

ICAEL STANDARDS FOR PEDIATRIC TRANSTHORACIC ECHOCARDIOGRAPHY TESTING

PART I

PEDIATRIC ECHOCARDIOGRAPHY LABORATORY OPERATIONS ORGANIZATION

In addition to all standards listed below, the Laboratory, the Medical Director and the Technical Director must comply at all times with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations and billing requirements.

SECTION 1 Personnel and Supervision

STANDARD - Pediatric Medical Director

1.1 The pediatric Medical Director must be a licensed physician.

1.1.1 Pediatric Medical Director Required Training and Experience:

The pediatric Medical Director must meet one of the following criteria:

- A) Advanced level of expertise: high level of expertise in all aspects of pediatric echocardiography. Physicians with this level of training are expected to be able to perform independently and to interpret echocardiograms in patients with all forms of congenital and acquired pediatric heart disease, and to supervise and train others. In addition to the core requirement of 150 studies, each advanced level physician should perform and interpret at least 200 additional pediatric transthoracic echocardiograms and review, or perform and interpret, another 200 pediatric echocardiograms. At least 50 should be done in infants one year of age or younger. Each trainee should perform a significant number of echocardiograms independently (one-third to one half of the exams), with subsequent review and critique of the examination by the responsible staff pediatric cardiologist-echocardiographer.

- B) Three years of echocardiography practice experience with at least 1800 echocardiogram/Doppler examination interpretations in children and patients with congenital heart disease.

Comment: It is recognized that some pediatric echocardiography laboratories, particularly those that perform a majority of studies on adults, will not achieve the above numbers. However, the individual pediatric Medical Director must possess the outlined experience, while it is not necessary that it be obtained at a single institution.

1.1.2 Pediatric Medical Director Responsibilities:

- A) The pediatric Medical Director is responsible for all pediatric clinical services provided and for the determination of the quality and appropriateness of care provided.
- B) The pediatric Medical Director may supervise the entire operation of the laboratory as it relates to pediatric echocardiography or may delegate specific operations to associate directors and the Technical Director.
- C) The pediatric Medical Director is responsible for assuring compliance of the medical and technical staff to the standards outlined in this document and the supervision of their work.
- D) The pediatric Medical Director must be an active participant in the interpretation of studies performed in the lab.

1.1.3 Continuing Education Requirements:

- A) The Medical Director must document at least 30 hours of Category I AMA CME credits in echocardiography over a period of three (3) years. All of the CME must be Category I AMA and must be relevant to echocardiography. It is recommended that ten hours be relevant to pediatric echocardiography.
- B) Yearly accumulated continuing education must be kept on file and available to ICAEL when requested.

Comment: If the Medical Director has completed formal training as specified under 1.1.1(A or B) in the past three years, the CME requirement will be considered fulfilled.

STANDARD - Technical Director

1.2 A qualified Technical Director(s) must be designated for the facility. The Technical Director is generally a full time position. If the Technical Director serves as Technical Director in more than one laboratory, an appropriately credentialed sonographer who is a member of the technical staff must be present in the laboratory in the absence of the Technical Director and assume the duties of the Technical Director.

Note: In a laboratory with no sonographers, the Medical Director serves as Technical Director. In this case, in addition to submitting the Medical Director forms, the Medical Director must also submit all forms and representative cases required for the Technical Director. If the laboratory is a combined adult/pediatric laboratory, the Technical Director may be the same.

1.2.1 Technical Director Required Training and Experience:

- A) The Technical Director must have an appropriate credential in echocardiography from the American Registry of Diagnostic Medical Sonography (ARDMS) or Cardiovascular Credentialing International (CCI). A credential in pediatric echocardiography is preferred if the Technical Director will be performing pediatric echocardiograms.
- B) In a laboratory with no sonographers, the physician Technical Director must have either advanced or core echocardiography training as defined by Task Force 2: Pediatric Training Guidelines for Noninvasive Cardiac Imaging¹ or an appropriate sonographer credential from the ARDMS or CCI.

