should be able to meet these performance expectations. The same is true for the physiological recorders and other specific devices used in the laboratories.

A QI program must be in place. The keys are to develop variables that reflect the quality of care, to collect these variables in a systematic manner, to have a means for

statistical analysis of the results, and to develop an approach to problem solving that involves feedback on the effectiveness of the solutions. These programs should provide ongoing educational opportunities for staff as well. The Committee also strongly encourages all laboratories to participate in a national data registry to help benchmark their results and provide an ongoing system for tracking complications.

D. Procedural Issues

Although no rigid protocol is applicable to all laboratories, certain procedural issues are worthy of comment. Patient preparation generally entails premedication with mild sedatives. During the procedure a conscious-sedation protocol should be followed.

Patients with contrast allergies should receive nonionic contrast and should be premedicated with steroids. Many laboratories also use antihistamines.

Patients with renal insufficiency should be adequately hydrated before and after the procedure. A minimal amount of radiographic contrast should be used along with biplane angiography when available. There is suggestive evidence that nonionic radiographic contrast may help reduce the incidence of nephrotoxicity. Initial studies using pretreatment with acetylcysteine are very promising for the prevention of nephrotoxicity.

Fasting patients with diabetes mellitus should receive a reduced dose of insulin on the morning of the procedure. Diabetic patients treated with metformin who have mild renal insufficiency rarely have been reported to develop profound lactic acidosis after receiving radiographic contrast. Therefore, the metformin dose should be withheld on the day of the procedure and not restarted until the creatinine is stable, usually 48 h after the procedure. Antiplatelet drugs need not be withheld before cardiac catheterization. Warfarin generally is discontinued until the international normalized ratio (INR) is <1.8. It can be reversed if necessary with vitamin K or fresh frozen plasma. Patients often undergo cardiac catheterization while receiving heparin therapy. In-laboratory activated clotting time (ACT) should be in the range of $\approx$300 s (200 to 250 s if glycoprotein IIb/IIIa inhibitors are used) during the procedure and <175 s when the catheters are removed.

Sterile preparation is mandatory for all vascular access sites. It is important for operators to wear masks, caps, and eye protection to prevent accidental operator contamination with blood.

Routine catheterizations of the right side of the heart should not be performed during diagnostic or interventional cardiac catheterizations unless specific information of clinical importance is being sought. Routine use of temporary pacemakers is also inappropriate. In an era of high-quality echocardiographic methods for assessing left ventricular function and valvular gradients, there is only an extremely rare indication for direct left ventricular puncture.

Certain provocative agents may be useful during adult cardiac catheterization. These include: 1) fluid loading to assess the hemodynamics associated with constrictive pericarditis or restrictive myocardial disease; 2) the use of afterload alteration or inotropic agents to assess maximal intraventricular gradients in hypertrophic cardiomyopathy or in patients with aortic stenosis and low output and low gradient; 3) the use of coronary vasoactive agents (especially in combination with coronary flow, pressure, or velocity measures); 4) the administration of pulmonary vasodilators in patients with elevated pulmonary vascular resistance; and 5) exercise during the procedure to assess cardiovascular hemodynamics during stress.

Proper procedural technique includes adequate injection of the coronary arteries and the use of multiple orthogonal views with appropriate radiographic angulation for visualization of the various cardiac structures. Pressure measurement requires attention to proper electrical filtering and patient respiration. Accurate measurement of cardiac output is difficult in the best of settings, and the vagaries inherent in all the available methods should be understood to interpret the results properly.

Postprocedural hemostasis is achievable by a variety of means, including manual methods, mechanical compression devices, and percutaneous closure devices. It is important to monitor the hematoma and pseudoaneurysm rate involving each method and each device used in any laboratory.

Catheterization reports should contain certain basic information, and the actual images should be kept for at least 7 years after the study.

E. Personnel Issues

Attending physicians should be credentialed according to local standards. The laboratory director should have extensive experience (>500 procedures performed over his or her career). If interventional procedures are performed in the laboratory, the director should be board certified in interventional cardiology.

The patient consent form should note if any designees other than the attending physician are participating in the procedure. Cardiology trainees (fellows) may be primary operators with supervision. Physician extenders (physician's assistants and nurse practitioners) can participate in cardiac catheterization procedures along with the attending physician, but they cannot be primary operators, and all clinical decision making must reside with credentialed physician operators.

Other cardiac catheterization personnel include nurse practitioners, nursing personnel, radiological or physiological technologists, and now both darkroom (if cinefilm is used) and computer specialists. All are critical professionals and should be treated as such. Continuing education should be provided for nonphysician staff.

F. Ethical Concerns

Ethical concerns include those related both to clinical practice and to biomedical research. Rarely do interven-

tional procedures require 2 cardiologists to be in attendance. Cardiologists should never receive an admission fee, referral fee, or other "kickback" for referring a patient to a facility; this is illegal. Collusion in fixing fees is illegal as well. Unnecessary services should never be performed or billed. Cardiologists must avoid any financial business or industry arrangements that might influence their decision to care for patients because of personal gain (5). Receipt of direct remuneration from device, catheter, or drug companies to use such products is a conflict of interest and should be avoided. Procedural information should always be presented honestly, and the collection of procedural outcome data should be systematic and standardized. Informed consent should note all participants in the procedure (physician and physician extenders) and should describe all possible procedures (including ad hoc intervention) should they become a consideration. Clinical research studies require special attention, with patient safety always overriding other aspects of any investigational protocol.

G. Imaging Equipment Issues

Radiographic equipment is now evolving after years of relatively little real change. X-ray tubes with high heat capacities have become commonplace. Image intensifiers have continued to improve, with better conversion factors, improved contrast ratios, less distortion, and better resultant spatial resolution. Image intensifiers optimized for coronary angiography may not be optimal for peripheral vascular imaging. Newer X-ray detectors, such as the flat panel devices, are being investigated as an alternative to the current image intensifier. Video cameras are slowly evolving from the standard 525 × 525 lines per video frame to 1,023 or 1,049 lines with accompanying higher resolution. The video "pickup tube" is also being replaced by charge-coupled devices (CCDs) in many systems.

Nearly all new X-ray equipment that is commercially available allows for digital angiography as cinefilm is gradually phased out. This process should be completed within the next decade. Elimination of cinefilm has many advantages, including the use of lower framing rates, freeze frames for roadmapping, immediate availability of images for final interpretation, improved image playback during the procedure, and elimination of film development, display, and storage problems. Elimination of cinefilm does not reduce the X-ray exposure per frame by much, however, as the primary source of quantum noise is in the X-ray system itself. Digital systems can reduce X-ray exposure and usage by reducing framing rates. Pulsing the fluoroscopic dose helps reduce overall X-ray exposure.

Although the DICOM (Digital Imaging and COmmunication in Medicine) standard has allowed for an acceptable format and media (the CD-ROM) for exchange of information between and among cardiac catheterization laboratories, there is still no uniform standard for short-, near-, and long-term storage. Many archival options are still being evaluated. One limitation that older laboratories face is the availability of an adequate interface that will write the DICOM standard from X-ray acquisition devices to storage and retrieval devices. Most digital cardiac systems incorporate resolutions of 512 × 512 × 8-bit deep images with the capability of acquiring 30 frames per second (fps). This results in a minimal spatial resolution in the order of 0.2 to 0.3 mm. Higher matrices such as 1,024 × 1,024 can deliver resolutions of up to 0.1 to 0.15 mm but at a marked increase in cost related to data acquisition, storage, and transmission requirements.

Data compression allows for more rapid transmission of images over lower bandwidth lines and requires less storage capacity. Although this is acceptable for many purposes, clinical errors can occur if lossy compression is used. Preliminary results from the multicenter clinical study sponsored by the ACC and the European Society of Cardiology suggests that only lossless compression (about 2:1 JPEG compression, for instance) should be used for permanent storage of data and clinical decision making. Higher compression of images may be used for nonclinical situations and certain teaching and demonstrative displays of information.

Digital imaging allows for a practical approach to telemedicine and for the widespread use of quantitative angiographic methods. Further DICOM developments will include standardized formats for physiological data such as hemodynamic and electrocardiographic (ECG) waveforms and patient record demographic and other information. Other modalities such as other radiographic procedures and intravascular ultrasound will eventually be incorporated into the standard.

H. Radiation Safety

The use of ALARA—"as low as reasonably achievable"—doses of X-ray radiation is important. Radiation exposure may be expressed in terms of rems. Radiation injury is defined by either stochastic effects (DNA injury) or nonstochastic effects (cellular injury). The average background radiation exposure is about 0.1 rem/year. Interventional cardiologists receive another 0.004 to 0.016 rem/case. The maximum recommended exposure by the National Council on Radiation Protection and Measurement (NCRPM) is 5 rems/year for the total body. Over an individual's lifetime, the accumulated maximum dose should be no greater than the accumulated rem exposure × age (or a maximum of 50 rems).

The risk of fatal cancer in the U.S. is about 20%. The additional risk from radiation exposure in the cardiac catheterization laboratory is about 0.04% × total cumulative rem exposure. Pregnant workers can continue to work in the cardiac catheterization laboratory if they so choose. Fetal exposure, as measured by a waist dosimeter, should be no more than 0.05 rem/month or $<$0.5 rem for the entire pregnancy.

Radiation exposure is measured by either X-ray film badges or transluminescent dosimeter (TLD) badges. It is

recommended that these badges be worn on both the thyroid collar and under the lead apron at the waist. Ring dosimeters are rarely worn in the cardiac catheterization laboratory, even though hand exposure may be high.

X-ray scatter is reduced by minimizing the number of magnified views, using digital-only cine runs, keeping the image intensifier as close to the patient as possible, and selecting the highest kilovolt level that provides acceptable image contrast (to reduce the milliamperes generated). Most of the radiation exposure during interventional procedures comes from the extended use of fluoroscopy rather than the brief cine runs. The closer the operator is to the X-ray tube, the greater the radiation exposure (left anterior oblique [LAO] cranial views may result in up to 6 times more radiation than right anterior oblique [RAO] caudal views, for instance). Proper collimation and shielding is important to help reduce exposure. To minimize patient exposure to scatter radiation, the same rules apply, with further efforts to reduce the X-ray dose most important.

I. Special Concerns for the Pediatric Catheterization Laboratory

The goals in the pediatric cardiac catheterization laboratory are to define internal cardiac and vascular structures and hemodynamics. Shunts frequently require evaluation. In recent years the pediatric catheterization laboratory has become as much a therapeutic arena as a diagnostic one, with atrial septostomy, valve and vessel dilation, and stent implantation available. In some institutions, closure of intracardiac defects such as patent ductus arteriosus or atrial septal defect may be accomplished.

A pediatric cardiologist should be responsible for invasive evaluation of patients from birth to 18 years of age. Adult patients with congenital heart disease may be studied by a pediatric cardiologist, a team of adult and pediatric cardiologists working together, or an adult cardiologist with specialized training and interest in adult congenital heart disease. Complication rates in the pediatric cardiac catheterization laboratory tend to be higher than those in adult laboratories. Overall complications are about 8.8%, with major complications about 2%. Neonatal patients and those undergoing interventional procedures are at greatest risk. Informed consent is usually obtained from parents or guardians. Many diagnostic procedures can be done on an outpatient basis, although this may not be practical for a variety of reasons. Eligibility for early discharge after cardiac catheterization must consider the child's age and size, patient or parent reliability, travel time and distance, duration of procedure, time of completion, cardiac physiology, and loss of blood. Overnight observation is often required to ensure safety.

Procedural issues in the pediatric laboratory include the use of deep sedation and even general anesthesia. Vascular access may be decidedly more challenging, although venous-only catheterization may be performed when there is an interatrial communication or by use of transseptal techniques. Biplane angiography is also more important to help visualize the cardiac structures adequately, to recognize catheter positions, and to help reduce the total radiographic contrast dosage. Heart rates in children are generally much higher than in adults, requiring higher framing rates for image acquisition (often 30 to 60 fps). Higher injection rates (up to 40 mL/s) are also useful to help define abnormal intracardiac anatomy.

The laboratory should perform a minimum of 75 pediatric cases/year. Generally, an individual cardiologist should perform at least 50 cases/year to maintain skills and reduce risk of complications. A detailed QA plan should be operative. The number of "normal" cardiac catheterizations should be zero.

Oximetry rather than indocyanine green dye methods is now used in shunt measurements. In pediatric cardiac catheterization laboratories, specialized staff should be available to ensure familiarity with the procedures performed.

I. INTRODUCTION

A. Organization of Committee and Evidence Review

The Writing Committee consisted of acknowledged experts in cardiac catheterization representing the ACC (9 members) and the SCA&I (2 members). Both the academic and private practice sectors were represented. The document was reviewed by 3 official reviewers nominated by the ACC, the ACC Cardiac Catheterization and Intervention Committee, the Diagnostic and Interventional Catheterization Committee of the Council on Clinical Cardiology of the AHA, the SCA&I, and 12 content reviewers nominated by the Writing Committee. The document was approved for publication by the ACC Board of Trustees and the SCA&I Board of Trustees in April 2001 and endorsed by the AHA and the Diagnostic and Interventional Catheterization Committee of the Council on Clinical Cardiology of the AHA. This document will be considered current until the Task Force on CECDs revises or withdraws it from distribution.

B. Purpose of This Expert Consensus Document

Cardiac catheterization settings and procedures have evolved since publication of the ACC/AHA Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories in 1991 (5). Whereas outpatient cardiac catheterizations were infrequent then, now almost all elective diagnostic cardiac catheterizations are performed on an outpatient basis. The setting for performance of cardiac catheterizations has expanded to include not only traditional medical centers with a cardiovascular surgical program, but also community hospitals without cardiovascular surgical backup and now some freestanding laboratories. The risks associated with both diagnostic and interventional cardiac catheterization have declined so markedly that older restrictions regarding the study of even higher-risk patients deserve reassessment. Now it is rare to perform interventional procedures with an empty operating room on standby

and a surgical team on full alert. Indeed, the safety of such interventional procedures is even being examined in hospital settings without cardiovascular surgical facilities. The driving forces behind some of these changes have raised concerns among the cardiology community, however, so the time seems appropriate to evaluate these potential ethical issues. Equipment is also rapidly evolving, especially in the imaging arena. With the impetus provided by the universal acceptance of the DICOM standards for cardiac angiography, cinefilm is rapidly being replaced by compact discs and computerized archiving systems. More changes, such as the expanded use of the Internet, are imminent. Furthermore, "ad-hoc" catheter revascularization is increasingly being performed immediately following the diagnostic angiographic procedure. The pediatric cardiac catheterization suite is also evolving from a purely diagnostic laboratory to an interventional laboratory.

II. THE EVOLUTION OF THE CARDIAC CATHETERIZATION LABORATORY

Over the last half century, cardiac catheterization laboratories have evolved from highly specialized research laboratories into heavily used procedure rooms in which an extensive array of diagnostic tests and therapeutic interventional procedures are performed on millions of patients yearly. Catheterization laboratories were first used to define the hemodynamic features of complex congenital and acquired valvular heart disease. The development of cardiopulmonary bypass expanded the potential for surgical correction in many of these patients. As surgical programs grew, catheterization laboratories likewise proliferated.

With the advent of selective coronary angiography in the late 1950s, physicians began to explore the possibility of identifying and quantifying the extent of coronary artery disease. Catheterization laboratories were few and largely limited to major academic medical centers. By the late 1960s the use of aorto-coronary bypass surgery was quickly expanding throughout the country, and the acceptance of surgical revascularization promoted the proliferation of cardiac catheterization laboratories. The decade of the 1970s was characterized by substantial improvements in imaging systems and catheterization supplies and methods. Preformed catheters, introduced by Drs. Judkins and Amplatz, facilitated safe and expeditious catheterization from the femoral route and rapidly became more popular than the brachial approach pioneered by Dr. Mason Sones. Although laboratories were disproportionately located in major medical centers with cardiac surgical programs, the improved safety and simplicity of diagnostic procedures fostered the proliferation of diagnostic laboratories in community hospitals in which cardiac surgery programs did not exist. These hospitals retained close ties to tertiary centers where patients could be easily referred or transferred for surgical procedures. During this period the National Institutes of Health funded several Myocardial Infarction Research Units (MIRUs) at select academic medical centers. It was in the context of MIRU research that the safety of cardiac catheterization in the setting of an acute myocardial infarction (MI) was first demonstrated.

The late 1970s heralded a major change in the practice of invasive cardiology. The introduction of intracoronary thrombolysis and subsequently percutaneous transluminal coronary angioplasty (PTCA) forever changed the character of the catheterization laboratory. What was previously only the setting for diagnostic testing became a therapeutic laboratory where patients with both stable and unstable coronary syndromes and valvular and congenital heart disease could be treated. The introduction of percutaneous balloon valvuloplasty procedures in the mid and late 1980s and advances in interventional procedures in the pediatric catheterization laboratory further expanded the range of therapeutic options. Because of the potential for catastrophic complications, especially with interventional procedures, these methods were appropriately confined to laboratories with immediate surgical backup.

The last time the ACC/AHA Task Force on Practice Guidelines developed a general document for cardiac catheterization laboratories (5), the majority of the workload in most laboratories consisted of diagnostic cardiac catheterization procedures. Computerized recording methods and digital angiography were considered research ventures, and most cardiac catheterization procedures were performed on inpatients. However, the use of balloon angioplasty was rapidly increasing, and the 1990s heralded the evolution of second-generation coronary therapeutic devices, including several coronary atherectomy and laser catheters, followed by the widespread use of coronary artery stents. Improvements in the quality of imaging equipment, new potent antiplatelet agents, and further improvements in coronary stent technology resulted in a high degree of safety for most interventional procedures. Furthermore, the majority of routine diagnostic cardiac catheterizations performed shifted to the outpatient setting.

Cardiac catheterization laboratories have further evolved into multipurpose facilities. Improvements in X-ray systems and the development of digital processing capabilities have facilitated "noncardiac" vascular investigations and interventions in other areas of the vascular system. At select centers, in addition to cardiac disease, cardiologists are now involved in the diagnosis and therapy of disease involving the peripheral, renal, and carotid vasculature.

