

ORIGINAL STUDY

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

American College of Cardiology Foundation Task Force on
Expert Consensus Documents Society of Thoracic
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PREAMBLE

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

The ACCF Task Force on Clinical Expert Consensus Documents (TF CECD) makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as *relevant* to the writing effort. This information is documented in a table, reviewed by the parent task force before final writing committee selections are made, reviewed by the writing committee in conjunction with each conference call and/or meeting of the group, updated as changes occur throughout the document development process, and ultimately published as an appendix to the document. External peer reviewers of the document are asked to provide this information as well. The disclosure tables for writing committee members

and peer reviewers are listed in Appendices 1 and 2, respectively, of this document. Additionally, in the spirit of complete transparency, writing committee members' *comprehensive disclosure information*—including relationships with industry and other entities that do not pertain to this document—is available online. Disclosure information for members of the ACCF TF CECD—as the oversight group for this document development process—is also available online.

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EXECUTIVE SUMMARY

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

THE CARDIAC CATHETERIZATION LABORATORY ENVIRONMENTS

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

CARDIAC CATHETERIZATION AT A HOSPITAL WITH CARDIOVASCULAR SURGERY

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

CARDIAC CATHETERIZATION AT A FACILITY WITHOUT CARDIOVASCULAR SURGERY

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

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

Certain *therapeutic procedures* should still be done only in facilities with cardiovascular surgical backup. These include therapeutic procedures in adult congenital heart disease and pediatrics. It is generally believed that elective and primary PCI are permissible in sites without cardiovascular surgery, if there is strict adher-

ence to national guidelines. In particular, there must be a documented working relationship with a larger facility with cardiovascular surgical services and an emergency transportation system operative. The document outlines the current guidelines where this is acceptable. The committee also believes that it is the responsibility of any facility performing coronary intervention without cardiovascular surgical backup to document that all national risk stratification and medication guidelines are being followed. In addition, a QA/QI system must be operative and active, and, if an ST-elevation myocardial infarction (STEMI) program is in place, the laboratory should be operational 24 hours a day, 7 days a week. Any national volume guidelines must also be strictly followed.

QUALITY ASSURANCE ISSUES IN THE CARDIAC CATHETERIZATION LABORATORY

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

PATIENT OUTCOMES

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

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

At least 60% of PCI procedures are done ad hoc following lesion discovery on a diagnostic angiogram. Although there is no evidence this practice has an adverse effect on outcomes, ad hoc procedures should be discouraged when the patient would benefit from a

multidisciplinary discussion regarding options for therapy or when an interventional procedure at a later time would reduce the risk of contrast nephropathy. In the acute STEMI setting, when multivessel disease is evident, only the culprit lesion should undergo emergency intervention.

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

PEER REVIEW CONTINUOUS QA/QI PROGRAMS

Most major QA problems are unrelated to equipment but are due to operational factors. These tend to include inadequate laboratory space, lack of a physician director or advocate, lack of specific operating rules, and a poor feedback mechanism. More than ever, a continuous QA/QI program must be considered an essential component of the cardiac catheterization laboratory. It should be dedicated to the lab but not be independent of the other hospital programs. It must be adequately staffed and appropriately funded. The basic components must include a committee with a chair and staff coordinator, a database, and a means of data collection. There should be goals to eliminate outliers, reduce variation, and enhance performance. Feedback mechanisms should be clearly in place. The committee should also be committed to educational opportunities for the staff and incorporating practice standards and guidelines into the laboratory operation. Some composite “scorecard” methods should be included that address cognitive knowledge, procedural skill, clinical judgment, and procedural outcomes. These data need to be collected in a systematic manner and analyzed appropriately. Often a simple comparison of outcomes among physicians in the laboratory is effective in modifying behavior.

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

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

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

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

MINIMUM CASELOAD VOLUMES

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

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

minimum of 12 CME hours per year. Stimulation training may assist in improving skills.