1.2.2 Technical Director Responsibilities:

The Technical Director reports directly to the Medical Director or his/her delegate. Responsibilities include, but are not limited to, and may be delegated to other staff:

- A) All laboratory duties delegated by the Medical Director.
- B) Performance of echocardiograms in the laboratory.
- C) General supervision of technical and ancillary staff if applicable.
- D) The delegation, when warranted, of specific responsibilities to the technical staff and/or the ancillary staff.
- E) Daily technical operation of the laboratory (e.g., staff scheduling, patient scheduling, laboratory record keeping, etc.)
- F) Operation and maintenance of laboratory equipment.
- G) The compliance of the technical and/or ancillary staff to the *Standards* outlined within this document.
- H) Working with the Medical Director, medical staff and technical staff to ensure quality patient care.
- I) Technical training.

1.2.3 Continuing Education Requirements:

- A) The Technical Director must document at least 30 hours of echocardiography related continuing education over a period of three (3) years. All hours must be relevant to echocardiography. It is recommended that ten of the hours be relevant to pediatric echocardiography.
- B) Yearly accumulated continuing education must be kept on file and available for submission upon request.

Comment: If the Technical Director has successfully acquired an appropriate credential within the past three (3) years, the CME requirement will be considered fulfilled.

STANDARD - Pediatric Medical Staff

1.3 All members of the medical staff must be licensed physicians.

1.3.1 Pediatric Medical Staff Required Training and Experience.

The pediatric Medical staff must meet one of the following criteria:

- A) Advanced level of expertise: high level of expertise in all aspects of pediatric echocardiography. Physicians with this level of training are expected to be able to perform independently and to interpret echocardiograms in patients with all forms of congenital and acquired pediatric heart disease, and to supervise and train others. In addition to the core requirement of 150 studies, each advanced level physician should perform and interpret at least 200 additional pediatric transthoracic echocardiograms and review, or perform and interpret, another 200 pediatric echocardiograms. At least 50 should be done in infants one year of age or younger. Each trainee should perform a significant number of echocardiograms independently (one-third to one half of the exams), with subsequent review and critique of the examination by the responsible staff pediatric cardiologist-echocardiographer.

- B) Core level of expertise: basic set of technical and interpretive skills required for graduation from a pediatric cardiology training program accredited by ACGME and includes 4 to 6 months of echocardiography, performance and interpretation at least 150 pediatric echocardiograms, including at least 50 in patients one year of age or younger, under the supervision of the laboratory director or other qualified staff pediatric cardiologist echocardiographer(s). Each trainee should also review at least 150 additional pediatric echocardiograms. Physicians with this level of expertise are expected to be able to perform and interpret TTEs in normal infants, children, and adolescents, and in those with childhood heart disease with consultation as needed.
- C) Three years of echocardiography practice experience with at least 450 echocardiogram/Doppler examination interpretations in children and patients with congenital heart disease

Comment: It is recognized that the number of pediatric echocardiography studies performed in some laboratories, particularly those that perform a majority of studies on adults, will not achieve the above numbers. However, the individual pediatric medical staff member must have this experience, even if it is not achieved at a single institution

1.3.2 Pediatric Medical Staff Responsibilities:

- A) The pediatric medical staff interpret and/or perform clinical studies.

1.3.3 Continuing Education Requirements:

- A) The medical staff must document at least 15 hours of Category I AMA CME credits in echocardiography over a period of three (3) years. All of the CME must be Category I AMA and must be relevant to echocardiography. It is recommended that five hours be relevant to pediatric echocardiography.
- B) Yearly accumulated continuing education must be kept on file and available to ICAEL when requested.

Comment: If the medical staff has completed formal training as specified under 1.3.1(A or B) in the past three years, the CME requirement will be considered fulfilled.

STANDARD - Pediatric Technical Staff

1.4 All members of the pediatric technical staff must be qualified sonographers.

1.4.1 Pediatric Technical Staff Required Training and Experience:

The pediatric technical staff members must meet one or more of the following criteria:

