Standards for a Cardiac Catheterization Laboratory

A Guide for Cardiologists and for Institutions Sponsoring Cardiac Catheterization Laboratories

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The purpose of this report is to propose cardiac catheterization laboratory standards necessary for currently acceptable diagnostic and therapeutic procedures.

Standards include these three categories: 1.) personnel, 2.) equipment, and 3.) case load. While the performance record (diagnostic accuracy and complication index) of a laboratory must be considered, this is an area in which standards cannot easily be defined.

The aims of the Committee in recommending these standards are: 1.) to assure patient and personnel safety in performing the cardiac catheterization, 2.) to promote maximal diagnostic accuracy, 3.) to obviate unnecessary procedures, and 4.) to minimize the need for repetition of procedures.

This laboratory—which should be used jointly by internal medical and pediatric cardiology services—should be located within a center completely equipped to take care of all aspects of the medical and surgical care of the patient as defined by the AHA “Standards for Cardiac Diagnostic and Treatment Centers.”

Personnel

1. Physician in Charge

The physician-in-charge of the procedure should be board-certified, either by the
Subspecialty Board of Pediatric Cardiology of the American Board of Pediatrics or the Subspecialty Board of Cardiological Disease of the American Board of Internal Medicine, or, lacking such certification, should have equivalent competence and professional standing in the specialty. These qualifications enable him not only to carry out the technical aspects of the procedures, but also to select patients requiring study, and to correlate the results of the study with clinical information in reaching sound anatomic and hemodynamic conclusions. He must be aware of both common and rare types of heart disease peculiar to the age group under consideration. He must also be aware of other organ system diseases which resemble heart disease or which may secondarily involve the cardiovascular system. He must have a familiarity with the potential complications of the catheterization procedures and with the prevention and management of these complications. It is strongly recommended that infants and children be studied in laboratories supervised by professional personnel skilled in pediatric cardiology, and that adults be studied in laboratories supervised by professional personnel skilled in the cardiac problems of this age group.

2. Associate Physician

A second physician should be available in the laboratory or at least close by, in the event that additional help is needed, or in case a complication develops. The presence of two physicians assures a greater chance of successful management of minor as well as major complications.

3. Consulting Physicians

In addition to the two physicians listed, an anesthesiologist and a surgeon—each with advanced training in the cardiovascular aspects of their specialty—should be immediately available within the center for consultation, assistance, and emergency surgical procedures. In many laboratories a radiologist with special cardiovascular training is in the laboratory for each procedure and makes a unique and important contribution to the total catheterization procedure by consulting in the planning and interpretation of angiocardiographic studies.

4. Nurse

Many laboratories will find that a nurse functioning as a full-time member of the team is desirable or even essential to their needs in the observation of the patient, administration of drugs, etc., while in other laboratories the functions of the nurse are carried out by both the physicians and the technicians.

5. Cardiac Catheterization Technician

The catheterization laboratory technician assists with procedures such as withdrawal and analysis of blood samples, performance of dye dilution curves, maintenance and sterilization of equipment and supplies, and handling and storage of radioactive materials or explosive gases.

6. Recording Technician

This technician operates the recorder, monitors physiologic variables displayed on the oscilloscope, reporting significant changes to the cardiologist, and preferably has no other responsibilities during the procedures. He is therefore a separate individual from the catheterization laboratory technician defined under 5.

7. Electronics Technician

A highly-trained technician should be available for consultation regarding operation and maintenance of all physiologic measuring and recording instruments in the laboratory. He must be immediately available to carry out repairs in the event of equipment failure during the course of the procedures.

8. X-Ray Technician

An x-ray technician should be available to the laboratory. Some facilities have found it desirable to have an x-ray technician functioning as part of the cardiovascular technician team. In either case this technician would be supervised by the cardiovascular radiologist to assure the attainment of high-quality films during the catheterization procedure.
Equipment

1. Recording Apparatus for Physiological Events
   A minimum of four channels for recording physiological events is recommended. An oscilloscope with multiple channels should be available for displaying the electrocardiogram and pressures in full view of physicians and laboratory personnel.

2. Image Intensifier
   The intensifier permits adequate visualization of the catheter, allows sufficient light for observation of the patient at all times, and reduces radiation exposure. It is ideal to have at least one television monitor to aid in teaching and to permit the assistant physician, as well as the operator, to monitor the course of the catheter.

3. Analyzer for Blood Oxygen Saturation
   Laboratories must have an oxygen analyzing technique which is periodically checked for accuracy by some standard such as the Van Slyke determination. The results of oxygen determinations should be immediately available while the catheter is still in place. In laboratories in which infants and children are being studied, an oxygen analyzer should be available which permits measurement with small amounts of blood. The laboratory should be equipped with sensitive means of detection of left-to-right shunts (such as, a hydrogen electrode), and for identifying the site of right-to-left shunts (such as, indicator dilution techniques). For this age group, an apparatus for determination of blood gases and pH is essential. The laboratory should also have the means of determining oxygen consumption for the calculation of cardiac output by the Fick principle in older children and adults.