III. THE CARDIAC CATHETERIZATION LABORATORY ENVIRONMENT

Although low, the risks from invasive cardiac procedures are not zero. In addition to procedural-related complications, occasional patients will become unstable during or after the procedure. For this reason, other ancillary services (Table 1) may be necessary to support the laboratory. At present, there are three basic environments in which invasive cardiac

Table 1. Optimal On-Site Support Services for Invasive Cardiac Procedures

For Adult Invasive Procedures
Adult cardiovascular surgery
Adult Coronary and Intensive Care Units
Vascular surgery
Adult nephrology consultation and dialysis
Adult neurology consultation
Hematology consultation and blood bank services
Imaging services (computed tomography [CT] and magnetic resonance imaging [MRI], ultrasound)
For Pediatric Invasive Procedures
Pediatric cardiovascular surgery
Pediatric intensive care unit
Pediatric anesthesia
Pediatric neurology consultation
Pediatric nephrology consultation and dialysis

procedures are performed: the in-hospital cardiac catheterization laboratory with cardiac surgery capability, the in-hospital laboratory without cardiac surgery capability in the same hospital, and the freestanding laboratory. Certain patient subgroups may be inappropriate for study in some of these environments. The following outlines the current laboratory environments and suggests patient populations appropriate for study in each of these settings.

A. The Cardiac Catheterization Laboratory at a Hospital With Cardiac Surgery Capability

The cardiac catheterization laboratory at a hospital with cardiac surgery capability is the classical or traditional type of cardiac catheterization laboratory facility. It is located at a hospital that offers a broad range of cardiovascular services, including cardiopulmonary bypass and coronary, cardiothoracic, and vascular surgery (i.e., full support services). The presence of on-site cardiac surgery capability is the defining service because it is unlikely that a cardiac surgical program would exist in the absence of the other support services listed in Table 1. If pediatric cardiac catheterization services are provided, additional ancillary services are necessary, and the availability of on-site pediatric cardiac surgery is essential if complex congenital heart diseases in infants and children are to be studied and treated.

Fully trained personnel dedicated to the facility should staff such a laboratory. This is the only setting in which patients with poorly compensated heart failure, severe left ventricular dysfunction (ejection fraction <20%), acute coronary syndromes, or other conditions that contribute to clinical instability can be studied safely. Elective coronary interventions are best performed in this setting. Physicians should have appropriate credentials for performing both diagnostic and interventional procedures or have ready access to interventional cardiologists should an emergency arise.

Although the majority of cardiac catheterization laboratories in this category are located within the main hospital building, there may be special situations in which a mobile laboratory is used temporarily at such a hospital or where a laboratory may be in a different, but adjacent building dedicated to outpatient services. Generally, these latter situations may be considered similar to a laboratory with full support services.

1. Patients Eligible for Invasive Cardiac Procedures at a Hospital With Cardiac Surgery Capability. A hospital with cardiac surgery capability provides an environment in which all diagnostic and therapeutic procedures can be performed on both stable and unstable patients, provided the operators are physicians with appropriate experience, adequate cumulative procedure volumes, and satisfactory outcomes. Even though a hospital may have cardiac surgery capability and is therefore technically eligible to provide every type of invasive procedure, patients requiring less commonly performed procedures (e.g., transseptal catheterization and balloon valvuloplasty) or patients with more complex conditions (e.g., adults and children with complex congenital heart disease) may be better served by referral to a more highly specialized center.

Performance of invasive cardiac procedures in the pediatric and especially neonatal age groups requires knowledge and skills that go beyond catheter manipulations and include the management of conscious sedation, administration of intravenous (IV) fluids, regulation of body temperature, and the postprocedural care of infants and children. These issues are important to understand, not only for the physician, but also for nurses and other paramedical personnel who assist in the procedure. For these reasons, pediatric procedures should only be performed if they are within the competence of the operator and the experience of the team supporting the physician in the invasive procedure. Pediatric issues are summarized later in this document.

B. The Cardiac Catheterization Laboratory at a Hospital Without Cardiac Surgery Capability

The performance of diagnostic cardiac catheterization in facilities without the capability for on-site cardiac surgery is now common in the U.S. About half of the 2,014 laboratories identified in 1996 had on-site cardiac surgery capability (6). The number of surgical programs has now increased, and 72% of the 2,142 laboratories reported in 2001 have cardiac surgical programs on-site (1). Many hospitals without cardiac surgery have permanent, in-house cardiac catheterization laboratories and provide the majority of supporting services except for cardiac surgery. Although cardiac surgery is the defining service, the importance of the other services listed in Table 1 cannot be overemphasized. This is especially true in situations in which a mobile cardiac catheterization laboratory operates at a smaller rural hospital. In this setting, support services such as vascular surgery and comprehensive imaging techniques may not be available should important complications develop. It is mandatory that catheterization laboratories operating in this setting have well-defined selection and exclusion criteria and provision for identification of emergency situations requiring

Table 2. General Exclusion Criteria for Invasive Cardiac Procedures in Settings Without Cardiac Surgery

	Type of Patient	Diagnostic Procedures	Therapeutic Procedures
Hospital	Adult	• Age >75 years • NYHA Class III or IV heart failure • Acute, intermediate or high-risk ischemic syndromes • Recent MI with post-infarction ischemia • Pulmonary edema thought to be caused by ischemia • Markedly abnormal noninvasive test indicating a high likelihood of left main or severe multivessel coronary disease • Known left main coronary artery disease • Severe valvular dysfunction, especially in the setting of depressed left ventricular performance • Patients at increased risk for vascular complications • Complex adult congenital heart disease	• All valvuloplasty procedures • Diagnostic pericardiocentesis when the effusion is small or moderate in size and there is no tamponade • Elective coronary interventions • Therapeutic procedures in adult congenital heart disease
	Pediatric	• No procedures approved	• No therapeutic procedures approved
Freestanding Laboratory	Adult	• All of the above plus • Patients at high risk due to the presence of comorbid conditions, including the need for anticoagulation therapy, poorly controlled hypertension or diabetes, contrast allergy, or renal insufficiency	• No therapeutic procedures approved
	Pediatric	• No procedures approved	• No therapeutic procedures approved

immediate transfer to a tertiary facility and insertion of an intra-aortic balloon pump. Written agreements should be signed with a tertiary center for the timely (<60 min) transfer and acceptance of patients in the event of a crisis. In some settings, a physician using a mobile laboratory may live in the local community and is available after the laboratory leaves to assess complications or assist in patient management. In other situations, however, the physician performing the procedure may live in a distant area and may leave the hospital after the procedure. In this latter circumstance, it is essential that local physicians and support staff have an understanding of the potential complications of cardiac catheterization and be an integral part of the management process.

It is possible for catheterization laboratories to function with high quality and safety in hospitals without a cardiac surgical program; however, services are necessarily limited.

To further ensure safety, a formal arrangement between the laboratory and a nearby institution with cardiac surgical services must be made. Regulatory authorities and third-party reimbursement agencies should demand formal documentation and periodic review of such arrangements.

1. Patients Eligible for Diagnostic Cardiac Catheterization at a Hospital Without Cardiac Surgery Capability. Patients undergoing invasive procedures in this type of facility require a higher level of screening to avoid situations that might require urgent cardiac surgery or result in a complication that could not be managed effectively with the inherent delays encountered during transfer to another facility. Clinically, adults at the greatest risk include the very elderly (>75 years of age), those with New York Heart Association (NYHA) functional class III or IV congestive heart failure, those with acute coronary syndromes or recent MI, and those in whom noninvasive testing demonstrates severe ischemia. Patients with suspected or known left main disease, markedly reduced left ventricular function (ejection fraction <20%), or severe valvular dysfunction, especially in association with poor left ventricular performance, are also at increased risk. Patients at increased risk for vascular complications should not be studied in facilities without the capability to diagnose and surgically treat such complications should they arise. Such patients include those with known severe peripheral vascular disease, severe systolic hypertension, a bleeding diathesis, the need for continuous anticoagulant therapy, or severe obesity. Pediatric patients should not be studied. Patients receiving dialysis who may decompensate after the procedure are generally best studied at a facility with rapid access to a dialysis center.

It is not feasible to list every possible situation that could develop, but general exclusions for the performance of invasive cardiac procedures at hospitals without cardiac surgery are summarized in Table 2. It is important to emphasize that these recommendations are based on the literature and the judgment and experience of Committee members rather than extensive clinical evidence developed from outcome measures.

2. Patients Eligible for Therapeutic Invasive Procedures at a Hospital Without Cardiac Surgery Capability. Therapeutic invasive procedures primarily consist of valvuloplasty, pericardiocentesis for tamponade, and PCIs, as well as certain procedures specific for the pediatric and adult congenital heart disease populations. In evaluating the use of these procedures at hospitals without cardiac surgery capability, it is important to consider the clinical situation for which the procedure is needed, and specifically whether it is an emergency or elective procedure. Valvuloplasty is not required on an emergency basis, and therefore it should not be performed at hospitals without full support services, including cardiac surgery. Moreover, because it requires a

unique knowledge base, special equipment, and technical expertise, it is advisable to refer the patient to a regional center with experience in this technique.

In the setting of pericardial tamponade, pericardiocentesis can be a lifesaving therapeutic procedure, and the potential benefits of the procedure far outweigh the risks. Although commonly performed in catheterization laboratories as a matter of convenience, ECG- or echocardiographic-guided pericardiocentesis can be performed in other areas of the hospital. In the setting of tamponade, therefore, pericardiocentesis should be immediately available, irrespective of the hospital status. In the absence of tamponade, diagnostic pericardiocentesis only rarely provides critical clinical information but can be performed with minimal risk of ventricular puncture or coronary laceration if the pericardial effusion is sizeable. Therefore, assuming that the operator is skilled and experienced, elective pericardiocentesis for large effusions is acceptable in hospitals without immediate cardiac surgery capability. Elective procedures in patients with moderate or small pericardial effusions are better performed at hospitals in which immediate cardiac surgery is available should ventricular perforation or coronary laceration occur.

The performance of coronary angioplasty and other PCIs at hospitals without immediate surgical backup is controversial. In simple terms, patients can be divided into two groups: 1) those having the procedure as an alternative to thrombolytic therapy within 12 h from the onset of acute MI and 2) all others who are assumed to be undergoing elective or semielective procedures. In the setting of an acute MI, several small studies (7–9) have suggested that patients presenting to hospitals without cardiac surgery capability can be treated with primary angioplasty without a measurable difference in complications or outcomes when compared with hospitals with on-site cardiac surgery capability. However, these are not randomized trials, and none of these studies are of sufficient size to detect a small difference between groups. Recently reported data from the National Registry of Myocardial Infarction Investigators have revealed 28% less mortality among patients undergoing primary angioplasty in high-volume hospitals than in those undergoing the procedure in low-volume settings (4). Most hospitals without cardiac surgery capability perform a relatively low volume of cardiac interventions.

Although some studies support the use of primary angioplasty at hospitals without on-site cardiac surgery capability, important operator, laboratory, and institutional requirements must exist (9). If it is accepted that it is possible to develop a program of primary angioplasty for MI at a hospital without on-site cardiac surgery capability, the important question still remains whether this is an appropriate decision based on a desire to provide the best possible care for the local community. For example, is it really necessary to offer primary angioplasty at a hospital without cardiac surgery capability if a hospital with a cardiac surgical program is $<$10 min away? Although it can be argued that should an interventional complication occur, transport time and delay to a surgical center would be inconsequential, it is also appropriate to make certain that the motives for offering this service at a hospital without on-site cardiac surgery capability are not based purely on financial considerations or physician convenience. Moreover, it is unlikely that smaller hospitals performing only emergency procedures on patients with acute MI can satisfy the procedure volume requirements that now are associated with better outcomes (3,4).

In the final analysis, this Committee endorses the opinions and recommendations of the current ACC/AHA Committee revising the 1993 PTCA guidelines (3). In brief, primary angioplasty for reperfusion therapy in the setting of acute myocardial infarction in hospitals without onsite cardiac surgery capability must only be performed in a setting where there is a proven plan for rapid access (within 1 h) to a cardiac surgery operating room in a nearby facility with appropriate hemodynamic support capability for transfer. The procedure should be limited to patients with ST-segment elevation MI or new LBBB on ECG, and done in a timely manner (balloon inflation within 90 $\pm$ 30 min of admission) by persons skilled in the procedure (those performing $\geq$75 PCIs/year) and only at facilities performing a minimum of 36 primary PCIs/ year (3). Newer thrombolytic regimens, especially those combining thrombolytic agents with glycoprotein (GP) IIb/IIIa inhibitors, have higher reperfusion rates approaching those achieved by mechanical means and could reduce this as an issue (10,11).

Although the need for swift intervention drives the argument for primary coronary intervention at hospitals without on-site cardiac surgery capability, this does not apply to elective coronary intervention. The risks of coronary intervention have diminished with the increased use of coronary artery stents and GP IIb/IIIa inhibitors. Nevertheless, complications that require urgent bypass surgery still occur, and there will always be some risk related to the transfer between hospitals of patients for whom an interventional procedure has failed. These risks, however small, must be balanced against the proven safety of performing the procedure at a hospital with on-site cardiac surgery capability. The performance of elective angioplasty in hospitals without such capability has been reported from several centers outside the U.S. (12,13) where cardiac surgery is generally less available. However, given the availability of cardiac surgery in the U.S., it seems quite unlikely that patients or their families are significantly inconvenienced by referral to a hospital with on-site cardiac surgery available. Therefore, in agreement with the upcoming ACC/AHA PCI guidelines (3), it is the opinion of this Committee that the performance of elective coronary interventions in hospitals without on-site cardiac surgery capability cannot be endorsed at this time. The Committee is aware that certain programs that do perform interventions in this setting are affiliated with a high-volume PCI/coronary artery bypass graft (CABG) center and have a well-organized plan for

emergency transfer of patients, a sophisticated communication system between the primary site and the tertiary center, and a means for measuring and reporting patient complications and outcomes. Such a strictly monitored and controlled setting may allow for elective interventional procedures without cardiac surgical backup on-site, but outcomes from such programs have yet to be reported. This is obviously a dynamic area that awaits further data regarding the safety and outcomes of patients treated.

In addition, the desire for an interventional cardiac catheterization program should not be used to justify the development of a low-volume cardiac surgery program. There is concern among Committee members that low-volume cardiac surgery programs may be developed for the sole purpose of allowing an interventional cardiac catheterization program to be operative. The development of a cardiac surgery program should reflect the need based on a high volume of cardiac catheterization procedures.

C. Cardiac Catheterization and Diagnostic Procedures in the Freestanding Laboratory

A freestanding laboratory is not physically attached to a hospital. By definition, it is a laboratory in which quick transportation of a patient to a hospital by gurney is not possible. Although some hospitals build such laboratories adjacent to their primary facility, many are privately owned, and the physicians who use the facility may also own it. In the 2001 Directory of Cardiac Catheterization Laboratories assembled by the SCA&I, 58 such laboratories submitted data (1), but this number is clearly increasing. It is the responsibility of each freestanding laboratory to have a formal relationship with at least 1 tertiary referral hospital so that a written established plan for the emergency transfer of patients is in place. Furthermore, freestanding facilities must have the necessary equipment for intubation and ventilatory support. Physicians using these facilities must be capable of performing endotracheal intubation and inserting an intra-aortic balloon pump. Appropriate QA and ongoing QI programs must be established in writing and documented. Oversight has traditionally been provided by a tertiary referral hospital, but alternatives that comply with the maintenance of the highest concern for patient care may be used if acceptable by local standards and if a well-defined QA program is operative.

1. Patients Eligible for Cardiac Catheterization in a Freestanding Laboratory. Patients undergoing cardiac catheterization procedures in a freestanding facility require the highest level of screening to avoid situations that might require urgent cardiac surgery or result in a complication for which time spent transferring the patient to a hospital could be detrimental. All of the exclusions that apply to cardiac catheterization laboratories at hospitals without full-support services also apply to freestanding laboratories. Other patients who should not be studied in a freestanding facility include those with cardiac or comorbid conditions of such severity that the patient's condition could potentially become unstable during or after the procedure (Table 2).

2. The Mobile Cardiac Catheterization Laboratory. The mobile cardiac catheterization laboratory may be located at a hospital with cardiac surgical backup, at a hospital without cardiac surgery capability, or even in a freestanding environment. These laboratories are subject to the same concerns and quality controls as those of any laboratory in the respective setting. Mobile laboratories are occasionally used as temporary facilities before completion of a fixed (permanent) laboratory. To be eligible for study in the mobile laboratory, patients must meet the same criteria as those for more traditional environments.

D. Candidates for Same-Day or Ambulatory Cardiac Catheterization

Improvements in the safety and ease of performing invasive cardiac procedures plus the constant pressure to minimize costs have made it quite uncommon to hospitalize patients for only an invasive cardiac procedure. Indeed, for the vast majority of adult patients, a diagnostic procedure can be safely completed in an ambulatory setting. Patients should be hospitalized if their clinical condition warrants it, after which an invasive cardiac procedure may then become part of their overall management. In some isolated situations, preprocedure hospitalization is still appropriate. For example, patients who require continuous anticoagulation therapy may require hospitalization to switch safely from warfarin to heparin anticoagulation. Patients with renal insufficiency benefit from preprocedural hydration or drugs to help reduce contrast nephropathy. Patients with brittle diabetes who also require steroids to reduce the risk of contrast-allergic reactions may require prehospitalization. Preprocedural admission may also be appropriate for other situations, and the decision of the individual practitioner should be respected when it is in the best interest of the patient.

Noninvasive testing can often identify patients with high-risk coronary or valvular disease before catheterization and is helpful for identifying patients who should not be studied in settings without cardiac surgery capability. However, diagnostic studies of high-risk patients may still be initiated in the outpatient setting before referral to the appropriate settings. If, as suspected from noninvasive testing, the catheterization study confirms a high-risk anatomic situation, admission to the hospital may become necessary after the procedure.