- A) An appropriate credential in echocardiography from the American Registry of Diagnostic Medical Sonography (ARDMS) or Cardiovascular Credentialing International (CCI). A credential in pediatric echocardiography is recommended.
- B) Successful completion of an ultrasound or cardiovascular technology program which includes verified didactic and supervised clinical experience in echocardiography. These programs should be accredited by either the Commission on Accreditation of Allied Health Education Programs (CAAHEP) or the Canadian Medical Association (CMA).
- C) Completion of 12 months full time (35 hours/week) clinical echocardiography experience performing echocardiograms plus one of the following:
 - 1) Completion of a formal two year program in another allied health profession.
 - 2) Completion of a bachelors degree unrelated to a CAAHEP/CMA accredited program or a bachelors degree in sonography, vascular technology or a minor in some aspect of ultrasound which is not CAAHEP accredited to offer echocardiography.
 - 3) Have an MD, DO degree or equivalent.
- D) Minimum of 12 months of echocardiography practice experience with the performance of at least 600 echocardiogram/Doppler exams. At least 100 of these examinations should be in children or patients with congenital heart disease.

1.4.2 Technical Staff Responsibilities:

The technical staff member(s) must report to the Technical Director. The technical staff member(s) assumes the responsibilities specified by the Technical Director and, in general, is responsible for the performance of clinical examinations and other tasks assigned.

1.4.3 Continuing Education Requirements:

- A) The Technical staff must document at least 15 hours of echocardiography related continuing education over a period of three (3) years. All hours must be relevant to echocardiography. It is recommended that ten of the hours be relevant to pediatric echocardiography.
- B) Yearly accumulated continuing education must be kept on file and available for submission upon request.

Comment: If the technical staff member has completed formal training as specified under 1.4.1 (B) or has successfully acquired an appropriate credential within the past three (3) years the CME requirement will be considered fulfilled.

STANDARD - Support Services

1.5 Ancillary personnel (clerical, nursing, transport, etc.) necessary for safe and efficient patient care are provided.

Required Characteristics

1.5.1 Supervision:

- 1.5.1.1 The pediatric Medical Director must ensure that support services appropriate for and in the best interest of patient care are provided.

1.5.2 Support Services:

- 1.5.2.1 Clerical and administrative support must be sufficient to ensure efficient operation and record keeping.
- 1.5.2.2 Nursing and ancillary services sufficient to ensure quality patient care are available when necessary.

SECTION 2

Physical Facilities

(Laboratory Space)

STANDARD - Examination Areas

2.1 Examinations must be performed in a setting providing patient and technical staff safety, comfort and privacy.

2.1.1 The adequate performance of an echocardiogram requires the proper positioning of the patient, the echocardiographic system and the sonographer. For this reason, adequate spacing is required for inclusion of a patient bed, which allows for position changes, an echocardiographic imaging system and patient privacy.

- A) Approximately 150 square feet is recommended for a transthoracic echocardiography exam room.
- B) Patient privacy must be assured with the use of either appropriate curtains or doors.
- C) A sink and antiseptic soap must be readily available and used for handwashing in accordance with the infection control policy of the laboratory.

Note: It is understood that many echocardiographic studies are performed on a portable basis, requiring performance of the studies in less than optimal conditions. All studies, regardless of the location, must be performed with adequate room for patient positioning and equipment use.

STANDARD - Interpretation and Storage Space

2.2 Adequate designated space must be provided for the interpretation of the echocardiogram and the preparation of reports.

Space should be provided for data evaluation, interpretation, and discussion of the study with the sonographer and/or referring physician as needed. Space permitted for storage of records and supplies must be sufficient for the patient volume of the laboratory.

SECTION 3

Examination Data Archiving, Examination Reports, and Laboratory Records

STANDARD - Echocardiography Examination Data

3.1 Provisions must exist for the generation and retention of examination data for all echocardiograms performed.

- 3.1.1 A system for recording and archiving echocardiographic data (images, measurements and final reports) obtained for diagnostic purposes must be in place.
- 3.1.2 A permanent record of the images and interpretation must be made and retained in accordance with applicable state or federal guidelines for medical records. Records for pediatric patients may need to be retained for a longer period of time than those of adult patients. Echocardiographic data should be readily retrievable for comparison with new studies.
- 3.1.3 Studies must be archived in the original format that they were acquired. Archiving media includes, but is not limited to:
 - A) Videotape: When utilizing videotape for archiving, at least 5-10 cardiac cycles of each portion of the M-mode, 2-D and Doppler study should be recorded in real time. The location and method of measurements performed should also be archived.
 - B) Paper: Strip-chart recordings are an acceptable alternative for M-mode and spectral Doppler information. Page prints (several cardiac cycles recorded on a single page) are also an acceptable alternative.
 - C) Digital Storage: The laboratory must ensure that a sufficient portion of the examination can be archived in digital storage and that a secure back-up system is in place. Digital studies must include information consistent with that required for videotape acquisition, although fewer cardiac cycles are generally recorded (the number of cardiac cycles acquired must be sufficient to allow for adequate review)⁴.