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

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

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

The guidelines for the performance of both elective and primary PCI in a facility without cardiovascular surgical backup are also evolving. Recent prospective studies and meta-analyses of available data both suggest these procedures can be done safely under restrictions. The minimum volume issue in this setting will be another focus of the ACCF/AHA/SCAI Writing Committee to Update the 2007 Clinical Competence Statement on Cardiac Interventional Procedures. Because these patients are at highest risk for complications, national guidelines for the proper PCI, particularly in the setting of an AMI, must be strictly followed. The facility must have a robust QA program, clear and documented systems for the urgent transfer of patients to a facility with cardiovascular surgical support,

documentation that all medication and indication guidelines are being observed, and 24/7 availability.

TRAINING IN INTERVENTIONAL PROCEDURES

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

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

PROCEDURAL ISSUES IN THE CARDIAC CATHETERIZATION LABORATORY

Patient Preparation

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

0.009w?>Patient preparation should include a checklist of items to be reviewed when the patient first arrives at the laboratory. Appropriate consent should include risks, benefits, alternative therapies, and the potential need for ad hoc procedures. All PCI consent forms should outline the potential for emergency surgery. A “time-out” should be a required part of each procedure and should include the name, the procedure, the signed consent, allergies, antibiotic administration, the correct site, confirmation of the pre-wash, the need

for any special equipment or imaging, and any pertinent clinical factors (including labs such as the creatinine level). If the radial artery is to be used, the Allen test results should be noted.

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

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

For patients with chronic kidney disease (CKD), there is a risk of contrast nephropathy following the procedure. The highest-risk patients are those with eGFR < 60 mL/min and diabetes mellitus. It is recommended that patients with CKD have nephrotoxic drugs, such as nonsteroidal anti-inflammatory drugs (NSAIDs), held on the day of the procedure and that adequate hydration with either intravenous (IV) saline or sodium bicarbonate at 1.0 mL/kg/min to 1.5 mL/kg/min for 3 to 12 hours prior and 6 to 12 hours post-procedure should be completed as well. Contrast media should be minimized, and either low-osmolar or iso-osmolar contrast should be used. A contrast volume/creatinine clearance ratio of > 3.7 has been suggested as a ceiling for contrast use to reduce nephrotoxicity risk. A follow-up creatinine level should be

obtained in 48 hours. Acetylcysteine is no longer recommended.

Patients with a strong atopic history or prior contrast allergy should be considered for pre-medication with steroids and/or H1 and H2 blockers. Shellfish allergies are not considered important for contrast reactions. Diabetic patients usually have the insulin dose reduced by half the night prior and then held the morning of the procedure. Diabetic patients should have procedures early in the schedule, if possible, to avoid hypoglycemia. Metformin should be held regardless of the creatinine clearance and not restarted until there is postprocedural documentation that the creatinine has returned to baseline. An awareness of the treatment of anaphylactoid reactions to contrast is important. Delayed hypersensitivity rashes should not be confused with reactions to new drugs initiated after the procedure.

PROCEDURAL ISSUES

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

TECHNICAL AND HEMODYNAMIC ISSUES

Except for the equipment advances, the actual performance of coronary angiography has changed little over the last decade. Facilities with biplane capabilities are less common now. Biplane coronary angiography may reduce total contrast load in patient with CKD and is important in structural heart intervention. Hemodynamics are less stressed in most laboratories despite accurate hemodynamic measurements being critical in certain disease states (such as constrictive pericarditis). Intracoronary hemodynamics have most recently focused on the use of the pressure wire. The cardiac catheterization procedure can provide information regarding ventricular performance, cardiac output, vascular resistance, and shunt magnitude. The hemodynamics before and after pulmonary vasodilators are also critical to the decision algorithm on therapy for patients with pulmonary hypertension. Vasodilator or inotropic stress testing in patients with low-gradient, low-valve area aortic stenosis, likewise, provides vital information on the best therapeutic option in these patients. Transseptal catheterization has had resurgence with the success of such procedures as balloon mitral valvuloplasty and atrial fibrillation ablation. Entry into

the left atrium (LA) provides percutaneous therapeutic options for pulmonary vein stenosis and, for some cases, with mitral regurgitation. Myocardial biopsies are useful in restrictive heart disease and in heart transplant patients. Within the hybrid laboratory environment, LV puncture allows for percutaneous aortic valve replacement via an apical approach. Intracardiac ultrasound and Doppler imaging methods have proven their value in a number of situations, including atrial septal visualization during percutaneous patent foramen ovale (PFO) or atrial septal defect (ASD) closure, left-sided electrophysiological ablation studies, mitral valvuloplasty, and LA appendage occluder deployment.