Because of the overall safety of diagnostic procedures, patients are often discharged within 2 to 6 h of completion of the study. This applies not only to outpatients, but also to inpatients for whom a disposition is made rapidly after completion of the procedure. A general scheme for the disposition of patients after diagnostic catheterization is shown in Figure 1. Rarely, a patient will develop a procedure-related complication that requires hospitalization. More patients will require admission because of the

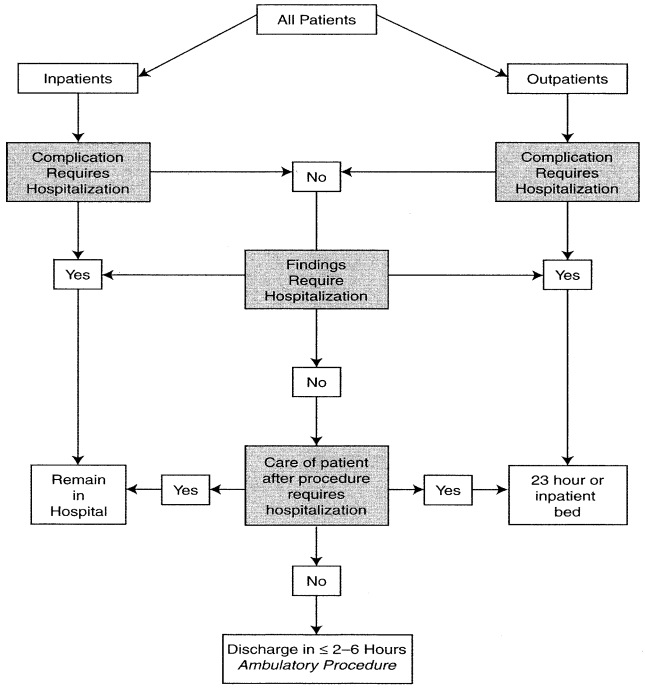

Figure 1. General scheme for the disposition of adult patients after diagnostic cardiac catheterization

findings from the procedure. A patient who develops a large hematoma may require a more prolonged period of bed rest and observation to ensure that the puncture site has stabilized. Patients who are found to have important left main disease should be considered for admission pending early surgical therapy or at least until it is clear that the diagnostic procedure has not caused clinical instability. Finally, some patients may require observation overnight simply because they do not have a supervised home setting. Table 3 lists possible situations for which early (<2 to 6 h) discharge after diagnostic catheterization may be unwise. These are not meant as absolute exclusion criteria prohibiting early discharge, but the practitioner should consider hospitalization when treating such patients. Based on the judgment of the physician, it would be appropriate to observe patients with 1 or more of these clinical risks for a longer period of time.

Because of the improving safety of coronary interventions and newer access techniques, such as the radial approach as well as the availability of vascular closure devices, outpatient coronary intervention may become a reality. This concept is currently being investigated. At this time it is not approved by the Committee.

Because of the simplicity and safety of diagnostic catheterization, the vast majority of patients can be discharged home within 2 to 6 h. This applies to inpatients as well as outpatients. For example, a patient may be admitted for evaluation of a prolonged episode of chest pain, but subsequent testing shows no evidence of MI. In some patients, it may be appropriate to consider coronary angiography as the first diagnostic test. If coronary angiography shows no evidence of coronary disease, the patient may be discharged 2 to 6 h after the procedure to complete evaluation as an outpatient. Patients undergoing radial artery cardiac catheterization may be discharged as early as 90 min after the procedure.

There are three basic steps in determining the appropriateness of early discharge for patients. First, a patient may require a prolonged stay if an important complication has occurred. Second, the procedure may reveal new findings for which hospitalization is indicated. Finally, appropriate care of the patient for noncardiac issues may be necessary for safety.

Table 3. Suggested General Exclusion Criteria for Early (<2–6 h) Discharge after Invasive Cardiac Procedures

Type of Patient	Diagnostic Procedures	Therapeutic Procedures
Adult	• High risk due to identification of left main disease • NYHA Class III or IV heart failure • Unstable ischemic symptoms at any time after the procedure • Recent MI with post-infarction ischemia • Pulmonary edema thought to be caused by ischemia • Severe aortic stenosis with LV dysfunction • Severe aortic insufficiency with a pulse pressure >80 mm Hg • Poorly controlled systemic hypertension • Inadequate or unreliable follow-up over the next 24 h • Generalized debility or dementia • Renal insufficiency (creatinine >1.8 mg/dl) • Need for continuous anticoagulation therapy or treatment of a bleeding diathesis • Large hematoma or vascular complication	• All procedures are excluded at this time, but the early discharge of selected patients after coronary intervention is under investigation (i.e., patients with radial artery access or after the use of percutaneous closure devices)
Pediatric	• Young age (≤5 years of age) • Complex congenital heart disease • Any condition resulting in important cyanosis • Most cases requiring a large arterial sheath	• All procedures excluded

Table 4. Complication Rates (%) During Diagnostic Cardiac Catheterization: Results from the SCA&I Registry (18)

Year(s)	Death	MI	Neurological	Arrhythmia	Vascular	Contrast	Other	Total
1979–1982	0.14	0.07	0.07	0.56	0.57	—	0.41	1.82
1984–1987	0.10	0.06	0.07	0.46	0.46	0.23	0.28	1.74
1990	0.08	0.03	0.06	0.33	0.40	0.37	0.48	1.77

IV. QA 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 not only chronic stable disease, but also acute life-threatening illnesses. In any complex, procedure-oriented area, it is necessary to have a well-organized program of QA that focuses on individual and laboratory outcomes. In addition, a continuous program of quality improvement (QI) should be implemented to provide ongoing feedback and structure for change. The following discussion summarizes the key components of a QA program for both diagnostic and interventional cardiac catheterization laboratories. These components are: 1) clinical proficiency, 2) equipment maintenance and management, and 3) a QI process. A fourth component, radiation safety, is discussed separately later in this document.

A. Clinical Proficiency

The assessment of clinical proficiency in the catheterization laboratory is based on a composite of cognitive skills, procedural conduct, and clinical judgment. A deficiency in any one element is enough to worsen clinical outcomes; thus, all elements must be considered. Unfortunately, there is no unique source that details "how to do things correctly." Although clinical experience is the sine qua non of proficiency, the myriad of techniques and technology preclude rigid delineation of a singular "right way." There is, however, one incontrovertible bottom line—patient outcomes.

1. Patient Outcomes in the Diagnostic Cardiac Catheterization Laboratory. a. RATES OF "NORMAL" CARDIAC 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 as those with no or physiologically insignificant diameter stenosis by visual inspection in patients studied specifically to assess coronary anatomy. Few contemporaneous sources of data give an acceptable percentage of normal cases. Administrative databases generally lack the requisite clinical information, whereas most clinical databases fail to include such preprocedural data as preopertive (procedure) diagnosis and appropriate ancillary diagnostic data. In an exhaustive, although now dated, review of coronary arteriography, the RAND Corporation study group found rates of normal diagnostic cardiac catheterization studies ranging from 9% to 36% (average, 21%) (14). These data must be viewed circumspectly, given the relatively unsophisticated X-ray imaging systems in use at that time, the variable criteria for "normal," and the differing pretest likelihood of finding significant disease. In the Coronary Artery Surgery Study (CASS) Registry (15), the rate of normal arteriograms was 19%, although the appropriateness of extrapolating these data to the present is also questionable. More recent data from the SCA&I indicate that the frequency of normal angiograms is 20% to 27%, which appears to vary little over a reporting period of several years (16,17).

It is recognized that many cardiac catheterization studies include patients with insignificant disease (<50% coronary diameter narrowing by visual estimate). Among those considered "normal" it is evident that many patients may have significant coronary plaque burden before the coronary lumen is obviously reduced. Clearly many acute coronary syndromes occur in patients without significant luminal narrowing. In addition, certain clinical syndromes may relate to coronary endothelial dysfunction. Some laboratories may also have a high prevalence of patients studied for non-coronary issues, such as pulmonary hypertension, cardiomyopathy, valvular disease, or adult congenital heart disease. These issues should be taken into account when assessing the rate of "normal" cardiac catheterization procedures performed by any facility.

The vast majority of reported data refer to coronary artery disease. It is of interest to note that no data are reported for evaluation of hemodynamic problems. This may reflect the proliferation of noninvasive modalities as an integral part of the cardiologic evaluation of patients with suspected valvular or myocardial disease. Nevertheless, there are occasions when cardiac catheterization is recommended to clarify uncertainties related to valvular disease or ventricular function that remain after noninvasive assessment.

b. COMPLICATION RATES DURING DIAGNOSTIC CATHETERIZATION. There is extensive literature on the major complications of diagnostic cardiac catheterization (18). Fortunately, the (composite) rate of major complications is "acceptably" low at 1% to 2% (Table 4). As expected, the likelihood of major complications increases significantly with the severity of the underlying cardiac and noncardiac disease (19). Patients with both valvular and coronary artery disease are slightly more likely to sustain a complication than patients with isolated coronary artery disease (20). 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 (21) and endomyocardial biopsy (22) have been reported and fall within the range referenced earlier. Because of patient selection, the likelihood of complications during outpatient studies is less than that found during inpatient examinations (19), although the constantly changing definition of "outpatient" may blur this distinction. It must be acknowledged that at present, dynamic changes are occurring in the choice of access site for procedures, the caliber of diagnostic catheters, and the means of achieving access site hemostasis. How these variables will change complication rates is unknown, although it is unlikely that any alternative access sites or vascular occlusion devices will significantly affect the already low major complication rate.

c. DIAGNOSTIC ACCURACY AND ADEQUACY. An important, although generally ignored area, is that of the completeness and diagnostic accuracy of catheterization procedures. Incomplete or aborted procedures, 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 the previous 2 areas. Failure to engage coronary arteries selectively often results in insufficient opacification of the artery to accurately assess stenosis. Failure to identify or engage all bypass grafts selectively is frequently another reason that angiograms are incomplete and need to be repeated. Inability to recognize the presence of coronary arteries with anomalous origins also contributes to this problem. Understandably, there is an absence of literature on this subject. The implications of inadequate or incomplete studies are significant and range from the need to perform repeat procedures to obtain the key information to performance of unnecessary and more invasive procedures. In the PCI era, the need for high-quality angiography is great. Inadequate attention to the details of accurate hemodynamic recording in patients with valvular heart disease and the failure to accurately demonstrate coronary anatomy must be viewed as important measures of outcome. It seems clear that inadequate diagnostic procedures as defined earlier should occur in far fewer than 1% of cases.

d. THE SPECIAL CASE OF THE "AD HOC" PCI. The performance of a coronary interventional procedure at the conclusion of the diagnostic session presents several important issues for assessment of quality. Complications engendered during diagnostic catheterization and angiography, e.g., coronary dissection or abrupt occlusion, may well be treated with prompt intervention. Does the success of the intervention mitigate the inciting event? Although the composite procedure was "successful," how is the original complication recorded? The majority of such "ad hoc" procedures are currently performed as the result of efforts to improve cost-efficiency as well as patient convenience and satisfaction. The ad hoc procedure also facilitates the management of patients with both stable and unstable coronary syndromes. In these cases, 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 hybrid approach, it will be important to carefully define its indications, clinical outcomes, and overall cost effectiveness.

2. Patient Outcomes in the Interventional Cardiac Catheterization Laboratory. Although patient outcomes are clearly the most important indicators of proficiency and competency in interventional cardiology (2), they are arguably the most difficult to quantify accurately. The importance of risk-adjustment of crude event frequencies cannot be overstated (35). Therefore, it is essential that careful and complete preprocedural and intraprocedural information be 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. Without a complete recording of such variables, meaningful analysis of event rates is impossible. It is very difficult to risk-adjust variables for low-volume operators based on the wide confidence intervals for outcomes in this situation.

Given this caveat, the emphasis on individual and institutional outcomes is appropriate (2). Operators must be responsible for their actions and resulting consequences. The ability to estimate the likelihood of significant complication (36,37), choose devices and conduct procedures appropriately (38), promptly recognize and treat ischemic complications (39), select cases appropriately, and be able to say "no" are 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). In addition, periodic review of less severe complications (e.g., hematoma or pseudoaneurysm rates) should be part of any ongoing QI program. Admittedly, many outcomes are hard to measure, 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 2% and rates of emergent CABG averaging $<1\%$, a major complication rate $\leq 3\%$ (95% CI 1.9%, 4.1%) is to be expected.

Table 5 summarizes in-hospital outcomes from recently published data on this subject. Each series includes patients undergoing PCI for a variety of indications, e.g., stable angina, post-infarct angina, and acute MI. 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 not only vary according to the definition applied, but almost universally reflect the clinical trial literature. Complication rates in community-based practice must await the development of an appropriate data collection instrument. The use of 30-day event rates to benchmark operator performance has been advocated by some (40).

Table 5. Major In-Hospital Complication Rates (%) Related to Contemporary PCIs

Study	Year	Reference	Death	Q-Wave MI	Emergency CABG	Neurological	Major Vascular
NHLBI-DR	2000	(23)	1.9	2.8	0.4	0.3	3.8
SCA&I	2000	(24)	0.5	N/A	0.5	0.1	0.2
BARI	1996	(25)	0.7	2.8	4.1	0.2	0.2
NY State* (Balloon)	1997	(26)	0.85	N/A	2.7	N/A	N/A
NY State* (Stent)	1997	(26)	0.71	N/A	1.66	N/A	N/A
Northern New England	1996	(27)	1.2	2.0	1.3	N/A	N/A
Medicare	1997	(28)	2.5	N/A	3.3	N/A	N/A
EPILOG† (Abciximab)	1997	(29)	0.3	0.4	0.4	0.2	1.1
EPILOG† (Placebo)	1997	(29)	0.8	0.8	1.7	0.0	1.1
EPISTENT† (Abciximab)	1998	(30)	0.3	0.9	0.8	0.4	2.9
EPISTENT† (Placebo)	1996	(30)	0.6	1.4	1.1	0.1	1.7

*Overall risk-adjusted rates; †30-day event rate; N/A = data not available.

Table 6 summarizes representative outcomes from the published literature on PCI for acute MI. Here, too, event rates are unadjusted, and rates of access site and bleeding complications reflect a complex mix of systemic anticoagulation, systemic lytic activity, and the adjunctive use of platelet antagonists. These issues are particularly critical in the interpretation of central nervous system complications during PCI in this setting.

Although the frequencies of adverse events are likely to change over time as the result of continuing improvements in technology, clinical competence and its assessment will remain the foundation on which a QI program rests. Table 7 summarizes current approaches to the assessment of proficiency in coronary intervention for both individuals and institutions.

B. Equipment Maintenance and Management

The modern diagnostic and interventional catheterization laboratory uses many sophisticated radiological, electronic, and computer-based systems, which require 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 cutting.

A program of periodic assessment of system performance and (cine) image quality has been recommended by the SCA&I (41). Additional programs, which will address issues specific to digital imaging systems, are under evaluation (41). A representative outline of the performance characteristics needed to assess radiographic cardiac imaging systems is presented in Table 8.

Note that at present the only federally mandated parameter of image performance is the maximum table-top exposure rate (10 R/min) for conventional cardiac fluoroscopy. The concept of minimum performance standards must await universal acceptance of a suitable test instrument for cardiac fluoroscopy. There is considerable heterogeneity across laboratories in selective measurements of image quality (42). 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.

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

Table 6. Major Complication Rates (%) Related to PCI for Myocardial Infarction

Study	Year	Reference	Death	Emergent CABG	Neurological	Vascular*
RAPPORT† (Placebo)	1998	(31)	1.7	5.4	0.0	3.7‡/9.5‡
RAPPORT† (Therapeutic)	1998	(31)	1.2	1.2	0.0	12.0‡/16.6‡
PAMI§ (PTCA/tPA)	1993	(32)	2.6	N/A	0.0	2.1
PAMI§ (tPA)	1993	(32)	6.5	N/A	3.5	0.5
PAMI* (Stent)	1999	(33)	3.5	N/A	0.2	5.1
PAMI* (No stent)	1999	(33)	1.8	N/A	0.2	3.8
GUSTO IIB* (PTCA)	1997	(34)	5.7	N/A	1.1	12.3
GUSTO IIB* (tPA)	1997	(34)	7.0	N/A	1.9	9.5

*Vascular, including bleeding unless noted; †RAPPORT data are 7-day event rates; ‡Vascular only; §Bleeding only.

RAPPORT data are 7-day event rates; PAMI data are in-hospital event rates for PTCA or tPA and 30-day event rates for stent/no stent; GUSTO IIB data are 30-day event rates.

Table 7. Assessment of Proficiency in Coronary Intervention

Type	Component	Mode of Assessment
Individual	Cognitive	• Formal training program • Present requirement by ABIM for CVD: 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. As of 2003, only candidates who have successfully completed the 12-month fellowship will be allowed to sit for the examination. Before 2003, "practice pathway" possible (150 cases over 2 years or 500 since training).
	Procedural	• Recommended average procedural volume: ≥75 cases/year • Risk-adjusted outcomes • Individual data benchmarked against the ACC NCDR™ or similar database
	Judgment	• Board certification • Peer recognition
Laboratory	Procedural outcomes	• Risk-adjusted outcomes • Comparison with similar institutions • Laboratory data benchmarked against national databases such as the ACC NCDR™
	Activity	• Minimum performance of 200 interventions/year; ideally, a minimum of 400 interventions/year
	Oversight	• Director with career performance of >500 invasive cases and board certification in interventional cardiology • Establishment of a mentoring program for operators who perform <75 procedures/year by those who perform >150 procedures/year
	Support	• QA staffing to monitor complications and outcomes • Experienced support staff to handle emergencies • Facilities and equipment for high-resolution fluoroscopy and digital video processing

ABIM = American Board of Internal Medicine; ACGME = Accreditation Council of Graduate Medical Education; NCDR™ = National Cardiovascular Data Registry™.

data for numerous purposes (e.g., billing, QA, report generation), flawless and lossless transmission must take place all the time. Backup systems and low-cost storage media are essential.

The need for patient safety–related precautions is self-evident. The operational efficiency of infrequently used equipment (e.g., defibrillators) must be tested routinely and appropriate logs kept. Electrical isolation and grounding systems must be regularly assessed. The number of ancillary devices used in coronary intervention (e.g., Doppler and pressure-tipped sensor wires and ultrasound catheters) now requires that electrical safety precautions that were adequate in the past (43) be revisited.