3.2 Provisions must exist for the timely reporting of examination data.

- 3.2.1 If preliminary results are provided by an interpreting physician, the final report should be generated within two working days. Sonographer worksheets, comments, or other communication of findings must not be issued as preliminary reports for the purpose of clinical management. The findings of a STAT echocardiogram must be made available immediately by the interpreting physician.

Note: Suggested method for reporting life-threatening findings: Optimally, the interpreting physician in the laboratory will call the appropriate physician or his/her delegate. Alternatively, the sonographer may call the appropriate physician after conferring with the interpreting physician or his/her delegate.

- 3.2.2 Final physician interpretations of routine echocardiographic studies must be provided within two working days. A mechanism for communicating any significant changes must be defined for those situations in which the final interpretation differs significantly from the preliminary report.

Comment: An interpretation can be in the form of paper, digital storage or an accessible voice system. The final verified signed report must be available in a timely fashion, generally within 4 working days.

SECTION 4

Laboratory Safety and Patient Confidentiality

STANDARD - Laboratory Safety

4.1 Patient and employee safety is ensured by written policies and procedures approved by the Medical Director.

- 4.1.1 Standard echocardiograms are safe to both patients and sonographers. Special echocardiographic procedures, such as transesophageal echocardiograms, sedated echocardiograms and stress echocardiograms, pose potential risks to the safety of the patient due to either their semi-invasive nature, or the physiologic stress placed on the cardiovascular system of the patient. For this reason, an echocardiography laboratory providing special echocardiographic procedures must have an emergency procedure and the following emergency supplies readily available:
- A) A fully equipped cardiac arrest cart (crash cart). The size and dosage differences between pediatric and adult patients must be recognized. Pediatric dosing information and/or appropriate pediatric dose of emergency medications must be available.
 - B) A defibrillator
 - C) Appropriate sized pediatric equipment for starting and maintaining intravenous access.
 - D) Oxygen tanks or wall mounted oxygen sources with appropriately sized cannulae and/or masks.
 - E) Suction equipment
- 4.1.2 The laboratory must meet the standards set forth by the Occupational Safety and Health Administration (OSHA) and by The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), where applicable.
- 4.1.3 The laboratory must have a written procedure in place for handling acute medical emergencies.
- 4.1.4 The laboratory must recognize the potential need for patient sedation in pediatrics to obtain an adequate examination. Written policies must exist for the use of conscious sedation in children including but not limited to:
- A) Type of sedatives and appropriate dosing for age and size
 - B) Monitoring of children during and after the examination

STANDARD - Patient Confidentiality

- 4.2 All laboratory personnel must ascribe to professional principles of patient-physician confidentiality as legally required by federal, state, local or institutional policy or regulation.**

SECTION 5

Quality Assurance

STANDARD - Quality Assurance

- 5.1 There must be a written policy regarding quality assurance for all procedures performed in the laboratory. The quality assurance program must be comprehensive and include, but may not be limited to:**

5.1.1 Instrument Maintenance

Instrumentation used for diagnostic testing is maintained in good operating condition. The accuracy of the data collected by ultrasound instruments is paramount in the interpretation and diagnostic utilization of the information collected. Guidelines for equipment maintenance include, but are not limited to, the following:

- A) Recording of the method and frequency of maintenance of ultrasound instrumentation and digitizing equipment.
- B) Establishment of and adherence to a policy regarding routine safety inspections and testing of all laboratory electrical equipment.
- C) Establishment of and adherence to an instrument cleaning schedule that includes routine cleaning of equipment parts, including filters and transducers, according to the specifications of the manufacturer. The cleaning schedule for each system should depend on the degree of use and should be frequent enough to allow for accurate collection of data.

