

PART IV

FETAL ECHOCARDIOGRAPHY LABORATORY OPERATIONS

FETAL ECHOCARDIOGRAPHY TESTING

SECTION 1 Instrumentation

STANDARD - Primary Instrumentation

1.1 Cardiac Ultrasound Systems

Ultrasound instruments utilized for fetal echocardiographic studies must include the echocardiographic imaging system requirements, as outlined in *the ICAEL Standards for Pediatric Transthoracic Echocardiography Testing*, Part II, Section 1, Instrumentation.

1.2 Fetal Ultrasound Transducer

- A) Ultrasound transducers must be those manufactured for the ultrasound system of the laboratory.
- B) Fetal ultrasound transducers must be in the range of 5-3 MHz transmitted frequency. Sector or linear array transducers are acceptable.
- C) M-Mode, Doppler, color-flow Doppler and image enlarging (zoom) are features which must be incorporated into each fetal ultrasound imaging system.

SECTION 2 Indications, Ordering Process and Scheduling

STANDARD - Indications

2.1 Fetal echocardiographic testing is performed for appropriate indications.¹

2.1.1 Verification of the indication: A process must be in place in the laboratory for obtaining and recording the indication. Before a study is performed, the indication must be verified and any additional information needed to direct the examination must be obtained.¹

STANDARD - Ordering Process and Scheduling

2.2 Fetal echocardiography is appropriately ordered and scheduled.

- 2.2.1 Ordering process: The echocardiogram order and requisition must clearly indicate the type of study to be performed, the reason(s) for the study and the clinical question(s) to be answered. The order/requisition must be present in the medical record of the patient.
- 2.2.2 Definition of procedure types and protocols
- A) A complete fetal echocardiographic study is one that examines all of the cardiac chambers, valves, great vessels, septa, and venous connections from multiple imaging planes. The examination must include an assessment of cardiac position, ventricular function, extracardiac fluid, and heart rhythm. This study must include appropriate Doppler interrogation of all cardiac valves and structures and provide any hemodynamic data felt to be of importance for patient care.
 - B) A follow-up or repeat fetal echocardiographic study may contain all of the elements found in a complete study, but is more often used to re-examine specific elements of cardiac structure or function or to evaluate the changes in the abnormal or suspected abnormal fetal heart which have may have occurred with fetal growth or to evaluate the effects of therapy (e.g., fetal arrhythmia treatment).
- 2.2.3 Scheduling: Sufficient time must be allotted for each study according to the procedure type. The performance time for an uncomplicated, complete study, is estimated to be 30 to 60 minutes.

SECTION 3

Elements and Components of Examination Performance

STANDARD - Elements of Examination Performance

3.1 Examination performance must include proper technique.

All procedures must be explained to the patient (mother) and/or parents or guardian. Echocardiogram examinations of the fetal heart must examine all cardiac chambers and structures and areas of abnormality. The course and extent of disease should be documented.

- 3.1.1 Elements of study performance and quality include, but are not limited to:
- A) Optimization of equipment gain and display setting
 - B) Performance of a 2-D/M-Mode/Doppler examination according to the laboratory specific and appropriate protocol that incorporates all views and imaging planes mandated by the *ICAEL Standards (3.2.4)*
 - C) Examination of fetal lie and position
 - D) Measurement of BPD, head circumference or other measure for estimation of fetal size/gestational age
 - E) Delineation of fetal visceral situs
 - F) Delineation of cardiac position
 - G) Delineation of a four-chamber anatomy
 - H) Delineation of great vessel relationships
 - I) Demonstration of atrioventricular valve integrity by Doppler
 - J) Delineation of aortic arch anatomy
 - K) Assessment of fetal heart rate and rhythm
 - L) Assessment of intracardiac and ductal shunting
 - M) Appropriate assessment of areas of abnormality
 - N) Determination of presence or absence of fetal hydrops

STANDARD - Components of the Fetal Echocardiogram

3.2 Fetal echocardiograms must be comprehensive and include standard components.

- 3.2.1 Preparation of the patient: To perform fetal echocardiography the patient (mother of the fetus) must be comfortably positioned and adequate privacy maintained.
- 3.2.2 Technical personnel: These personnel may include a sonographer and a nurse. Many fetal echocardiograms are performed by the physician. The duties of the technical personnel include, but are not limited to, preparing the patient for the test, assisting the physician with the ultrasound equipment, and monitoring the patient during and after the examination.
- 3.2.3 Components of the examination: Components of the standard fetal examination must be defined for the laboratory. A technical protocol including the components of the examination must be written and adhered to in the laboratory. Indications for the performance of a fetal examination must be included.