Table 8. Performance Characteristics of Radiographic Imaging Systems

Category	Example
System measures	• Image quality • Dynamic range • Modulation transfer function
Component measures (not inclusive)	• Cinefilm sensitometry • Cinefilm spatial resolution • Fluoro spatial resolution • Fluoro field of view size accuracy • Low-contrast video resolution • Cine and fluoro automatic exposure control

C. QI Program Development

A continuous QI program with regard to clinical proficiency must function under the broad rubric of system-level performance analyses, which should connote a more constructive (rather than punitive) context (38). Table 9 outlines some of the essential elements of such a program.

An overall continuous QI program is only as effective as the commitment of all involved in the process of healthcare delivery. Clearly, the most conspicuous components are procedural outcome and individual operator proficiency. Thus, the emphasis and direction in the profession alluded to earlier, in which sub-subspecialty "boards" in interven-

Table 9. Essential Data Elements for a Quality Improvement Program

- Individual operator procedural volume and major complication rate
- Institutional procedural complication rate
- Relevant clinical and demographic information
- Verification of data accuracy
- Patient and operator confidentiality
- Comparison of outcomes with benchmark data
- Ability to risk-stratify patients

tional adult cardiology have been developed, is properly focused on proficiency, both cognitive and technical. For coronary interventional procedures, proficiency is intimately related to procedural volume, although the latter is not synonymous with the former. However, sound quantitative support now exists for these once presumed arbitrary cut points. The situation is less clear with respect to diagnostic catheterization. Given the absence of similar quantitative data for diagnostic procedures, as well as the significantly lower 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 diagnostic quality of studies, rates of referral for intervention, and perhaps development of criteria of the appropriateness of these studies are suggested as methods of incorporating physician practice into the QI process of diagnostic procedures. It is recognized that the latter depends critically on the development of locale-specific "pathways" of care. However, "outliers" in this process may be readily identified and constructively advised. Standards of performance and QA in either a diagnostic or an interventional catheterization laboratory must of course originate with the individual. However, processes for credentialing activity and the ongoing assessment of proficiency must be developed in accord with both local governance policies, as well as professionally developed standards. In particular, the granting of privileges by healthcare systems is properly within the legal and ethical purview of these institutions. It is hoped that these systems use criteria similar to those outlined in this document to support the decision to credential physicians and monitor system performance.

The key elements of such a program are: 1) the development of a consensus on variables that reflects quality of care, 2) the rigorous prospective collection of these variables, 3) appropriate statistical analysis of the data to identify deficiencies in the process of care, 4) the development of a multidisciplinary approach to problem solving, 5) subsequent data collection with analysis of the specific effect of the solution on the identified deficiency, and 6) benchmarking of the information against national database standards such as the ACC National Cardiovascular Data Registry (44). These data are perhaps best presented to involved practitioners at regularly scheduled conferences for appropriate critique and problem solving.

Over a 10-year period, improvements in instrumentation, imaging, data recording, and procedural outcomes have proceeded rapidly. Consequently, continuing education for practitioners beyond the level of training programs has become the norm for the acquisition of many of these skills. Training programs themselves are changing from the traditional 1-year program in interventional cardiology to 2-year programs in some institutions. The development of subsubspecialty certification boards in interventional cardiology reflects this burgeoning knowledge base. 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 experience within individual institutions. An organized program of didactics 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 both expertise and morale.

A recent review of cardiac catheterization laboratory settings has outlined certain practical lessons learned by the Laboratory Survey Committee of the SCA&I (45). This committee noted that the major QA problems were usually not 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. Not only must a QA program provide procedural complication information, but a feedback mechanism to modify behavior must be in place.

Benchmark data are important, and because these benchmark data are dependent on a high number of participating laboratories, the Committee strongly recommends that cardiac catheterization laboratories actively participate in the national data registries, such as the ACC NCDR.

D. Minimum Caseload Volumes

The use of a specific minimum number of cases to define the quality of operator performance is obviously fraught with problems. Because many laboratories may not adhere to appropriate oversight or may not have an established QA program, it has become popular to define minimum caseloads for both the operators and the laboratory in place of many of the issues described in detail earlier. Given the low risk for diagnostic cardiac catheterization, the Committee could not arrive at any consensus as to what would constitute a minimum workload for individuals with regard to diagnostic procedures. There have been no data to justify the prior recommendation of at least 150 cases/year (5). The minimum diagnostic caseload for the entire laboratory also varies widely from state to state, often depending on the presence of the certificate of need (CON) process or other occasionally 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 deciphered by observing the total laboratory volume alone (2).

Recommendations regarding interventional volumes are noted in Table 7. In general, the Committee thought that the minimum interventional caseload of 75 procedures/year for operators and a minimum performance of 200 cases/year by institutions, with the ideal being 400 cases/year per laboratory, both reasonable and supportable, based on current data (3,46). This minimum caseload for operators has

also been adopted by the ABIM as a prerequisite for eligibility to take the interventional boards.

Issues of training, competency, and operator volume are important. It was estimated that 6,100 physicians performed 428,000 interventional procedures in 1994. These physicians represented 40% of board-certified cardiologists in the U.S. (28). Over half of the physicians performing interventional procedures in the U.S. at that time did not meet the current minimum suggested volume recommendations for proficiency within the catheterization laboratory. Operators performing a low volume of interventions might be tempted to expand the indications for diagnostic or interventional procedures in their clinical practice, yet a more aggressive approach to invasive therapies may or may not be in the patient's best interest. Under these circumstances, low-volume operators may wish to consolidate practices and dedicate 1 individual to perform catheterization-related procedures instead of having multiple physicians perform such procedures.

The ACC/AHA guidelines for PCI (3) have reviewed this issue in depth, noting multiple studies that support a relationship between complications and procedural volume. The lowest complication rates are observed when interventional procedures are performed by higher-volume operators (≥75 cases/year) with advanced skills (e.g., subspecialty certification) at high-volume institutions. This concept has also been endorsed by the ACC/AHA Task Force on Practice Guidelines for Coronary Angiography and the SCA&I (18,45). Ideally, lower-volume operators (<75 cases/year) should only work at institutions that perform >600 procedures/year (3). Even in the high-volume setting, low-volume operators should develop a defining mentoring relationship with a highly experienced operator who performs >150 procedures/year (3).

V. PROCEDURAL ISSUES IN THE PERFORMANCE OF CARDIAC CATHETERIZATION

Although no rigid protocol is commonly followed for all patients or environments, some general procedural issues are pertinent to most cardiac catheterizations. The following discussion is meant to provide a general approach to some of the issues that frequently arise in the performance of cardiac catheterization.

A. Patient Preparation

1. Sedatives and Relaxants. Appropriate sedation ensures the comfort of the patient during the procedure. Initial premedication with diphenhydramine (Benadryl®) and/or diazepam (Valium®) is used in most catheterizations because of their respective antiallergic and sedative properties. If more sedation or relaxation is necessary once the patient is in the catheterization laboratory setting, additional sedatives can be given. Conscious-sedation protocols should be followed, with documentation of vital signs and oxygen saturations during the study in accordance with individual institutional guidelines. Alternative sedatives often used during the procedure include IV midazolam (Versed®), hydromorphone hydrochloride (Dilaudid®), and fentanyl citrate. Excessive sedation should be avoided so that the patient's state of consciousness is not severely altered, which would render the patient unable to report discomfort or symptoms that might herald a potential complication during the procedure. All patients should have pulse oximetry monitoring during conscious sedation, with periodic checks of blood pressure, heart rate, and blood oxygen saturation documented during the procedure (47).

2. Prevention of Contrast "Allergy". The preprocedural history should document any previous exposure to X-ray contrast and whether any reaction occurred. A complete description of the allergic reaction should be obtained to ascertain its validity and importance. When patients have previously had an allergic reaction to intravenously administered contrast material, a subsequent allergic reaction to intra-arterially administered radiographic contrast is rare, but these patients are at higher risk (48).

Given the rarity of true contrast-allergic reactions in the cardiac catheterization laboratory, it is difficult to recommend a preventive therapy with confidence. There are data that suggest that premedication with steroids before the administration of radiographic contrast for IV pyelography reduces contrast reactions in high-risk patients (49). This has led to the recommendation to administer an oral steroid 1 to 2 days before the procedure to patients at risk. In most cardiac catheterization laboratories, however, steroids are often only given intravenously a few h (or less) before the procedure. There are no data to support or refute the advantages of this practice. In addition, diphenhydramine (Benadryl®) and cimetidine (Tagamet®) or much more potent H_1 and H_2 blockers are often used to further reduce the possibility of an allergic reaction (50).

In addition to these precautions, a few laboratories give a 1-mL test dose of the contrast agent intra-arterially, then follow it with a 3-min observation period to watch for any signs of an anaphylactoid reaction (49). Anaphylactoid reactions are characterized by profound hypotension, hives, and bronchospasm. Treatment includes administration of large volumes of fluid to restore blood pressure. Antihistamines and epinephrine are also used to reduce the urticarial reaction and resulting bronchospasm. Anaphylactoid reactions must be differentiated from vagal reactions, a common event during the initial stages of the catheterization procedure, or contrast-induced bradycardia and hypotension, especially during coronary injections that involve the atrioventricular nodal artery. Anaphylactoid reactions generally result in more profound hypotension and are more prolonged than vagal episodes. Anaphylactoid reactions may not respond to the use of atropine and fluids, as would be expected with a vagal reaction. Tachycardia is usually present during anaphylactoid reactions, as opposed to the bradycardia seen with stimulation of the vagus nerve.

3. Patients With Renal Insufficiency. Patients with known renal insufficiency (creatinine >1.8 mg/dL) should

be treated with preprocedural and postprocedural hydration and observed. There is suggestive evidence that there may be an advantage in the use of nonionic contrast compared with ionic contrast agents in these patients (50–52). Diabetic patients with renal dysfunction are at particularly high risk for acute renal failure after exposure to contrast agents (53). The amount of contrast used during the study should be minimized, and if possible, a biplane laboratory should be used to obtain the maximum information with each injection. Eliminating left ventriculography may further minimize the contrast load because the same information may be available from noninvasive studies. Postprocedural hydration should be considered in all cases and is mandatory in patients with severe renal dysfunction. Because the rise in creatinine level after the use of radiographic contrast may continue for up to 72 or more h after the procedure, appropriate laboratory follow-up to document any late worsening of renal function should be arranged for those at risk. Pretreatment with acetylcysteine holds promise for reducing the risk of contrast nephrotoxicity (54), although confirmatory data are needed to validate this approach. Despite the popularity of ad hoc interventional procedures after a diagnostic angiogram, this practice should be discouraged in patients with renal insufficiency (in a nonemergent setting) to prevent excessive use of contrast.

4. Patients With Diabetes Mellitus. In patients who are insulin dependent, the dosage of insulin should be adjusted to correspond with food intake before the procedure, and if possible, catheterization for these patients should be scheduled early in the day to avoid a long period of altered food intake and insulin administration. Often half of the usual insulin dosage is administered on the morning of the procedure. Blood sugar should be monitored if any symptoms of hypoglycemia emerge. In patients with diabetes who take metformin (Glucophage®), there is a potential for development of profound lactic acidosis should contrast-induced renal dysfunction develop. As a position paper from the SCA&I points out, this is an extremely rare event and has occurred only in patients with abnormal renal function (55). Metformin is relatively contraindicated in diabetic patients with significant renal insufficiency. Because of the potential hazard, however, the current recommendation is that metformin be discontinued the morning of the procedure and not restarted until the creatinine level is shown to be stable, usually 48 h after the procedure (55).

5. Patients Receiving Antiplatelet or Antithrombotic Medications. Patients who take warfarin (Coumadin®) should generally discontinue their drug for 3 doses before the cardiac catheterization procedure. An acceptable INR just before the cardiac catheterization varies according to individual practitioners, but the consensus is that an INR of <1.8 is acceptable without an increased risk of bleeding after the procedure. The overuse of vitamin K reversal of warfarin effects may make it difficult to re-establish a warfarin effect afterward. Patients receiving heparin may undergo cardiac catheterization without concern, although longer periods are required for hemostasis, and reversal of the heparin effects with protamine sulfate after completion of the study may be warranted. Closure devices may also help reduce groin bleeding in certain situations (56). Heparin activity may be estimated by the ACT. A fully heparinized patient in the cardiac catheterization laboratory would be expected to have an ACT >300 s, while it is generally safe to remove the catheters and sheaths once the ACT is <175 s. Heparin can be reversed by protamine, but profound allergic reactions may occur, especially in diabetic patients receiving NPH insulin (57). Aspirin is not stopped before cardiac catheterization. Use of the newer antiplatelet agents such as ticlopidine (Ticlid®), clopidogrel (Plavix®), eptifibatide (Integrilin®), tirofiban (Aggrastat®), or abciximab (ReoPro®), does not preclude a patient from undergoing cardiac catheterization; although the combination of GP IIb/IIIa inhibitors and standard heparin dosage (100 U/kg) results in a higher rate of groin bleeding complications (29). In patients receiving GP IIa/IIIb inhibitors, the heparin dose should be reduced to 70 U/kg.

B. Procedural Issues

1. Sterile Preparation of the Access Site and Vascular Access. Infection is rare after invasive cardiovascular procedures. In a retrospective study of 385 laboratories, an infection rate of 0.35% was noted, with the incidence for cut-downs 10 times higher than that for percutaneous sites (0.62% vs. 0.06%) (58). The Occupational Safety and Health Administration (OSHA) recommends that preparation of all patients include the removal of hair from the site, application of antiseptic to the skin, and the use of sterile drapes. 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. Operators should wear a sterile scrub suit. 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 sterile techniques used in the operating room are not necessary for most cardiac catheterization laboratory procedures, the operator should use appropriate hand washing and wear a sterile gown and gloves. Masks, eye shields, and protective caps are probably more important for keeping the patient's blood from splattering onto the operator than for protecting the patient from infection. In cases where greater wound exposure is necessary, such as pacemaker implantation or brachial cut-downs, the 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, transhepatic, 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.

The Sones brachial cut-down technique has largely been replaced by percutaneous methods. The Sones cut-down technique requires more specialized training, proctorship, and credentialing because of the unique training and skill level necessary for its safe use. This technique requires a more extended skin incision, blunt dissection, and arteriotomy and repair. Currently, the most common site for percutaneous arterial access for both diagnostic and interventional cardiac procedures is the femoral artery region. The radial artery approach is gaining some favor, especially for obese patients and outpatients. If venous access is required, in most cases it should be performed using the femoral vein or the internal jugular vein. Multiple venous catheters can be safely inserted in the same femoral vein; multiple arterial catheters require separate arterial access sites. Strict sterile procedures should be followed at each site.

2. Right-Heart Catheterization During the Evaluation of Coronary Artery Disease. The routine use of right-heart catheterization in a patient whose symptoms and objective studies suggest coronary artery disease without associated mitral regurgitation or congestive heart failure is discouraged (59). The additional information gained from a right-heart catheterization in patients with chest pain and suspected coronary artery disease is minimal. Unless concomitant valvular heart disease, presumed pulmonary hypertension, intracardiac shunts, or other diagnoses are suspected, a routine right-heart catheterization should not be performed. If it is anticipated that knowledge of right-heart pressures and cardiac output would be helpful in patients with left ventricular dysfunction and provide information that would enhance the safety of the procedure or affect decision making afterward, right-heart catheterization is acceptable.

3. The Routine Use of Temporary Pacing. Routine use of a temporary pacemaker during coronary angiography or interventional procedures is not indicated. However, use of a rotational atherectomy device (60) in right coronary artery disease or use of the Angiojet device (61) has been associated with an increased incidence of atrioventricular block. This is also true during percutaneous aortic balloon valvuloplasty or with alcohol ablation for hypertrophic cardiomyopathy. Thus, temporary pacing may be warranted in these instances. In patients with left bundle-branch block in whom a right-heart catheterization is being performed, there is a clear risk of complete heart block if the right bundle branch is injured during the procedure. Thus, temporary placement of a pacemaker may be appropriate. If it is anticipated that catheter manipulation or coronary obstruction during an interventional procedure might produce a bradyarrhythmia for which a temporary transvenous pacemaker would be necessary, a temporary pacemaker should be positioned before the need arises.

4. Transseptal Cardiac Catheterization and Percutaneous Balloon Mitral Valvuloplasty. The need for transseptal cardiac catheterization has persisted with the necessity of percutaneous mitral balloon valvuloplasty and the need to enter the left atrium during certain electrophysiological procedures. The technique is also useful in congenital heart disease and when left ventricular pressures and angiography are vital in patients with disk-type prosthetic aortic valve replacements. The technique is safe when performed by experienced operators (21).

Although percutaneous balloon mitral valvuloplasty can also be performed transseptally via the internal jugular vein (62) or retrogradely across the mitral valve via the arterial system (63), most procedures use the transseptal technique from the femoral vein. Single-balloon (primarily Inoue) or double-balloon methods are both effective (64). The Committee is not aware of any specific data regarding the minimum numbers for competency because the procedure is, for the most part, limited to major medical centers with a specific interest and expertise. Previous guidelines (5) suggested a minimum caseload of 25/year, and although this seems reasonable, there are no data to support this number. As with many "orphan" procedures, it is critical that the QA system be operative and that all transseptal procedures be closely monitored and any complications reviewed. Percutaneous balloon mitral valvuloplasty carries a small but well-documented risk (65), and its performance should be restricted to those operators who are aware of the appropriate indications for the procedure, skilled in the technique, and capable of handling any complications that may arise.

5. Role of Left Ventricular Puncture in the Era of Echocardiography. In the current era, the information gained from both transthoracic and transesophageal echocardiography allows for an excellent estimation of ventricular function and a reasonable sense of the severity of stenotic or regurgitant valvular lesions. The use of direct left ventricular puncture thus provides minimal additional information beyond that gained by echocardiography yet exponentially increases the chance of a serious complication even in experienced hands. The need most often arises in patients with 2 disk-type prosthetic mitral and aortic valves that prevent left ventricular access by any other means. It is the consensus of the Committee that left ventricular puncture should be used only in very rare instances in which the information needed to make a diagnostic or therapeutic decision is not available by any noninvasive method.