5.1.2 Procedure Volumes

Annual individual and laboratory procedure volume statistics must be recorded. Records must be maintained that permit evaluation of annual procedure volumes for the laboratory and each member of the medical and technical staff. The records should include information on the indication, test(s) performed and the findings. Individual staff members should maintain records of their own procedure volumes obtained from all laboratories where they perform/interpret echocardiograms.

5.1.3 Continuing Medical Education

Documentation of regular, echocardiography related continuing education for all medical and technical personnel must be maintained. Continuing education credit may be earned through a combination of materials such as approved CD, journal, internet or videotape materials as well as departmental, local, regional and national conferences and courses.

5.1.4 Peer Review

Intermittent peer review of both the performance and interpretation of studies should be performed to determine the quality, accuracy and appropriateness of the examination. Both physicians and sonographers should be involved in the peer review process. Differences in interpretation styles and performance should be reconciled to achieve uniform laboratory diagnostic criteria and standardized reporting. Results of peer review should be discussed in an appropriate manner to assure correction of negative results as well as to preserve physician, sonographer and patient confidentiality. (Strict attention must be paid to physician, staff and patient confidentiality as required by federal, state, local or institutional policy or regulation).

5.1.5 Correlation and Confirmation of Results

A) Correlation of Transthoracic Echocardiograms

For those patients who have undergone transthoracic echocardiograms and other diagnostic procedures (such as cardiac catheterization, MRI, CT), surgical intervention or post mortem examination, the results of transthoracic echocardiograms and other procedures must be routinely compared. Correlation data for each physician responsible for the interpretation of transthoracic echocardiograms in the laboratory must be accumulated by the laboratory and distributed to the interpreting physician. A process for addressing discrepancies between echocardiogram examination results and results of other procedures must be in place. Appropriate components and areas for correlation of transthoracic studies include, but are not limited to:

- 1) Echocardiographic studies which are the primary diagnostic imaging utilized prior to surgical repair.*
- 2) Semilunar valve stenosis.
- 3) Selected anatomies or functional evaluations which are of diagnostic interest to the laboratory.

*Patients who are sent for surgical repair of congenital heart defects on the basis of echocardiography alone must be recorded and the operative findings compared to the echocardiographic findings. Studies of a pertinent feature of anatomy may be selected for quality review to ensure a consistent approach to the imaging and evaluation of this patient group.

B) Correlation of Transesophageal Echocardiograms

For those patients who have undergone transesophageal echocardiograms and surgical repair or other diagnostic procedures such as coronary angiograms the results of transesophageal echocardiograms and other procedures must be routinely compared with regard to valvular abnormalities, left ventricular function and abnormalities of the aorta. Comparison studies for each physician responsible for the performance of transesophageal echocardiograms in the laboratory must be accumulated by the laboratory and distributed to the physician. Statistics must be generated to ascertain the overall accuracy of the transesophageal echocardiograms being performed in the laboratory. A process for addressing discrepancies between echocardiogram examination results and results of other procedures must be in place. Appropriate components and areas for correlation of transesophageal echocardiograms include, but are not limited to:

- 1) Left or right ventricular function
- 2) Presence and severity of valvular dysfunction
- 3) Defects of atrial and ventricular septa
- 4) Presence or absence of thrombi or vegetations
- 5) Presence or absence of anomalous venous connections

C) Correlation of Fetal Echocardiograms:

For those patients who have undergone fetal echocardiograms and other diagnostic procedures (such as postnatal echocardiography, postnatal cardiac catheterization or angiography), or post mortem examination, the results of fetal echocardiograms and other procedures must be routinely compared with regard to the accuracy of the fetal echocardiography examination. Comparison studies for each physician responsible for the performance/interpretation of fetal echocardiograms in the laboratory must be accumulated by the laboratory and distributed to the physician. Statistics must be generated to ascertain the overall accuracy of the fetal echocardiograms being performed in the laboratory. A process for addressing discrepancies between echocardiogram examination results and results of other procedures must be in place.

5.1.6 Echocardiography Conferences:

5.1.6.1 A minimum of two echocardiography quality assurance conferences per year must be held to review the results of comparative studies and peer review, to address discrepancies and to discuss difficult cases and laboratory issues. Attendance by all medical and technical staff is required for at least one meeting. Minutes of the meeting and attendance must be recorded.