A complete two-dimensional and Doppler examination of the fetus includes standard views from multiple planes including views of all cardiac structures and selected extracardiac structures. It is recognized that the orientation of the fetus does not always allow the examiner to obtain “standard” images as in transthoracic echocardiography. Therefore, imaging views may be defined by their functional components rather than their specific orientation.

- 3.2.4 The complete examination may include the following standard views and images:
- A) Survey of fetal lie and position defining fetal orientation
 - B) Presence of single or multiple gestations
 - C) Measurement of BPD, head circumference or other measure for estimation of fetal size/gestational age
 - D) Short axis view of fetal umbilical cord vasculature
 - E) Doppler evaluation of flow in the fetal umbilical vessels
 - F) Fetal cardiac position and visceral situs
 - G) Imaging of the pericardial space, abdomen, and skin for extracardiac fluid/edema
 - H) Imaging and Doppler/color flow Doppler interrogation of the pulmonary veins and their cardiac connection
 - I) Imaging and Doppler/color flow Doppler interrogation of the systemic veins and their cardiac connection
 - J) Multiple imaging planes of the atrioventricular (mitral and tricuspid) valves, with appropriate Doppler
 - K) Four-chamber view of the heart for assessment of cardiac chamber size
 - L) Assessment of ventricular outflow and semilunar valves including the relationships of the great arteries and ventriculoarterial connections with appropriate Doppler/color flow Doppler
 - M) Multiple imaging planes of the atrial septum, foramen ovale, ductus arteriosus and ventricular septum, with appropriate Doppler/color flow Doppler
 - N) Short and long axis views of the ascending, descending and transverse arch of the aorta with appropriate Doppler/color flow Doppler
 - O) Short and long axis views of the main pulmonary artery and proximal portions of the right and left pulmonary arteries
 - P) Assessment of fetal heart rate and rhythm using appropriate M-Mode/Doppler techniques

SECTION 4

Examination Interpretation

4.1 Echocardiography reporting must be standardized in the laboratory. All physicians interpreting echocardiograms in the laboratory must agree on uniform diagnostic criteria and a standardized report format.

The report must accurately reflect the content and results of the study. The report must include, but may not be limited to:

- A) A report header must include, but may not be limited to:
- the date of the study
 - the name and/or identifier of the laboratory
 - the name and/or identifier of the patient
 - the date of birth and/or age of the patient
 - the primary indication for the study
 - the name of the performing sonographer
 - the name of the ordering physician and/or identifier
 - documentation of estimated gestational age (EGA)
 - the information must be sufficient to allow for the identification and retrieval of previous studies on the same patient.
- B) Report of measurements must include but not be limited to:
- the measurements performed in the course of the examination where normal values are known and/or interpretation appropriate to the clinical issue or area(s) of abnormality
- C) A report of the Doppler evaluation must include, but not be limited to:
- the Doppler values, normal and abnormal, obtained in the course of the examination appropriate to the clinical issue or area(s) of abnormality
- D) Report text must include comments on:
- components of procedure, i.e color flow Doppler, PW/CW Doppler
 - all structures evaluated in the examination as specified above
 - if any structure is not well visualized this should be noted
 - The report text must be consistent with the quantitative and Doppler data. Where appropriate, this must include localization and quantification of abnormal findings.

- E) Summary of pertinent findings
- F) Reports must be typewritten, include a physician signature line (the printed name of the interpreting physician) and be manually or electronically signed by the interpreting physician

SECTION 5

Procedure Volumes

STANDARD - Procedure Volumes

5.1 The annual procedure volume is sufficient to maintain proficiency in examination performance and interpretation.

Ideally, a laboratory should perform a minimum of 50 fetal echocardiograms annually and that each member of the staff who performs or interprets fetal echocardiography should do a minimum of 25 studies annually. The total volume of studies interpreted and/or performed by each staff member may be combined from sources other than the applicant laboratory. It is recognized that some laboratories performing quality studies will not meet this minimum number, therefore lower volumes than those recommended here should not dissuade a laboratory that is otherwise compliant with the *ICAEL Standards* from applying for accreditation. These laboratories or individuals will be required to demonstrate competence through the submission of additional case studies and quality assurance documentation.

Bibliography:

1. **American Society of Echocardiography Guidelines and Standards for Performance of the Fetal Echocardiogram.** A statement of the Pediatric Council of the American Society of Echocardiography represented by, Jack Rychik, MD, Nancy Ayres, MD, Bettina Cuneo, MD, Nina Gotteiner, MD, Lisa Hornberger, MD, Philip J. Spevak, MD, and Mary Van Der Veld, MD; J Am Soc Echocardiography 2004;17:803-10.