6. Use of Provocative Agents During Diagnostic Cardiac Catheterization. Certain provocative pharmacological agents may be used during cardiac catheterization to unmask pathology that is not evident without the intervention. Fluid loading may unmask latent pericardial constriction or tamponade. Afterload reduction or inotropic stimulation may be used to increase the outflow tract gradient in hypertrophic cardiomyopathy. Similarly, the use of afterload reduction or an inotropic agent may assist in the assessment of the severity of aortic stenosis in patients with low cardiac output and low transvalvular gradient (66). The use of provocative coronary vasoreactive agents (e.g., methylergonovine, acetylcholine, adenosine, or papaverine) should be confined to situations in which specific coronary artery

questions are being asked, because they have little clinical utility otherwise. Measures of coronary flow reserve or pressure-derived fractional flow reserve (FFR), by use of methods such as the Doppler or pressure sensor guidewires often require the use of coronary vasodilators such as adenosine, dipyridamole, or papaverine. A variety of pulmonary vasoreactive agents (e.g., oxygen, calcium channel blockers, adenosine, nitric oxide, or prostacyclin) may help define prognosis and potential responders to drug therapy in patients with primary pulmonary hypertension (67). These agents are only now being studied in secondary pulmonary vascular disease. The use of any of these agents carries potential risks, and the risk/benefit ratio of the procedure must be determined by the individual cardiologist. In each case, however, the catheterization laboratory committee should have a detailed and approved procedural protocol for the use of these agents. This protocol should include the steps to be taken immediately to treat any potential complications that may arise.

7. Operator Safety During Cardiac Catheterization in Patients With Communicable Diseases. All cardiac catheterization procedures must be conducted as if there were a risk of infection. Heightened protective care should be taken in any case in which a communicable disease such as hepatitis or human immunodeficiency virus (HIV) positivity is present. Because there is no assurance that individual patients without these diagnoses do not carry a serious communicable disease such as HIV, the prudent operator must always use optimum care during each study. 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. In addition to the usual surgical gown, disposable shoe covers for the cardiologist and all technicians in the room should be considered. 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. Extra clean-up of the laboratory space should also be performed before it is used again.

C. Performance Issues

1. Injection of Coronary Arteries. 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 a bubble-free connection between the contrast manifold port or syringe and the catheter must be established. Careful replenishment of contrast in the injection syringe and the maintenance of a bubble-free environment is the responsibility of the operating cardiologist. Most invasive cardiologists inject the coronary arteries manually, although power injectors can be used safely with appropriate equipment and training. Coronary injections should include a tiny test dose of contrast once the catheter tip is in position to be certain 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.

The use of nurses, cardiovascular technicians, or physician's assistants to inject the coronary arteries has become increasingly popular. It remains the responsibility of the individual invasive cardiologist to ascertain whether paramedical personnel or power injectors are capable of administering contrast into the coronary arteries. Physician extenders should always be viewed as extensions of the primary operator's hands, with the responsibility for safety ultimately residing with the invasive cardiologist.

2. Angiography. In the majority of cases, the use of single-plane X-ray imaging is satisfactory, recognizing that many laboratories do not have biplane capabilities. Laboratories contemplating angiographic evaluation of patients with congenital heart disease, however, should have biplane capabilities. In the case of left ventriculography in patients with coronary artery disease, an appropriate view should be selected to gain the most information regarding left ventricular function.

The use of multiple orthogonal views of the coronary arteries is of obvious importance. The invasive cardiologist must be certain that appropriate information is obtained and recorded in order to make an accurate diagnosis and help determine suitability for PCI. Each segment of the coronary artery should be seen in at least 2 orthogonal views. Angulation to obtain the "worst stenosis" of any lesion is important. 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 (68). Table 10 lists suggested appropriate views of each coronary as a guideline.

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 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 designed for that purpose.

Because there is considerable degradation in the image quality when copies of cineangiograms are transferred onto videotape, diagnostic decisions are best made on original cinefilm or digital media.

Table 10. Suggested Views for Coronary Angiography

Coronary Artery	Suggested Views
Left Main	
• Ostial	Shallow RAO; LAO cranial; AP caudal
• Body	RAO shallow/caudal/cranial; AP
• Distal	LAO caudal/cranial; RAO caudal
Left Anterior Descending	
• Ostial/proximal diagonals	Cranial LAO; RAO shallow/cranial/lateral
• Proximal/mid diagonals	LAO cranial; RAO cranial/lateral
• Distal/apical	RAO lateral
Left Circumflex	
• Ostial/proximal	LAO; LAO cranial/caudal
• Ostial/ramus	LAO; LAO caudal; RAO caudal
• Mid/marginals	RAO shallow/caudal; LAO caudal
• Distal (dominant)	LAO shallow/cranial; RAO shallow/caudal
Right Coronary	
• Ostial/proximal	LAO; LAO cranial; left lateral
• Mid	LAO; LAO cranial; RAO shallow; left lateral
• Distal/bifurcation of posterior descending	LAO cranial; RAO shallow/lateral; AP caudal
• Posterior descending	RAO shallow; LAO cranial; AP caudal
• Posterolateral to left ventricle	RAO shallow; LAO cranial; AP caudal

Angulation refers to the location of the image intensifier relative to the patient: AP = antero-posterior; Caudal = toward the feet; Cranial = toward the head; LAO = left anterior oblique; Lateral = 90° from vertical; RAO = right anterior oblique; Shallow = 15° to 30° angulation from vertical with neither caudal or cranial angulation.

3. Pressure Measurement. The importance of high-quality pressure measurements unfortunately has been de-emphasized in many laboratory facilities. The availability of numerous types of hemodynamic equipment precludes detailed description here. Appropriate filtering of the hemodynamic signal is important for adequate interpretation of individual waveforms. Careful balancing and zeroing of the system at the level of the 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 knowledge of each laboratory's transducers and recorders should be part of the 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. Invasive cardiologists using the laboratory should review the quality of the pressure recordings obtained, and any deficiency should be corrected by the company providing the equipment.

During a routine left-heart and coronary arterial catheterization, a preprocedural and postprocedural aortic pressure tracing as well as the recording of the left ventricular systolic and end-diastolic pressure should be obtained. Some laboratories find it useful to repeat the left ventricular pressure after the left ventriculogram, although the actual value of this exercise is questionable. During right-heart catheterization, the acquisition of right atrial, right ventricular, pulmonary artery, and pulmonary artery wedge tracings is routine, and sufficiently long strips of phasic recordings should be obtained to assess respiratory variation. Obtaining the end-expiratory pressure may help 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. 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 one chamber to another. Simultaneous pressures to gauge gradients across valvular lesions are preferred. Care should be taken if the femoral artery pressure is used as a substitute for aortic pressure in younger patients. 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. On occasion, the pulmonary capillary wedge pressure will also not correspond well to the left atrial pressure (especially after mitral valve replacement), and a transseptal puncture with simultaneous measurement of the left atrial and left ventricular pressure is required for an accurate transmitral gradient.

Rarely a pressure gradient across a lesion in a coronary vessel may provide information regarding the hemodynamic significance of that lesion. Coronary pressure wires and flow wires may be used to help evaluate severity of coronary stenosis.

4. Measurement of Cardiac Output. Cardiac output measurements commonly used in the cardiac catheterization

Table 11. General Recommendations Regarding Postprocedural Hemostasis After Prior Femoral Artery Access

Situation	Recommendation
Following hemostatic closure device	1–2 h recumbent in position of comfort, then ambulate × 30 min before discharge
Following removal of venous sheath	1 h with leg straight, then ambulate × 30 min before discharge
Following removal of femoral arterial sheath (ACT <175 s)	
Manual compression	10–20 min (until hemostasis achieved)
Clamp	15 min to 1 h to achieve hemostasis
Bedrest	Leg straight, slight head elevation × 2–6 h
Ambulation	30 min to 1 h before discharge

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 now rarely used. As a consequence, most cardiac catheterization laboratories rely on 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 usually the most difficult variable to obtain. Most laboratories use an assumed value, either from an established reference table or the following formula: oxygen consumption = 125 mL/min/m^2 BSA. 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 left ventricular 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 the prolated ellipse 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.

D. Postprocedural Issues

1. Vascular Hemostasis. The most frequent complication of coronary angiography and coronary interventions occurs at the vascular access site. Careful vascular entry is the first guard against such complications. Unfortunately, the use of heparin and/or thrombolytic or antiplatelet agents sets the stage for vascular complications (see Tables 5 and 6). Vascular hemostasis obtained after the procedure should be viewed as a crucial component of the procedure. In cases of femoral puncture, where a vascular closure device is not used, it should be routine to assess the influence of procedural heparin using the ACT value before access-site compression. Once the ACT has returned to near normal (<175 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. Most patients should be confined to bed for a minimum of 2 h after the procedure. The use of the radial or brachial artery approaches obviates the need for prolonged bed rest, but hemostasis must still be achieved by manual or device pressure.

The use of percutaneous vascular closure devices is becoming increasingly popular, and although these devices carry their own set of complications, they provide excellent hemostasis and allow for early ambulation of most patients. Operators who use vascular closure devices should first undergo careful training and proctorship before accreditation. Table 11 outlines some general recommendations regarding postprocedural hemostasis after femoral artery access.

In cases of both diagnostic and interventional procedures, it is the responsibility of the QA program to ascertain that careful clinical follow-up during time in-hospital and for 24 h after the procedure are reported in terms of vascular complications for each practitioner and the laboratory as a whole.

2. Reporting of Cardiac Catheterization Results. The formal cardiac catheterization and angiographic report should contain a certain critical amount of information. The indication for the procedure should be clearly stated. The time course of the procedural events should be documented and recorded. The time and dose of all medications used

during the procedure should be noted. All catheters, sheaths, and special guidewires used should be reported in a procedural section. Any pertinent hemodynamic data obtained should also be reported. The minimum hemodynamic data that should be reported from a left-heart catheterization and coronary angiography study with left ventriculography should be the initial and ending aortic pressures and the left ventricular systolic and end-diastolic pressure. If right-heart catheterization is performed, the right atrial, pulmonary artery, and pulmonary artery wedge pressure values should be reported, as well as mean pressures. The right ventricular pressure should include the systolic and end-diastolic pressures. Transvalvular mean and peak pressure gradients and valve area determinations should be reported when appropriate, along with the cardiac output determination and any shunt data if indicated.

In addition to a detailed summary of the procedure, a description of the angiographic findings is required. A visual diagram of the coronary tree is helpful to communicate vascular anatomy and lesion location. Minimum findings to be reported should include: 1) the presence or absence of the right and left coronary ostia and detailed descriptions of any abnormalities in the left main coronary artery; 2) the left anterior descending coronary artery and its diagonal and septal branches; 3) the left circumflex coronary artery and its obtuse marginals and inferolateral branches; and 4) the right coronary artery and its posterior descending and posterolateral branches. The dominance of the coronary vessels should also be noted. The left ventriculogram assessment should include the regional wall motion abnormalities seen in the left ventricle contour in terms of anterior, inferior, apical, posterior, and lateral segments. Terminology for each segment should include normal, hypokinesia, akinesia, dyskinesia, and aneurysmal wall motion. Quantitative methods are also useful when available. A measured or estimated ejection fraction should also be reported and the presence and severity of any valvular regurgitation noted. Pertinent additional details such as calcium in the coronary arteries, valves, or pericardium should also be included if these data have potential clinical relevance. A final diagnosis should be clearly stated. In some laboratories, the management decision is also included in the report.

Procedural and hemodynamic records should be stored in some form for at least 7 years and should be accessible within a reasonable time frame. Angiographic findings should also be available for subsequent review for 7 years, although the quality of cineangiograms clearly degrades over time. The findings of catheterization or angiography should be available to the patient and any physician or facility that the patient so designates by written request.

VI. PERSONNEL ISSUES AND LABORATORY DESIGN

A certain critical mass of personnel is required to safely perform cardiac catheterization. The following is an outline of pertinent personnel requirements, roles, and obligations.

A. 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 is a credentialed physician, experienced in all aspects of the performance of the procedure, including preprocedural and postprocedural care of the patient.

B. 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.

C. Secondary Operators

Secondary operators are additional attending physicians or physician extenders who assist the primary attending physician. These physicians may fulfill the requirements for an attending physician but are not in charge of the procedure at hand and are not considered the primary operator. They should not take credit for the case for the purpose of fulfilling minimum performance volume requirements.

D. Laboratory Director

The laboratory director should be a physician with the experience and leadership qualities needed to control the laboratory environment (69). 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 an adult cardiologist or a pediatric cardiologist and may have special interests such as in interventional cardiology or electrophysiology. The director should be 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 must be a skilled administrator supportive of the needs of the departments served. The director's qualifications should include at least 5 years of catheterization experience and recognized skill in the laboratory. Preferably, he or she should be board certified in interventional cardiology if interventional procedures are performed in the laboratory.

The duties and responsibilities of the director are multiple and wide-ranging and demand strong management skills. 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 nonprofessional staff, and provide necessary training to personnel. The director shall establish and monitor quality control, including morbidity and mortality. Other responsibilities include control of patient scheduling,

Table 12. Levels of Operator Training and Proficiency in Adult Cardiac Catheterization and Coronary Intervention

		Training			Yearly Proficiency
Level	Proficiency Level	Mos. of Training	No. of Diagnostic Cardiac Catheterizations	No. of Coronary Interventions	No. of Coronary Interventions
Level I	Basic training required of all trainees to be a competent, consulting cardiologist	4 months	100	—	—
Level II	Additional training in diagnostic cardiac catheterization to perform specific diagnostic procedures at an intermediate level	12 months	300, with 200 as primary operator	—	—
Level III	Advanced training in interventional cardiac catheterization to perform, interpret and train others to perform and interpret specific interventional coronary procedures at a high skill level	12 months	—	250 as primary operator	≥75 as primary operator

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.

E. Operating Physicians

As suggested in several recent documents (2,70–73), all physicians credentialed to operate in the laboratory must have proper training. This includes those classified as the attending physician of record and those functioning as teaching attending or secondary operators. This training may be in adult or pediatric cardiology. Clinical training in one of these fields should fulfill requirements for that specialty board. The physician must also be trained in emergency care and radiation physics and be certified as competent 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 at least board eligible. A physician who would provide only laboratory service without being a full member of the hospital staff should not be granted laboratory privileges. He or she must participate in the laboratory's QA program, including peer review. Physicians performing interventional procedures should be board eligible or certified in interventional cardiology.

F. Cardiovascular Trainee (Fellow)

The primary role of the cardiovascular trainee is to learn cardiac catheterization procedures. The trainee also provides preprocedural care, procedural performance, and postprocedural care. In so doing, trainees obtain the critical knowledge and skills to become qualified attending physicians. Trainees may perform all functions of the procedure as the primary operator, but only under the direct supervision of a credentialed physician who assumes responsibility for the procedural results. The use of house staff not directly engaged in a formal cardiovascular training program is inappropriate. Table 12 outlines the current recommendations for training and maintaining proficiency in invasive skills. All trainees should receive at least 4 months of training and participate in 100 procedures (level I). For diagnostic catheterization skills, trainees should perform 300 procedures, with 200 as the primary operator (level II). For interventional catheterization skills at level III, trainees are required to perform 250 interventional procedures as the primary operator (74).

G. 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 secondary operators. It should be recognized that extenders should never be primary operators. The physician extender should be proficient in both the technical and cognitive aspects of cardiac catheterization, including: 1) preprocedural evaluation, 2) indications, 3) cardiac physiology and pathophysiology, 4) emergency cardiac care, 5) radiation safety, and 6) application of diagnostic catheterization data regarding the procedure, according to the standards established by the SCA&I, ACC, and AHA (5,75,76).

Although there has been some controversy about whether physician extenders are qualified to perform cardiac catheterization and coronary angiography as primary operators in lieu of physicians (75), it is the position of the Committee that nonphysicians should not perform catheterization as primary operators (76). The primary operating physician must be in the catheterization suite during the procedure when secondary operators are performing the procedure. The primary physician operator must always be immediately present to direct the physician extender and provide all clinical decision making.

Specially trained nurses may assist attending physicians in much the same role as physician's assistants in the perfor-

mance of procedures. They may be able to assist in place of cardiovascular trainees, but they require greater supervision during all aspects of the procedure. Specialized experience in both clinical care and cardiovascular procedures is required.

H. Nursing Personnel

The type and number of nursing personnel required in the catheterization laboratory depend on the laboratory caseload and mix and may include nurse practitioners, registered nurses, licensed vocational or practical nurses, or nursing assistants. In most laboratories, the nursing supervisor is a registered nurse. This nurse must be familiar with the overall function of the laboratory, help set the tone of patient surroundings, and influence the efficiency and safety of procedures. The registered nurse may also directly participate in observation and nursing care of the patient during catheterization and be ready to respond to any emergency. The nursing supervisor should be in charge of the preprocedure and postprocedure holding areas.

The background of a catheterization laboratory nurse should include critical-care experience, knowledge of cardiovascular medications, ability to start an IV infusion, and experience in sterile techniques. Experience with vascular catheter instrumentation, especially with identification, cleaning, sterilization, and storage, is necessary. Knowledge of vascular catheter materials and the proper size correlations for catheters, guidewires, and adapters is important, as is experience in the manipulation of manifolds, injection of contrast, and changing of guidewires and catheters. The catheterization laboratory nurse must have a thorough understanding of the flushing of catheters and prevention of clots or air emboli.

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.

I. Non-Nursing Personnel

Several kinds of technical knowledge are required in the cardiac catheterization laboratory, although any one person may not possess all the different types of technical expertise. At least one technologist, who may or may not be 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, automatic film-processing equipment (if used), pressure injection systems, video systems, and cine cameras. 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 radiation physicist, should monitor radiation safety techniques for both the patient and laboratory personnel. Immediate availability of a radiological engineer in the event of equipment failure is highly desirable.

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. Training should include skills in patient observation and preparation for assistance in acute cardiac care, including resuscitation and related therapeutic efforts.