5.1.6.2 A minimum of four echocardiographic departmental conferences per year, in conjunction with or in addition to quality assurance conferences, must be held for the continuing education of the laboratory. Attendance by all medical, technical and appropriate ancillary personnel involved in echocardiography is required for at least 50% of the meetings. Minutes of the meeting and attendance must be recorded.

5.1.7 Quality Assurance Record Keeping

Regular records must be maintained of the quality assurance process. These records should include, but not be limited to, correlation data and information gained from the areas outlined in 5.1.1, 5.1.2, 5.1.3, 5.1.4, 5.1.5 and 5.1.6. The records must include a description of how the information is used to improve quality in the echocardiography laboratory.

SECTION 6

Multiple Sites and Mobile Services

STANDARD – Multiple Sites

6.1 When testing is performed at more than one physical facility, the laboratory may be eligible to apply for a single accreditation as a multiple site laboratory.

6.1.1 All facilities have the same Medical Director.

6.1.2 All facilities have the same Technical Director.

6.1.3 Identical testing protocols are used at all sites.

6.1.4 Identical diagnostic criteria are used at all sites.

- 6.1.5 Quality assurance must be evaluated for each site for all areas of testing performed at the site.
- 6.1.6 Equipment of similar quality and capability must be used at all sites.

STANDARD – Mobile Service

6.2 A mobile service is comprised of one or more units (sonographer and equipment) that provide echocardiography testing services at one or more locations.

Comment: Some laboratories provide only mobile services and do not have a primary site laboratory. These mobile service laboratories are required to complete the entire accreditation application.

- 6.2.1 The entire mobile service has the same Medical Director.
- 6.2.2 The entire mobile service has the same Technical Director.
- 6.2.3 All mobile echocardiography examinations are interpreted by medical staff included in the application.
- 6.2.4 All mobile echocardiography examinations are performed by technical staff included in the application.
- 6.2.5 Equipment of similar quality and capability must be used for all mobile testing.

Comment: If the mobile service is a component of a primary site laboratory, the equipment used by the mobile service must be of similar quality and capability of the equipment used in the primary site.

- 6.2.6 The entire mobile service utilizes identical protocols.
- 6.2.7 The entire mobile service utilizes identical diagnostic criteria.
- 6.2.8 Quality Assurance must be evaluated for testing performed by the mobile service.

Bibliography:

1. "ACC/AHA/AAP Recommendations for Training in Pediatric Cardiology, Task Force 2: Pediatric Training Guidelines for Noninvasive Cardiac Imaging endorsed by the American Society of Echocardiology and the Society of Pediatric Echocardiography." Silverman, Mark S. Sklansky and Paul M. Weinberg Gregory J. Ensing, Tal Geva, Thomas R. Kimball, David J. Sahn, Norman H. Stephen P. Sanders, Steven D. Colan, Timothy M. Cordes, Mary T. Donofrio; *J. Am. Coll. Cardiol.* 2005;46;1384-1388; originally published online Sep 22, 2005.
2. "Guidelines and Standards for Performance of a Pediatric Echocardiogram: A Report from the Task Force of the Pediatric Council of the American Society of Echocardiography." Wyman W. Lai, MD, MPH, FASE, Tal Geva, MD, FASE, Girish S. Shirali, MD, Peter C. Frommelt, MD, Richard A. Humes, MD, FASE, Michael M. Brook, MD, Ricardo H. Pignatelli, MD, and Jack Rychik, MD; *J Am Soc Echocardiography* 2006;19:1413-1430.
3. "Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnosis and Therapeutic Procedures," Committee on Drugs for the American Academy of Pediatrics, *Pediatrics*, Vol 89, No. 6, June 1992, pp 1110-1115
4. "Guidelines and Recommendations for Digital Echocardiography: A Report from the Digital Echocardiography Committee of the American Society of Echocardiography," Thomas, et al, *J Am Soc Echocardiography* 2005;18:287-97

Appendix:

In-house departmental correlation conferences must not be counted as ongoing CME but rather as part of the laboratory's ongoing quality assurance program. Continuing education may be obtained in several ways. These include self-study materials such as approved CD, journal, internet and videotape materials, as well as departmental, local, regional and national conferences and courses.