4. Contrast Angiocardiography
   Equipment should be available which permits selective rapid injection of controlled amounts of contrast material. For the study of complex forms of heart disease, especially congenital heart defects, it is recommended that simultaneous biplane filming be utilized. This may be accomplished with serigraphy (roll film—cut film) methods or motion picture (cine) techniques. Ideally, both modes of filming could be available in the same laboratory. A video tape recorder with facilities for rapid playback of the cineangiogram offers patient safety, since information is immediately available. In laboratories planning to do cine coronary arteriography, there should be an x-ray table equipped with a rotating cradle.

5. Generators, Controls and Tubes
   There should be a separate generator for each plane, each having a 1,000 mA capacity at 150 Kv. The controls for each should be independently variable to allow for selection of optimal technical factors through a wide range of tissue density and thickness. For direct biplane filming a minimum capacity of five exposures per second is needed to record details of anatomic change in infants with tachycardia. For cine filming in such infants 60 frames per second are necessary. To meet these demands heavy duty x-ray tubes with high heat storage capacity, high-speed rotating anodes with small focal spots are mandatory. For cine filming an effective focal spot should be less than 1.0mm². In addition, cine exposures should be pulsed in a low millisecond range.

6. Film Processors
   There should be an automatic cine film processor and a serigraphic film developer in the catheterization laboratory area (or within easy access).

7. Resuscitation Equipment
   Resuscitation equipment and supplies are to be available at all times for immediate use in the laboratory. The equipment must be periodically checked for reliable performance.
   
   A. D.C. defibrillator and cardioverter.
   B. Bag-valve-mask type manually operated ventilation device.
   C. Endotracheal intubation equipment appropriate for all age groups.
   D. Facilities for oxygen administration.
   E. Appropriate suction device.
   F. Emergency drugs necessary for immediate administration.
G. Facilities for insertion of transvenous pacemaker for temporary pacing.

8. Body Temperature Monitoring Device and Warming Pad
   Or some means for maintaining an infant's body temperature.

   Electrical Safety
   The hazard of electrical shock to patients must, of course, be considered in any facility in which electrical equipment is used. This is particularly important during the course of cardiac catheterization, since electrical currents transmitted through the cardiac catheter directly to the heart induce ventricular fibrillation at a lower level than if applied to the skin surface. In the cardiac catheterization laboratory, provision must be made for common electrical ground bonding for both fixed and portable equipment. The bonding must be sized to maintain a difference of potential during normal operation of less than 5 millivolts R.M.S. between any two items of electrical equipment within the room.

   After the initial installation is complete, and after any future electrical modifications or additions, the installation must be checked to assure that these bonding standards have been maintained. All portable equipment must be bonded through the power cord to meet these same standards, and checked on a documented maintenance schedule.

   Radiation Protection for Patient and Personnel
   Recommendations of the National Council of Radiation Protection and Measurements should be followed.

   For adequate protection of the patient, the following are required:
   1. Filtering of x-ray beam with aluminum.
   2. Proper collimation of the x-ray beam for the field in use.
   3. Fluoroscopic timer.
   5. Recording on the data sheet of fluoroscopy and angiography exposure factors.

   6. Image intensification.
   For adequate protection of personnel the following are required:
   1. Film badges with records of total radiation for personnel over a given period of time.
   2. Lead aprons to be worn by all personnel present in the laboratory during fluoroscopy.
   3. Radiation protected x-ray control booth.
   4. Radiation protection for uncontrolled areas in adjacent rooms and corridors.

   Procedures
   There are three categories of patients requiring special skills on the part of the cardiac catheterization laboratory team: 1.) infants under two years of age, 2.) adults requiring left heart catheterization or selective coronary arteriography, and 3.) critically ill patients who require brief but definitive procedures. Since it is not always possible to distinguish, in advance, cases which are “simple” from those which may become complex, all cardiac catheterization laboratories should be staffed and equipped to carry out all necessary diagnostic and therapeutic procedures. The laboratory must be able to assemble personnel for emergency night-time or weekend procedures.

   The physicians attached to the laboratory should review the clinical data on each patient prior to the study. The clinical evaluation should include the history, physical examination, electrocardiogram, and chest roentgenograms. In addition, vectorcardiograms and indirect graphic records such as phonocardiograms, impulse (apex) cardiograms, etc. are highly desirable for a careful precatheterization evaluation, necessary to determine 1.) whether the patient requires study, 2.) to select the methods most appropriate for the resolution of the problem, and 3.) to judge the risk of the procedure and the need for special precautions.

   Case Load
   While a large number of procedures performed in a cardiac catheterization facility does not guarantee a high level of performance, the laboratory which functions only
occasionally cannot expect to produce excellent results, no matter how well-staffed and equipped it is. The ideal number of procedures that a cardiac catheterization team should carry out to maintain satisfactory performance is difficult to define, but it is the opinion of this Committee that the minimum number is an average of at least three per week. In the laboratory which intends to accept infants and young children for study, this minimum number applies to procedures performed in that age group.

These “Standards for a Cardiac Catheterization Laboratory” will be reviewed and up-dated as the need indicates.
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