In laboratories in which cinefilm is still used, at least 1 technologist should be skilled as a darkroom technician, because the quality of images recorded on film is heavily dependent on darkroom technique. This person must be trained in photographic processing and the operation of automatic film processors and must be familiar with the characteristics of film and chemicals used for cardiovascular procedures. Skills should be acquired in the techniques of day-to-day calibration and maintenance of automatic processors and the use of sensitometric/densitometric equipment and data. These skills, plus skills in digital image acquisition, storage, transfer, and processing are necessary for the technologist to ensure high quality of the diagnostic images. As laboratories move to a cineless environment, a technician with computer skills is very valuable for handling film transfer methods and archival storage devices and equipment necessary to maintain the digital libraries and produce compact discs or other transfer media when needed. As all-digital laboratories become the norm over the next few years, the role of the darkroom technician will evolve into that of a digital archive technician. This will undoubtedly require retraining and a new set of skills unlike those needed in film development. Knowledge of X-ray systems, acquisition of digital images, and handling of the resultant digital information will remain important adjunct skills.

J. Staffing Patterns

An invasive cardiologist must be present in the laboratory during each procedure and must be responsible for the outcome. 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

Table 13. Suggested Minimal Room Sizes in the Cardiac Catheterization Suite (5)

Use	Suggested Minimum Size (sq ft)
Procedure room	500–600
Control room	150–200
Equipment room	100–120
Scrub facility (if independent from the procedure room)	30
Holding room	>120
Patient preparation room	120
Recovery room	120
Catheter and other storage room	100
Patient dressing room	70
Staff dressing room	70
Patient toilet	30
Staff toilet	30
Pharmacy space	30
Blood gas analysis	20
Staff lounge	70
Reception area	70
Film viewing area	70
Archival area (film and/or computerized archival)	70
Darkroom processing (or computer management)	70
Soiled utility	70
Janitorial space	20
Offices (space per office)	70
Conference room	120
Library	70

responsibilities and provide 24-h coverage of essential team functions. Complex studies, especially those of children and acutely unstable patients, require personnel with special training to deal with the particular requirements of these procedures. Frequently, the presence of a second physician is important for optimal care in many such difficult cases.

K. Cardiopulmonary Resuscitation

All members of the catheterization team—physicians, nurses, and technologists—should complete a course in basic CPR. Certification in advance cardiac life support is also strongly urged for all members of the cardiac catheterization team. Yearly recertification is recommended.

L. Suggested Space Requirements

Table 13 outlines some suggested minimum room sizes for the cardiac catheterization laboratory. It should be obvious that these recommendations are only suggestions and that space for development and access to newer technology will require modification. For instance, cinefilm and record storage is gradually being replaced by computer review stations and computer archival and retrieval areas. Many physicians review digital angiographic results immediately after the procedure in the control room, and this capability means that control room space should be expanded to accommodate this activity. Database requirements also require appropriate space for computers, not only for data entry but also for compilation of the results and preparation of the final catheterization report. Because most diagnostic cardiac catheterization procedures have moved to the outpatient environment, appropriate check-in, patient waiting, and holding rooms have become necessary for any cardiac catheterization suite. In some situations these areas are shared with other areas of the hospital, such as ambulatory surgery or radiology; in others, these areas are occupied solely by the cardiac catheterization laboratory.

Room heights are commensurate to room-need requirements. Procedure rooms require a minimum height of 9 feet, 10 inches. Heights of the control room and most other rooms are generally 8 feet.

VII. ETHICAL CONCERNS

In medical school physicians are taught that their primary obligations are to act in the best interest of the patient and society (beneficence), to do no harm (nonmalfeasance), and to maintain respect for patient autonomy (77–79). The last obligation mandates that patients be given free and uncoerced choices about their medical care and requires that physicians provide accurate and unbiased information about the patient's medical condition, disclose alternative choices and potential conflicts of interest, and obtain informed consent, delineating the potential risks and benefits (and alternatives) of the diagnostic and therapeutic strategy (77).

Changing practice patterns in medicine, including the expansion of both managed care and for-profit physician entrepreneurial ventures, have altered the relationships among physicians, patients, and payers (79–81), creating potential conflicts of interest for the physician in maintaining the patient's best interest. The availability of sophisticated yet costly diagnostic and therapeutic technologies has also created new challenges for physicians, who may now serve simultaneously as physician, inventor, and investigator of new therapies for vascular intervention. Government and regulatory authorities now seek greater assurances that physicians respect the best interest of the patient in their clinical practice. Physicians who participate in clinical investigation must now report any real or perceived financial "conflict of interest" with industry sponsors (81,82) as well as with their academic institutions (76). Physicians who have a direct conflict of interest should avoid being investigators of products for which they stand to gain financially, except under extraordinary circumstances.

Ethical issues facing the cardiologist also involve the performance of biomedical research. Patients are increasingly seeking information about the competency of their healthcare providers, often by reviewing "Best Practice" listings provided by potentially conflicted third parties or Internet sites created by hospitals who seek to attract new patients into their healthcare system. Competency information is rarely made available by organized medical societies to the general public. A steady stream of new cardiovascular training graduates in this country has also resulted in the availability of an increasing number of physicians who perform interventional procedures. A possible excess in the number of interventionalists could also result in overutiliza-

tion of services, conflict of interest, and self-referral. 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.

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

With continuing competition for patient referrals, there is close scrutiny of the ethical (and financial) relationships between the referring cardiologist or internist and the interventional cardiologist. Although some procedures may require the participation of two cardiologists (e.g., mitral valvuloplasty or complex coronary or pediatric intervention), it is not ethical for a cardiologist to charge an operator assistant's fee when he or she has not directly participated in the procedure or when the cardiologist's efforts were not needed for the procedure. Furthermore, offering or providing a shared fee with another physician for the performance of cardiac catheterization is unethical and potentially 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 (83). This principle applies not only to fees, commissions, and compensations 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 (5). Collusion with any healthcare provider may be unethical. Furthermore, such collusion may be illegal when such arrangements involve Medicare funds and are construed as inducement for referral (83). Collusion with other cardiologists in an attempt to fix fees for catheterization services may also violate antitrust laws (5).

B. Unnecessary Services

Without specific indications, "routine" right-heart catheterization, pacemaker implantation during elective coronary angioplasty, and simple coronary angioplasty in a patient without ischemia may be unnecessary (83). A charge to overread either hemodynamic data or angiograms by a physician who has not performed the procedure is also an unnecessary duplication of services and fees.

C. Self-Referral, Self-Ownership, and Self-Reporting

Changing relationships among hospitals, managed care groups, and physicians have led to the development of freestanding catheterization facilities that are not strictly associated with hospitals but are owned instead by investors or even physicians within a cardiovascular practice. Under these circumstances, some practitioners may have financial interests in diagnostic laboratories, including cardiac catheterization facilities, radiological imaging centers, and ambulatory surgery centers (84). The investing physicians may benefit financially from the referral of patients to these facilities (79,80,84–87). Cardiologists must avoid any financial business or industry arrangements that might influence their decision about the care of patients because of personal gain (5).

Law in some states prohibits financial investments to "self-referral" facilities (5,84). The national "federal physician self-referral law" (or "Stark Law"), however, explicitly exempts cardiac catheterization. For other services designated in the Stark Law, physicians are allowed to personally provide services in institutions in which they have direct or indirect ownership or financial relationships. Referral of patients to a catheterization laboratory facility (from which the patient's cardiologist collects earnings or shares in profits) based solely on an effort to maintain volume expectations, however, is a conflict of interest.

Direct remuneration from manufacturers for the use of their devices, catheters or drugs may be illegal when the patient is also charged for the use of the catheters or devices or when governmental funds are used for payment (5). Cardiologists should never engage in any practice that would violate state or federal law regarding referral to a facility in which they have financial interest. It is unethical to refer patients to such a facility for financial gain alone. The quality review process should be in place and enforced to provide appropriate oversight to prevent these relationships from becoming problematic. A second opinion from another qualified cardiologist who has no fiscal connection to the primary cardiologist or the catheterization laboratory should be obtained if any questions arise about the appropriateness of a procedure being performed in such a facility.

Concerns have been raised about the accurate reporting of individual operator and catheterization laboratory outcomes. Local competition could result in the suppression of clinical reporting of adverse events, and there may also be pressure to maintain low costs and a low adverse event rate to solicit institutional contracts with third-party payers. Given the sensitive information related to individual operator success and complication rates, there may also be a general reluctance to provide this information to potentially nonobjective sources (91).

Physicians and hospitals should be encouraged to collect procedural outcome information according to standardized criteria such as those provided by the ACC and the SCA&I, to compare these outcomes with "benchmark" standards provided by the ACC and/or the SCA&I, and to subject outcomes to peer review (91). These outcomes should be risk-adjusted to account for complex patient subsets (e.g., cardiogenic shock and nonoperative candidates). The peer review team should include individuals without a fiscal interest in the laboratory and those not personally involved in the procedures.

D. Informed Consent

Patient autonomy and, in many cases, the law mandate that informed consent must be obtained before performance

of any invasive diagnostic or therapeutic cardiovascular procedures (77). 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 during the process of informed consent. Because the patient and physician together determine the diagnostic and treatment strategy, medical facts should be presented accurately to the patient (and/or family or person responsible for the patient's care) at a level of communication that the patient can easily understand (5). A discussion of the risks, benefits, and alternatives should be undertaken in an unpressured environment well before the procedure. It is recognized that, on occasion, urgent situations may arise in the catheterization laboratory, making it difficult to prepare the patient for all possible emergency procedures. Particular attention is needed for ad hoc interventional procedures following cardiac catheterization in patients with a clear indication for coronary revascularization. It is better to explain the potential risks, benefits, and alternative therapies to coronary intervention before administration of sedatives or other agents that may affect the patient's judgment at the time of cardiac catheterization. Written informed consent should be obtained and documented in the medical record before the procedure.

E. Ethics of "Teaching" Diagnostic and Therapeutic Procedures

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 with the patient's consent and under the attending physician's supervision (5). Fellows or physician's assistants, if qualified, can also perform certain invasive procedures, provided that they are closely 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 in the performance of the procedure.

F. 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 (92). 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 (83).

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.

Through the difficult times facing physicians 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.

VIII. IMAGING ISSUES

The primary technical focus in the cardiac catheterization laboratory is the generation, recording, and display of high-quality X-ray images during diagnostic and interventional catheterization procedures. With greater numbers of increasingly complex interventional procedures being performed, acquisition of fluoroscopic and cineangiographic images of the highest quality remains crucial for the optimal performance of the catheterization laboratory. The ongoing trend toward more complex interventional procedures results in greater exposure to radiation for the patient and laboratory staff (93). The longer procedure times associated with these procedures also place greater demands on the X-ray generator and tube than may have been the case previously. During the last half-decade, the prominent role of 35-mm cine film as the recording and archiving medium has been challenged, and cine-less operation has become accepted as routine practice in many laboratories (94). The movement toward digital technologies in the catheterization laboratory and throughout the hospital and community continues to change the interaction between the laboratory and the outside world. The rapid evolution in information technology in turn changes users' expectations regarding the accessibility of medical image data (95). These significant technical changes require that the basic requirements in the catheterization laboratory be revisited with some frequency to ensure that the technical needs of the laboratory are being met appropriately.

A. Radiographic Equipment

The conflict between acquisition of high-quality angiographic images and limiting X-ray exposure of patients and staff has always been difficult to resolve satisfactorily. Cardiac angiography, with its simultaneous requirements for high acquisition rates and the need to visualize very small objects, places some of the most severe demands on X-ray generating equipment. Although there has always been optimism that improvements in technology would help resolve the conflict, the increasing clinical requirements instead have led to yet greater demands on the equipment. The wide acceptance of digital angiographic systems, which have advantages in a variety of procedures, has led to new challenges and concerns about issues of data rates, amounts, and storage (96,97). High-quality video display has become standard in the laboratory, and the use of pulsed-progressive fluoroscopy is assumed with any currently available equipment (98).

B. Generators

The rising proportion of interventional procedures performed in the catheterization laboratory increases the demands placed on the X-ray angiographic equipment, including the X-ray generator. These requirements typically include a high-frequency generator with outputs of 80 to 100 kW at X-ray pulse rates of 30 pulses per second (60 pulses per second for pediatric applications). The ability to perform pulsed fluoroscopy and angiography with short exposure times—sufficient to avoid motion blur of objects moving at high speeds but still able to maintain a high degree of contrast—has become a minimum requirement in angiography. Modern equipment designed for the catheterization laboratory should also have automatic exposure control (AEC), which provides the optimal combination of X-ray tube voltage, current, and exposure time most suited for visualization of rapidly moving coronary arteries with adequate contrast. Many laboratories choose to use the high-level control (HLC) fluoroscopic technique, which can produce exposure rates beyond the standard regulatory limit of 10 roentgens per minute (R/min) but less than that used during cineangiography. There are broader implications for this higher exposure mode related to the resulting exposure to the patient and staff, but if the capability is deemed a requirement for a particular laboratory, a generator with such capability will be required regardless.

C. X-Ray Tubes

Along with the high-output generator, the X-ray tube used in cardiac catheterization laboratories—especially for long, complex interventional procedures—must meet the most demanding technical requirements (99). To visualize the smallest coronary arteries and complex variations in lumen geometry, focal spots of 0.6 to 0.8 mm are necessary. To acquire multiple angiographic sequences lasting up to 10 to 30 s at rates of 30 fps (and higher), the tube must be able to absorb large amounts of energy and dissipate the resulting heat quickly to avoid delays between acquisitions—and serious damage to the X-ray tube. Similarly, the extensive fluoroscopic times required for interventional procedures will be limited by the heat dissipation characteristics of the X-ray tube. Heat storage capacities >1 million heat units (HU) and even approaching 3 million HUs have been found invaluable in the catheterization laboratory. A tube with greater heat storage capacity provides several significant advantages in the modern clinical environment: 1) it reduces delays during clinical procedures if lengthy fluoroscopic and angiographic exposures result in the heating of the tube to its maximum capabilities; 2) it allows for penetration of larger patients (or at steeper angulations) without resorting to higher X-ray tube energies and the resulting reduction in vessel (and device) contrast and increase in image noise; 3) it provides the option for use of filtering materials that can either reduce patient skin exposure, improve image noise characteristics, or both.

D. Image Intensifiers

The performance characteristics of image intensifiers used in the catheterization laboratory have improved continuously over the years. Higher conversion factors—greater efficiency in light output as a function of X-ray input exposure—along with improved contrast ratios and a reduction in geometric distortion have led to improved image quality. As a result, image intensifier performance—in dedicated cardiac catheterization systems—has been optimized for the task of imaging the heart and coronary arteries at the X-ray exposure levels used in that application. In general terms, this translates to a high-contrast spatial resolution >3.0 line pairs/mm at the entrance plane of the image intensifier and acceptable signal-to-noise quality at cineangiographic entrance exposures of 20 to 25 microR/frame in the typical magnification mode used for coronary angiography (100). On the other hand, systems optimized for other imaging tasks, such as peripheral and vascular angiography, cannot at the same time deliver the required performance in the heart, and users should be aware that there will be degradation in performance for the task of imaging the heart and coronary arteries. The different X-ray tube design, e.g., target size and angle, required for covering a field of view corresponding to a 40-cm image intensifier will not deliver the same results at the same X-ray exposure for the 12- to 20-cm field of view customary in cardiac imaging. Similarly, the light-gathering characteristics of the larger image intensifier may compromise performance for cardiac imaging at the smaller fields of view when only a fraction of the intensifier input surface is used. In turn, there are implications for the electrostatic optics within the intensifier as well as for the light-gathering optics at the output surface of the intensifier; in general, these effects will degrade the image quality relative to an intensifier specifically designed for the cardiac application. In summary, the effects that can occur in such a system are degradation in

spatial resolution, increased image noise in fluoroscopy and angiography, increased X-ray exposure rates, and delays due to exceeding heat capacity for X-ray tubes.

E. Developments in X-Ray Detectors

As mentioned earlier, the image intensifier is a vital component for X-ray angiographic imaging in the cardiac catheterization laboratory, because no better alternatives exist (to date) that can convert the X-ray intensity information exiting the patient into usable, visible light information. This visible light is converted to an electrical video signal and in turn to a stream of numbers for subsequent processing and storage. Recent developments in digital X-ray detector technology demonstrate significant potential for application in cardiac fluoroscopic and angiographic applications in the future. The first commercial systems have only recently been introduced, and it is expected that they will become more common; readers should thus be aware of how these systems differ from those to which they have been accustomed. The most significant difference between the image intensifier–based imaging chain and those based on digital detector technologies is that the entire image intensifier tube will disappear, along with the video camera used to convert the output light signal to an electronic voltage. The promise is that this will deliver significant improvements in spatial resolution because it will not be limited by "blurring" processes inherent to the image intensifier systems, greater dynamic range and contrast resolution, and because the new detectors are much simpler mechanically, with less likelihood of failure and gradual degradation in performance (101).

The candidate detectors that will most likely be appearing in cardiac catheterization laboratories are digital "flat-panel" detector systems that use a compact box in place of the image intensifier tube to convert the incident X-ray signal directly, essentially to an array of discrete electrical signals that are read individually and processed, displayed, and stored for further processing and review. These types of detectors are characterized as direct digital because the intensity values are generated as an array of digital values (ones and zeros) at the detector without the need for additional conversion processes that can add noise or degrade performance (102). These detectors have been made possible by improvements and cost reductions in the manufacture of flat-panel displays used in the computer industry (e.g., laptop computer monitors). Essentially, these active matrix arrays are combined with an X-ray–sensitive layer that converts the X-ray signal to light incident on an array of light-sensitive cells, anywhere from 1,000 × 1,000 to 2,000 × 2,000 cell arrays. Clinical testing of the first of these devices has begun, and these detectors are now becoming available as product options.

F. Video Components

1. Video Cameras. Along with image intensifiers, high-quality video cameras have been an assumed component of modern cardiac angiographic systems for generation of high-quality images during fluoroscopy and to provide the analog signal source for the conversion process used in all current-generation digital angiographic systems. The traditional "pickup tube" camera, based on a scanning electron beam to read off the spatially varying electrical signal produced by the light output of the image intensifier, is well understood and has been described in detail in the previous guidelines (5). Modern systems use cameras that operate in "standard" resolution mode (525 lines per video frame) as well as "high" resolution mode (1,023 or 1,049 lines) for both fluoroscopic and angiographic applications. An important characteristic that should be carefully assessed in these systems is the introduction of additional electronic noise to the image in the higher-resolution modes requiring higher bandwidth electronics. Another aspect related to the discussion of "dual-use" systems earlier relating to image intensifier performance is the fact that video systems designed for slow frame rate angiographic applications (typically at higher X-ray entrance exposures) may demonstrate degraded temporal performance (i.e., blurring) when operated at the faster acquisition rates required for cardiac imaging.