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

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

POSTPROCEDURAL ISSUES

Vascular Hemostasis

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

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

The use of vascular occlusion devices has grown rapidly despite evidence their application does not reduce overall vascular complications. An AHA Scien-

tific Statement regarding these devices recommends a femoral arteriogram with identification of sheath site and vascular features be done before their use. The use of any vascular device is considered a Class IIa (Level of Evidence: B) indication.

MEDICATION USE

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

PERSONNEL ISSUES

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

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

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

safety and compliance with all regulations and possess strong management skills as well.

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

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

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

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

THE HYBRID CARDIAC CATHETERIZATION LABORATORY

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

removal, and certain emergency procedures such as ECMO insertion or emergent thoracotomy.

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

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

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

ETHICAL CONCERNS

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

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

X-RAY IMAGING AND RADIATION SAFETY

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

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

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

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

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

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

of these data should be incorporated in the patient record and part of the QA/QI process.

SPECIAL CONCERNS FOR THE PEDIATRIC CATHETERIZATION LABORATORY

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

DIFFERENCES IN GOALS BETWEEN THE PEDIATRIC LABORATORY AND THE ADULT LABORATORY

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

WHO SHOULD PERFORM PEDIATRIC CATHETERIZATIONS?

All pediatric catheterizations should have a director responsible for all aspects of the laboratory operation, similar to the adult laboratory. Attending physicians should be board-certified in pediatrics and at least board eligible in pediatric cardiology. There may be exceptional cases where a competent operator can be

granted privileges, but this should not be common practice.

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

QUALITY ASSURANCE ISSUES IN THE PEDIATRIC CARDIAC CATHETERIZATION LABORATORY

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

INPATIENT VERSUS OUTPATIENT SETTINGS FOR PROCEDURES

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

OPERATOR AND LABORATORY VOLUMES

Similar to the discussion regarding adult laboratories, the heterogeneity of the patient population and the low volume of procedures make specific minimum volumes problematic. The American Academy of Pediatrics Guidelines suggests the use of specific outcome benchmarks rather than minimum operator or

laboratory volumes as a guide to competence. The committee consensus, however, suggests a minimum operator volume of 50 per year and a minimum laboratory volume of >100 per year seems reasonable.

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

PROCEDURAL DIFFERENCES COMPARED WITH THE ADULT CARDIAC CATHETERIZATION LABORATORY

The need for specific baseline laboratory data greatly differs in the pediatric catheterization laboratory. Many patients do not have noncardiac disease and are not on any medications. There is no standard laboratory data required before the procedure, and no standard pre-medication regimen. Sedation is almost always required to perform the procedure. Vascular access is also individualized depending on whether the patient is a neonate, young or older child, or is of adult size. Most procedures are performed via the femoral artery and vein. Transseptal procedures are common. Newborn procedures are performed generally via the umbilical vein. Venous access can also be accomplished via the internal jugular, subclavian, basilica, and transhepatic approaches. In very young children, balloon aortic valvuloplasty or stenting open the patent ducts may require a carotid artery cut-down. Heparin is variably used during the procedure, whereas vascular occluders are not used in children. As more invasive percutaneous methods are being developed, the potential for catastrophic events increases. There should be access to ECMO in addition to routine resuscitation equipment.

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

HEMODYNAMICS AND ANGIOGRAPHY

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

LABORATORY PERSONNEL

There is essentially no difference in the types of personnel needed to run an efficient pediatric catheteriza-

tion laboratory dedicated to the highest standards compared with an adult laboratory.

RADIATION PROTECTION AND PREGNANT PATIENTS

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

SUMMARY

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

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

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

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

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

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

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(Continued)

**Appendix 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2012 ACCF/SCAI
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†Significant relationship.