Although the pickup tube video camera has long been the workhorse of cardiac angiographic systems, a relatively recent development has been the increasing availability of video cameras based on solid-state image sensors (e.g., the CCD cameras) (103). Charged-coupled device sensors consist of an array of discrete elements (typically 1,024 × 1,024) that store the light information from the image intensifier output until they are read by the camera electronics. Among the advantages of the CCD camera are simpler design, resulting in smaller size; improved dynamic range; improved spatial resolution; absence of temporal lag; prolonged life; lower cost and simplified maintenance requirements; and lack of sensitivity to magnetic fields. (Note that the flat-panel detectors described earlier also share a number of these advantages.) The advantages listed earlier have been extensively demonstrated and, in general, CCD cameras operating at the same pixel resolution do offer better image quality than video tube cameras. It should be understood, however, that the use of CCDs in the detector chain does not itself make this a direct digital detector. In most applications, the output of the CCD camera is a time-varying analog voltage signal that must be digitized before use as with pickup tube cameras. One issue that should be considered is the increased amount of data that can be generated by the larger matrix sensors.

G. Digital Angiography Issues

Among the most significant changes in practice in the cardiac catheterization laboratory in recent years has been the consistent move away from 35-mm cine film as the standard recording medium. In many laboratories in the U.S. as well as abroad, cine film is no longer used in any function of the catheterization laboratory. This has advan-

tages that have been well documented (103,104), but there are also a number of changes in the technical requirements for a laboratory and considerations that must be made in equipment purchase and use.

H. Effects on X-Ray Requirements

For many years, the promise of digital angiographic recording has been accompanied by the promise of reductions in X-ray exposure (105). This has in turn led to confusion when this reduction has not materialized as digital angiographic systems are implemented. The image quality in cardiac catheterization specifically at the exposure per frame that is customarily found in this application is primarily a function of the contrast signal and the image noise that are found acceptable for the application. With state-of-the-art equipment, the primary source of image noise resides in the image intensifier, and this may be objectionable. The light output of image intensifiers designed for cardiac catheterization is more than enough at standard entrance exposures for both cine film and digital recording. Elimination of the cine camera does not by itself mean that more light is available for the video chain; there are already adequate amounts of light to obtain good video signals. However, the noise is directly related to the statistical properties of the relatively low X-ray beam flux incident to the image intensifier. It is true that a digital-only angiographic system allows more flexibility with the light-limiting apertures in the video chain because one is not limited by the requirements of delivering adequate light to the cine camera. But the use of such apertures as a dose-adjustment method is not routine. More practically, the elimination of cine film does allow use of reduced frame rate acquisition with the proportional reduction in X-ray exposure (19). In the end, however, X-ray exposure per frame is affected more by other factors, such as those described earlier.

I. Digital Acquisition Requirements

As discussed earlier, at the time of this writing, essentially every digital angiographic system requires a conversion from an analog signal produced by a video camera to a string of numbers stored and processed for display and analysis. The spatial, contrast, and temporal resolution requirements for cardiac catheterization are well understood and have been met for the most part with digital systems operating at matrix sizes of 512 × 512 pixels, bit depths of 8 bits (corresponding to 256 intensity values), and acquisition rates of 30 fps. With the ongoing reduction in the cost of digital hardware, it has been possible to deliver improved performance as well. Newer digital systems can record to larger image matrices (1,024 × 1,024 is common) and greater bit depths, with 10- and 12-bit images becoming available. With pickup tube cameras, higher spatial resolution is a function of the camera scanning rate along with the image intensifier magnification mode (and geometric magnification). With CCD cameras, the size of the element on the camera is necessarily fixed, but improvements in resolution are still possible through the use of higher magnification modes, which map a fixed-size element to a smaller object in the patient. Similar factors apply as well to digital detector technologies, but in that case, the resolution cannot be improved through selection of a higher magnification mode. In a field of view of 15 cm—typical for coronary angiography—a 512 matrix results in a limiting resolution of 0.20 to 0.25 mm (in the plane of the imaged object), corresponding to a resolution of 2.0 to 2.5 lp/millimeter. While this has been found in general to be adequate for coronary imaging, it is less than the theoretical resolution of cine film. Accordingly, many vendors are offering higher resolution systems. In considering these systems, however, it is important to ensure that the contrast resolution is adequate as well. For instance, if there is insufficient contrast from small objects due to other factors in the imaging chain—X-ray energy, image intensifier or video issues, or radiation scatter— the improved spatial resolution will be of limited advantage. The issue of much greater data storage requirements must be considered as well.

J. Digital Storage and Display

In most digital angiographic systems in use today, there is limited storage capacity on the system itself, usually only enough for one to several days' worth of procedures. It is therefore necessary to have a mechanism for medium- and long-term storage. The development of the DICOM standard for cardiac angiography accelerated the use of digital storage media by ensuring that there was a well-understood method for exchanging digitally recorded procedures between laboratories and systems (106,107). Many laboratories purchased the capability for storing exams on CD-ROMs and have pursued that as a long-term storage medium. Other laboratories have implemented automated storage libraries, which provide access to many months or years of procedures without the need for manual intervention for retrieval and display. The specific archival systems used by a laboratory should be selected on the basis of clinical and financial considerations (96,97).

Whatever approach is taken, every laboratory should ensure that the version of data retrieved from the archive at some later date is identical to the version used for postprocedure diagnosis and decision making. In most laboratories the digital image data are typically not reintroduced into the digital angiographic system for later review, but rather are reviewed on a separate digital image review workstation. This workstation can be supplied by either the original X-ray equipment vendor or increasingly from a variety of third-party manufacturers. The quality and cost of such workstations can vary greatly. A laboratory should ensure that review performance from media or over a network is adequate for subsequent clinical assessment. Among the factors that must be considered are display rates equivalent to the original acquisition rate, full image display resolution, image processing and enhancement, and sufficient exam

storage capacity to avoid the need for delay in retrieval of older exams. It should be noted that both the technology and cost of imaging workstations are changing rapidly, and a laboratory should anticipate future needs at the time of equipment purchase.

K. Image Formats and Standards: The DICOM Standard

The acceptance of the DICOM standard for cardiac angiography provided assurance that a version of an angiographic exam exchanged with another laboratory or reviewed at a later date could be identical to that reviewed in the laboratory during and immediately after a catheterization procedure. It is unfortunately not always the case that every vendor claiming to subscribe to the standard delivers equipment that does in fact meet the functionality stated earlier. The DICOM standard does include a conformance mechanism by which a vendor is required to list the capabilities and supported features of the product, but the standard remains relatively new, and unfortunately, a laboratory cannot rely solely on such claims. Any archiving, exchange, or review system should be carefully assessed to determine whether the exam data stored for local archiving or written to media for exchange do in fact provide the same quality of diagnostic information achieved in the original.

One factor that can ensure such equivalence is the use of a direct digital interface between the angiographic acquisition system and the archiving or review system. Due to the relatively recent introduction of the standard and the fact that there is a large installed base of equipment of varying age, this digital interface is achieved through a range of sometimes complicated approaches or, for some of the oldest equipment, cannot be achieved at all.

Newer digital angiography equipment is available with a DICOM network interface, meaning that the exam information leaving the system is already formatted according to the DICOM standard. This has two advantages: 1) data equivalence is assured and 2) any receiving system that supports this interface can be used for storage and review (i.e., a laboratory has more choices). An alternative approach typically used with older equipment is a digital interface, which requires an additional step to format exam data to the DICOM standard. This approach can work as well, but it requires that the developer of the interface, usually the manufacturer of the X-ray system, make the interface specification available to other vendors. Otherwise, only equipment from the original vendor will support the interface. Again, it should be noted that either type of interface will usually work, but it should be understood from the onset which type is being provided.

Another alternative that has also been implemented, especially with older equipment, is an analog capture interface rather than a digital interface. In this approach, the analog video signal is captured and digitized somewhere in the acquisition or display chain, and this second digital version is then formatted according to the DICOM standard and used for archiving, display, and exchange. Laboratories should be cautioned that the image data resulting from this approach is not strictly equivalent to the information available at the time of the procedure. With appropriate precautions, the quality can still be quite high, but, in many cases there is significant degradation in image quality. In the case of older equipment for which no alternative exists, this approach does provide a digital archive and exchange approach of nearly equivalent image quality, but only if the parallel image capture is performed to a specification close to that incorporated within the original X-ray vendor's analog-to-digital conversion. In some cases, irreversible data compression is also used during the capture process to save costs and improve performance, but this leads to artifacts in the stored archival copy, which degrade image quality and can affect visualization of the anatomy.

L. Digital Image Resolution

As discussed earlier, digital cardiac angiographic systems have most often incorporated digital resolutions of 512 lines by 512 columns by 8 bits per sample—usually together with acquisition rates of 30 fps. The initial basic version of the DICOM standard for digital cardiac angiography supported only this format to provide at least one format that many vendors could support. In recent years the number of cardiac angiographic systems available at higher resolutions has increased, and the issue of digital equivalence between the acquired exam information and the stored and exchanged versions has emerged. The issues include the clinical requirement for the higher resolution and whether the permanently stored copy should also be stored with the higher resolution. In general, a matrix size of 512 × 512 has been deemed acceptable for clinical applications despite the fact that this corresponds to a minimum spatial resolution on the order of 0.2 to 0.3 mm.

For some applications, such as quantitative coronary angiography of complex stenoses, higher resolution (e.g., 0.1 to 0.15 mm) is seen as optimal (100). In that case, the 1,024 × 1,024 matrix size will deliver improved resolution but at the cost of increased data acquisition, storage, and transmission requirements. Under these circumstances, the version of the exam stored locally as well as used for exchange should accommodate the higher resolution images on which the clinical diagnosis was made. The DICOM standard does accommodate these higher image matrices, but a laboratory should ensure that the equipment purchased for this application does indeed store all the acquired information and can write exchange media in the larger format (assuming that the receiving laboratory in turn has the ability to display the larger format images). Similar concerns apply to network transfer, which will require greater bandwidth capacity for the larger amounts of data or, alternatively, greater delays in transmission.

M. Data Compression

Despite the rapid improvements in digital storage and transmission technology, the data requirements of digital

cardiac angiography remain among the most demanding in medical imaging. As a result, some equipment vendors and suppliers of imaging applications have sought to reduce the amount of data through the use of mathematical techniques or compression methods (108). Some compression methods are completely reversible or lossless, and in the end the recipient or user has precisely the same equivalent data that were available initially. In contrast, irreversible or lossy compression methods reduce the amount of data, but the resulting image information is not strictly identical to the original angiographic information. The variation that can be detected visually and the effect it may have on clinical assessments made from the images depends on the type of compression method and degree of reduction. Lossy compression methods can result in much greater amounts of data reduction, but the resulting images may contain detectable artifacts that were not in the original image. The basic problem with the use of irreversible compression methods is that a user at a later time is not provided with the same information used initially; this may be acceptable in some applications, but none in which the original information is no longer available if needed. The ACC and the European Society of Cardiology have sponsored a multicenter clinical study to assess the effects of one of the more common compression methods (motion JPEG) on critical diagnostic tasks. The results of that study indicate that as the amount of compression is increased, the ability to detect clinical features is impaired. It is strongly suggested that laboratories avoid the use of lossy compression methods for the permanent storage of digital angiographic data (109).

N. Telemedicine Applications

Routine storage and availability of angiographic records in a digital format makes possible a new class of clinical applications, which fall under the general category of telemedicine—referring to the electronic transmission of clinical image data over large distances to support clinical decision making at remote sites (110). In addition to the digital format of the procedure data in the acquiring laboratory, this requires an accepted standard format for the image data that can be displayed at the receiving site as well as a reliable digital network link between the sending and receiving centers. Such Wide Area Network (WAN) applications extend, in simplest terms, the network from within a laboratory or hospital to much greater distances. The network in effect provides a user hundreds of miles away with the ability to display and review the procedure image data as if he or she were in the procedure laboratory.

In one example of this type of application, simple "store and forward" transmission of a procedure from a referring hospital to another medical center may be performed, in effect replacing the mail or courier service with electronic transfer. One advantage of this approach is that the original copy of the exam record remains in the acquiring laboratory. At the other end of the spectrum, "expert" physicians at one center can participate in and provide advisory support in real time for a procedure being performed at another center.

Although the cost of digital network transmission is being reduced and networks are being extended to more locations, the bandwidth needed to transmit cardiac catheterization examination results rapidly and completely remains costly and/or relatively rare at this time. As with many networking applications, users must choose between speed and expense. As a result, some attempts to provide telemedicine services for catheterization procedures in a less costly manner have incorporated data compression methods to reduce the size of the data files being transmitted and, in turn, reduce the time required to transmit the files. As with the issues raised in the discussion earlier, this means that the data being reviewed at the distant location may differ to a clinically relevant degree from the data used in the initial review and diagnosis. There may be applications for which this is acceptable, but laboratories and hospitals should not use such systems for an application that involves decision making solely on the basis of compressed images, which are degraded in diagnostic quality. Specifically, systems developed for routine video conferencing over standard telephone lines do not as a rule have adequate image quality for transmission of clinical image data acquired under the conditions required for cardiac angiography. Similar concerns apply to transmission over the Internet using standard networks. There are technical means available to deliver diagnostic image quality of digital angiograms in a timely fashion; laboratories considering a telemedicine application should examine the technical specifications of such systems carefully. In the near future, clarification of privacy concerns for individual patients should allow for discussions of patient cases without jeopardizing patients' confidentiality.

O. Quantitative Measurement Methods

With increasing storage and easy access to catheterization results in a digital format, the use of computerized methods to measure coronary artery stenosis severity, left ventricular function, regional wall motion, and other techniques becomes much more feasible (111,112). These methods provide objective, reproducible measures for assessment of disease and physiological function and are available for use in all laboratories rather than being limited to multicenter clinical trials. Laboratories should ensure that systems being used have been fully validated in well documented in vitro and in vivo studies and that technicians are familiar with the procedures necessary to produce measurements that are reliable, accurate, and reproducible. With the elimination of cine film and its replacement with digital images that are readily accessible, one of the greatest sources of variability is no longer an issue with the elimination of the need to convert cine film to a digital file. Consistent procedures must be followed, and it is important that the analysis be performed on the original image data acquired at the time of the procedure. As mentioned earlier, systems are available that store and exchange versions of the images that differ

significantly from the original acquired data; in general, results on such secondary capture images or, possibly, compressed images will not be as reliable.

P. Further Developments in the DICOM Standard

Just as the DICOM standard for digital images made it possible for catheterization laboratories to routinely exchange high-quality digital images, other developments are under way to enable similar standardized formats for other types of information gathered during catheterization procedures (113). An outgrowth of the DICOM effort extends the standard format to include physiological data: hemodynamic and electrocardiographic waveforms and measurement results. The primary focus of the effort was to facilitate a "unit patient record" for the catheterization procedure that includes all information necessary as a local record and for interchange between laboratories and hospitals. Although the standard is in a preliminary stage at this time, newer versions of imaging and waveform recording equipment will support the standard, and laboratories that wish to incorporate such capabilities should obtain assurance that all required equipment supports the standard. In a related development, standard formats can ensure that the results of the procedure data can be exported electronically in a format compatible with national data registries such as the ACC NCDR (114). Other developments include the integration of other imaging modalities such as intravascular ultrasound, as well as standard formats for clinical reports that can be transmitted electronically in such a manner that they can be displayed in other laboratories regardless of which vendor's equipment was used to generate the original procedure report.

IX. RADIATION SAFETY ISSUES

Two recent reviews of radiation safety in the cardiac catheterization laboratory outline in detail many of the major issues (93,115,116). The National Council on Radiation Protection and Measurement (NCRPM) provides radiation exposure guidelines for medical workers. There is no threshold below which harmful effects may not occur. The use of ALARA—"as low as reasonably achievable"—doses of radiation should always be considered. A recent membership survey performed by the Ad Hoc Committee on Women in Cardiology sponsored by the ACC indicated that concerns surrounding exposure to X-rays was a leading factor in the decision of both men and women to avoid interventional cardiology as a profession (93).

A. Terms for Understanding Radiation Exposure in the Cardiac Catheterization Laboratory

In the cardiac catheterization laboratory, ionizing radiation is produced by the interaction of X-rays and matter. The basic units of measurement are summarized below (93). The measure of exposure is the roentgen (R). The roentgen is a unit of radiation exposure defined by noting the amount of ionization per mass of air due to X-rays or gamma rays. It is described in terms of coulombs per kg (C/kg).

Table 14. Pertinent Radiation Exposure Recommendations and Concerns

Average background radiation exposure	0.1 rem/year
Average operator exposure per interventional cardiac catheterization	0.004–0.016 rem
Maximum annual recommended exposure for medical workers	5 rem/year
Maximum lifetime accumulated exposure for medical workers	1 rem × age (in years) or 50 rem
Maximum fetal exposure	0.05 rem/month or 0.5 rem total

The amount of energy absorbed per unit mass of material is defined by the rad (radiation absorbed dose). It is described in terms of gray units (Gy), in which 1 Gy = 100 rad.

The amount of energy absorbed by different materials for the same exposure can vary depending on the type of radiation and the atomic number of the material absorbing the radiation. In radiation protection this is expressed in terms of the rem. A rem is basically a rad multiplied by some quality factor. In cardiology the quality factor of X-rays and gamma rays is 1. Therefore, 1 rem = 1 rad. The units for rems are expressed in terms of sieverts (Sv). There are 100 rems in 1 Sv. Because radiation effects are often expressed in mSv; there are 10 mSv/rem.

B. Biological Risks From Radiation Exposure

The biological risks from radiation exposure depend on the amount of energy absorbed and whether there is injury to the DNA or the cell itself. A stochastic effect is an all-or-none effect that results in DNA injury. This can lead to an increased risk of cancer or other genetic effects. Stochastic effects occur with increasing frequency as the cumulative radiation exposure increases, but once the injury has occurred, a further increase in the dose for that cell does not change the injury afflicted. Nonstochastic effects, also referred to as deterministic effects, are dose dependent and result in cell death. Erythema, desquamation, cataracts, marrow suppression, organ atrophy, gonadal injury, sterility, and fibrosis are clinical expressions of this type of injury. The greater the radiation exposure, the greater the amount of injury that occurs with nonstochastic or deterministic injury.

Table 14 summarizes current recommendations and concerns. The average background exposure that may be expected is about 0.1 rem/year. During an average interventional cardiac catheterization procedure, the physician operator receives about 0.004 to 0.016 rem of exposure (117–120). In 1 review, the operating physicians in the cardiac catheterization laboratory received from 0.2 to 6.0 rems/year, the nurses received from 0.8 to 1.6 rem/year and

the technologists about 0.2 rem/year, as documented by collar and waist badges (120). Ancillary personnel in the cardiac catheterization laboratory thus receive about 10% to 30% of the dose received by the primary operator. The maximum allowable occupational exposure from all sources for medical workers is 5 rems/year for the whole body. Over a total career, no one should receive a cumulative exposure >1 rem × age (or 50 rems) (93).

The cancer risk from radiation exposure is a stochastic effect and appears to be related to the lifetime cumulative dosage received. The risk of fatal cancer increases by about 0.04% × rem of lifetime exposure (121). The estimated risk of fatal cancer in the U.S. is about 20% (122). If a busy interventional cardiologist receives about 3 rems/year and practices for 25 years, the total dose received would be 75 rems. This would translate into an added risk of fatal cancer of 75 × 0.04% or 3%, resulting in a total projected overall lifetime risk of 23% for development of a fatal cancer.

Radiation exposure of the fetus in the pregnant worker is a special case that deserves comment. It is permissible for a pregnant worker to make a decision as to whether to continue working in the cardiac catheterization laboratory during her pregnancy. There must be no repercussions whether or not a pregnant worker chooses to work in the laboratory itself (93). Appropriate protection and monitoring must be provided. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) estimates that the risk of a congenital malformation or of developing a malignancy after in utero exposure of 1 rem is about 0.2% (123). Fetal exposure to high doses of radiation between weeks 8 and 15 may also result in mental retardation, as determined from Japanese survivors of the atomic bomb. The risk of mental retardation in this instance is about 0.4%/rem of exposure (121). On the basis of these data, it is recommended that fetal exposure to radiation, as monitored by a waist dosimeter worn under the outer lead apron, should be no more than 0.5 rem for the entire pregnancy or <0.05 rem/month (93). This can be accomplished through careful attention to radiation dose exposure.

The greatest concern about the nonstochastic effect of long-term occupational exposure is the formation of cataracts. The risk is small, but cataracts have been associated with single doses in the range of 200 rads (124). Cumulative doses of up to 750 rads have also been reported, with no evidence for cataracts (124). Cataracts usually form after a latent period of several years. The recommended maximum exposure to the eye lens is 15 rems/year. Eye protection is therefore warranted. Leaded eyeglasses help reduce the exposure risk.

C. Measuring Radiation Exposure

Radiation exposure is commonly measured by one of two methods, either a film badge or a transluminescent dosimeter (TLD) badge. The film badge basically contains a piece of X-ray film. The magnitude of exposure to X-rays is derived based on the density of the exposed photographic film within the badge compared with densities from film that has had known amounts of exposure. The TLD badge contains a disk with lithium fluoride crystals. The lithium fluoride crystal absorbs the X-rays, raising the electrons to a higher state. When heated, the electrons in the crystal return to their baseline state, releasing light in proportion to the X-ray exposure.

Proper measurement of radiation exposure requires the dosimeter badge to be worn with the front of the badge in the direct line of the scattered X-rays. If a single badge is worn, it is usually placed on the thyroid collar. It is recommended, however, that two badges be worn during all cardiac catheterizations, with the second badge placed under the protective lead at the waist (93). Cardiac angiographers receive the highest exposure on the hands, but these are not usually monitored because of sterility issues with wearing a ring badge. When a ring badge is worn, it should be placed with the label (the TLD chip) palm side down (93).

D. Minimizing Occupational Exposure

The three tenets for reducing occupational exposure to radiation are time, distance, and barriers. X-ray scatter is also reduced by minimizing the number of magnified views, using digital-only cine acquisition, keeping the image intensifier as close to the patient as possible, and selecting the highest kVp that will provide acceptable image contrast. Obviously, reducing the time of exposure results in a reduction in overall radiation exposure. Scatter exposure is reduced by using lower framing rates and pulsed fluoroscopy and by minimizing both fluoroscopic and cine time. Although fluoroscopic radiation may result in 1/10 or so of the exposure per sec compared to cine, the far greater duration of fluoroscopic use during procedures in the cardiac catheterization laboratory can result in a 6-fold greater radiation exposure from fluoroscopy than from cine for many interventional procedures (125). The radiation beam attenuates based on the inverse square law ($1/d^2$), and distance becomes an important means of reducing operator radiation exposure from scatter radiation. Most X-ray scatter occurs at the entry surface of the patient. The nearer the operator is to the X-ray tube (not image intensifier), the greater the X-ray exposure. For instance, in the cranial LAO view, where the operator is closest to the X-ray tube and the bottom of the table, the operator exposure may be 2.6 to 6.1 times that observed in the caudal RAO view, where the X-ray tube is on the other side of the table (125). Finally, barriers are important. Proper collimation of the X-ray beam and copper filters helps reduce exposure from the source. Shielding such as side table drapes, properly positioned door- or ceiling-mounted acrylic shields, lead aprons, thyroid collars, and protective eyeglasses are all important in limiting occupational radiation exposure.

E. Minimizing Radiation Exposure to the Patient

Radiation to the patient can be minimized by some simple rules. Some of the same concepts apply here as noted

earlier for reducing exposure to the medical worker. Because the patient is directly in the X-ray beam, the patient benefits primarily from measures that reduce X-ray dose. These include collimation of the X-ray beam, use of pulsed fluoroscopy, copper filters, digital-only cine acquisition, limiting magnified views, reduction of fluoroscopy and cine times and framing rates, keeping the source-to-image distances as narrow as possible, using the highest kVP acceptable to maintain the lowest mA possible, and direct shielding of sensitive areas, such as the gonadal regions.

F. Quality Management

Quality management in the catheterization laboratory must include: 1) an effective and ongoing educational program in the diagnostic use of X-rays, 2) accurate monitoring and timely reporting of personnel exposure, and 3) modification of procedural conduct in those cases where exposure levels are of concern. These issues are addressed earlier in this document (see QA Issues in the Cardiac Catheterization Laboratory).

X. SPECIAL CONCERNS FOR THE PEDIATRIC CARDIAC CATHETERIZATION LABORATORY

The Pediatric Cardiac Catheterization Laboratory (PCCL) presents several challenges and differences not faced by the adult invasive cardiovascular specialist. The following is a general overview of these issues.

A. Differences in Goals

The PCCL should function as an element within a pediatric cardiovascular center or program. The overall goal of such a center or program should be to provide both comprehensive diagnostic services and a full range of treatments, interventions, and surgeries needed to provide high-quality pediatric cardiovascular care. Within the center or programmatic context, the goal of a PCCL is to perform a range of cardiac catheterizations in children with congenital or acquired heart disease and in adults with congenital heart disease. Unlike in adult cardiology, the usual case is that the heart internal structure is abnormal. Diagnostic catheterization may include quantitation of cardiac index, and calculations of left-to-right and right-to-left shunts and pulmonary vascular resistance are more often required. Right- and left-heart catheterization is the norm rather than the exception. Measurement of cardiac index by thermodilution is possible when there are no shunts, but measurement or assumption of oxygen consumption for Fick shunt determinations is more commonly performed. Because of periods of rapid growth in infancy and childhood and the need for comparison of data across sizes of patients or over time in the same person, output and resistance values are indexed or corrected for body surface area in pediatric cardiology. Furthermore, pediatric angiographic studies have goals that include defining and displaying intracardiac anatomy in a projection-type medium to complement the planar media of echocardiography and magnetic resonance or computerized tomographic imaging. A wide variety of congenital and acquired defects are investigated in the PCCL.

Pediatric interventional procedures are a primary or secondary objective in approximately half of all PCCL catheterizations. A wide range of unique interventional procedures is now possible. These procedures include balloon atrial septostomy, blade or balloon dilation atrial septostomy, valve and vessel dilation, stent implantation, patent ductus arteriosus and other vascular closure, endomyocardial biopsy, foreign-body retrieval, and the full range of electrophysiological procedures. Special expertise in pediatric patients is gained in these procedures during pediatric cardiology fellowship training and in pediatric cardiology postfellowship training in the interventional cardiac catheterization laboratory (often during an additional training year). PCCLs that routinely perform pediatric transcatheter interventional procedures should exist only in clinical environments where pediatric intensive care and pediatric cardiovascular surgery are available.

Sedation is an important function in the PCCL, where patients cannot be calmed or reassured without medication or even assumed to be able to remain on the procedure "bed." The pediatric cardiologist assumes responsibility for the safe conscious sedation of the patient, and the importance of monitoring is no different from that described earlier for adults receiving sedation.

B. Who Should Perform Catheterization in Adult Congenital Heart Disease?

Pediatric cardiac catheterization laboratories, 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 fall under the director's guidance.

Other than the PCCL director, 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 should be granted is left to the discretion of the individuals involved and the hospital credentialing process.

Although it is recognized that the definition of the "pediatric" age range is somewhat variable, it usually encompasses the period from birth through 18 (or 21) years of age.

It is recommended that for patients under the age of 18 years who require cardiac catheterization for congenital cardiac problems, the procedure should be performed by a pediatric cardiologist. 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 (with one or both scrubbed), or 3) by an adult cardiologist with an established special interest and expertise in adult congenital heart disease. Adult cardiologists with little experience in congenital heart disease should not perform cardiac catheterization in patients with congenital cardiac problems.

C. QA Issues

Representative complication rates for pediatric cardiac catheterizations are available from a number of reviews. A recent study of complications in 4,952 consecutive pediatric catheterization procedures found an overall complication rate of 8.8%, with a major complication rate of 2.06% and a death rate of 0.14% (126). A higher risk for complications was present in patients who were younger and in those undergoing interventional procedures. Fellows et al (127), noted that the rate of complications for therapeutic catheter procedures depended primarily on the type of intervention. In that study, the rate of complications for aortic valve stenosis dilation was 10 times that for recurrent coarctation treatment. The Valvuloplasty and Angioplasty in Congenital Anomalies (VACA) study group (128) reinforced this finding in 1990 in its series of articles concerning various types of interventional catheterizations. These complication rates might be expected to improve because of advances in catheter technology and techniques. However, the increasing percentage of interventional cases and postoperative catheterizations in smaller and smaller children may hold the complication rates at current levels. A center's catheterization-related mortality should be $<1\%$, and death should be extremely rare outside of neonatal and high-risk interventional cases. In addition, major complications (potentially life-threatening events) should occur in $<2\%$ of cases (126). In radiofrequency ablation procedures, the incidence of permanent complete atrioventricular block should be $\leq 2\%$ (129).

Informed consent in the PCCL 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.

D. 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. In general, patients and their parents may have to travel farther for treatment at a PCCL than at an adult catheterization laboratory. The patient may also be farther from appropriate medical attention after returning home. Despite the smaller size of the patient, the sheath sizes used in pediatrics may be nearly the same size (5F to 8F) 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 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.

E. Operator and Laboratory Volume

If a PCCL routinely performs <75 cardiac catheterizations/year, consideration should be given to whether the volume justifies the program. Although the Committee recognizes that access to services is important, there is also the valid impression that a minimum experience is required for the cardiologist and staff to maintain proficiency. In the previous ACC/AHA guidelines (5), the pediatric caseload for an individual was estimated at 50 to 100 cases/year. In the 1991 American Academy of Pediatrics guidelines (130), it is recommended that a minimum of 1 to 2 catheterizations be performed/week to maintain skills. Thus, for a single cardiologist, the minimum number of cases is still thought to be 50/year. Because, as noted, the level of skill and expertise required and the complication rates experienced are related to the type of intervention, credentialing for therapeutic cardiac catheterization should be procedure specific (131).

A number of considerations must be taken into account when a decision is made regarding the minimum number of cardiac catheterizations that should be performed by a pediatric cardiologist or a PCCL. Importantly, 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.

QA plans must be in effect in all PCCLs to monitor outcomes of cardiac catheterization. There are some similarities and differences between the strategy 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 the published complication 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 of a ductus arteriosus or 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.

F. Procedural Issues

1. Premedication. The choice, dose, timing, route, and overall use of premedication varies widely with age, size, and condition of patient and the experience and training of the operator. There is no "standard" premedication. Chloral hydrate, diphenhydramine (Benadryl®), and diazepam (Valium®) are frequently given orally for sedation. Intravenously, midazolam (Versed®), morphine, fentanyl, hydromorphone (Dilaudid®), and other medicines can be used to 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 (Phenergan®) is sometimes used intravenously or by the intramuscular route for analgesia and sedation. Chlorpromazine (Thorazine®) is used less often than previously, because of the availability of and experience with other medicines.

2. Vascular Access Issues. Techniques for venous and arterial access are similar for children and adults. In young children with congenital heart disease, however, much (or all) of the catheterization can often be done from the venous approach. Therefore, there is a greater opportunity for placement of a small cannula in the artery at the beginning of a procedure (rather than the larger sheath). This allows monitoring of blood pressure and sampling of blood gases without the arterial trauma that might be caused by the sheath. If and when the need for retrograde heart catheterization arises, the area around the artery may then be re-anesthetized and the small cannula changed for the appropriate-sized arterial sheath. The transseptal procedure is frequently used for access to the left atrium. Properly performed, this approach does not add significantly to the incidence of complications. It is an important technique for radiofrequency ablation, mitral valve stenosis investigation and valve dilation, prosthetic aortic or mitral valve assessment, and many other catheterization functions. 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, or even basilic approaches is frequent. More recently, the transhepatic approach has been used very successfully for both diagnostic and interventional procedures.

The use of heparin in the flush solutions is routine, but the additional use of bolus-dose heparin depends on the patient's ACT, procedure type, and vascular approach. It would be usual, for example, not to use bolus heparin for a right-heart catheterization or the prograde right and left-heart catheterization, but heparin would be used in aortic valve dilation. 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 described earlier for adults. Mechanical plugs or compression devices are rarely used in the PCCL because of the small vessel size. Hemostasis is almost always achievable by direct manual pressure followed by placement of an adhesive or elastic tape over a gauze pad on the access site.

3. Medications Used During the Procedure and Use of Anesthesia. 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. It may be useful to consider turning a continuous infusion down or off after the last angiogram or pressure measurement to allow the sedation to begin wearing off as hemostasis is achieved. Systemic arterial oxygen saturation should be continuously monitored by pulse oximetry.

General anesthesia is performed by an anesthesiologist or

trained nurse anesthetist under the supervision of the anesthesiologist. Possible indications for anesthesia consultation 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 radiofrequency ablation or those that require transesophageal echocardiography may be greatly facilitated with general anesthesia. Certain interventional procedures such as aortic or mitral valve dilation, atrial septal defect occlusion, and others may be made significantly easier, safer, and more effective by collaboration with anesthesiologists. Surgical procedures such as pacemaker placement or lead extraction are usually done with the patient under anesthesia. The use of anesthesia is a judgment made by the attending cardiologist in consultation with the anesthesiologist, just as it is in surgery. Wide discretion is allowed and encouraged.

4. Procedural Performance Differences Compared With the Adult Cardiac Catheterization Laboratory.

a. 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 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 atrial septal defect occlusion, and others. Atrial septal defect occlusion is often performed with localization and positioning of the device using transesophageal 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.

b. HEMODYNAMICS. As noted, right- and left-heart catheterization are performed in combination in many pediatric and congenital heart catheterization procedures. In addition to the left ventricular 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 pulmonary arteries 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, a left ventricular pressure may not be obtained at all, whereas a right ventricular systolic and diastolic pressure recording is mandatory. On the other hand, pulmonary artery pressure, routinely obtained in a right-heart catheterization, may be difficult to obtain or even ill advised in a patient whose pulmonary arteries might have to be entered via a tenuous surgically created shunt. 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 gases is essential for interpretation of shunt physiology and patient safety.

c. ANGIOGRAPHIC ACQUISITION DIFFERENCES. Angiograms are routinely performed with framing rates ranging from 15 to 60 fps. The framing rate depends on the patient's heart rate and the types of images to be acquired. For example, during balloon dilation, angiographic images may be acquired at 15 (or even 7.5) fps, whereas a ventriculogram in an infant with a high heart rate may require imaging at 30 or 60 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 s, 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 on some type of "instant replay" digital playback high-speed disk. Short- and long-term archival of digital data or cineangiograms does not differ from that described in prior sections.

d. RADIATION PROTECTION AND THE PREGNANT (OR POTENTIALLY PREGNANT) PATIENT. 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 testing to ensure that they are not pregnant before having a cardiac catheterization. This might be based on history in some cases (such as 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 human chorionic gonadotropin level.

If a pregnant patient must be studied, the abdominal and groin areas should be shielded to help reduce any direct X-ray exposure. As noted in the section on radiation exposure, though, scattered X-rays will still occur and could be harmful to a newly developing fetus. Efforts to minimize exposure should include using fluoroscopy 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 views when possible.

e. 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 pulmonary artery 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. Measurement of oxygen consumption should also be available.

f. LABORATORY PERSONNEL ISSUES. The laboratory staff in the PCCL should be specifically trained and experienced in the care of infants and children during performance of a cardiac catheterization. The specific responsibilities within the laboratory may necessitate the services of a registered nurse, a licensed practical or vocational nurse, a radiography technician, a certified catheterization technician, or others. It is the responsibility of the director and supervisor of the Pediatric Cardiac Catheterization Laboratory to ensure adequate staffing. On-call cases must be considered, and a complement of personnel adequate for the safe, efficient, and informative conduct of emergent or urgent pediatric catheterizations must be available at all times.

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