STANDARDS FOR PEDIATRIC CARDIOLOGY DIAGNOSTIC AND TREATMENT CENTERS

I. Introduction

The Division of Specialized Care for Children (DSCC) has long provided services for children with heart disease in the state of Illinois. The Division recognizes that pediatric patients with significant heart disease have identifiable needs which can only be adequately met by a team of experts with training and experience in the management of cardiovascular disease in this age group. In order to assure the highest quality of care and the most efficient use of available resources, the specialized diagnostic and treatment facilities for children with cardiac disease should be concentrated in a limited number of regional treatment centers. These centers must meet specific standards in order to be designated as Pediatric Cardiology Diagnostic and Treatment Centers for patients referred by the Division of Specialized Care for Children. These standards are listed below.

II. Background

The state of Illinois has a population of approximately 12,420,000 people of whom 43% reside in Cook County and the remaining 57% reside in the rest of the state. There are approximately 181,700 live births in the state of Illinois yearly. Assuming an incidence of eight cases per 1,000 live births, approximately 1,454 children are born each year with congenital heart disease, the most common form of pediatric cardiac disease.

III. Pediatric Cardiac Centers

A Pediatric Cardiac Center is an institution or closely affiliated group of facilities providing comprehensive pediatric cardiology care including medical and surgical diagnosis and treatment. Appropriately equipped staffed and supported centers serving larger populations are preferable to multiple minimum population centers. Because Illinois is a large state geographically with large rural populations as well as large urban populations, logistic considerations may make it appropriate to establish centers in large geographic areas whose population might not produce a volume of clinical cases usually considered essential for the establishment of a center. In some cases affiliated facilities will be recognized which offer some but not all available services to pediatric cardiology patients. The scope of services which can be authorized and levels of services to be provided by various DSCC approved specialists are shown in the *Cardiac Services Matrix* attached to these standards.

IV. Standards of Care for Pediatric Cardiac Centers

A. **Pediatric cardiology patients**. Infants, children, and adolescents from birth to age 21 years with congenital or acquired diseases of the heart shall be defined as pediatric cardiology patients.

B. **Pediatric cardiologists**. An approved Pediatric Cardiology Diagnostic Center or one seeking approval should be under the direction of a physician currently certified by the American Board of Pediatrics and the Sub-Board of Pediatric Cardiology. Each approved center will have a minimum of two specialists in pediatric cardiology, at least one of whom is board certified. A pediatric cardiologist must be available to the regional center 24 hours per day. Centers with large outpatient, teaching and research responsibilities will require additional medical personnel.

C. **Pediatric cardiac surgeons**. There should be at least two board qualified cardiac surgeons on the staff of the hospital with a cardiac surgical program; at least one should be certified by the American Board of Thoracic Surgery. One surgeon should be readily available at all times. Responsibility rests on both the hospital administration and the director of the program to insure adequate professional staff coverage at all times, with hospital support systems and services sufficiently integrated to effectively manage medical and surgical emergencies. The cardiac surgeon requires a full background in basic medical principles and surgical techniques, with special competence in pediatric cardiology to include the disciplines of cardiopulmonary anatomy, embryology, physiology, pathology, pharmacology, extracorporeal perfusion technique, and the integration of echocardiographic, hemodynamic and angiographic data in infants, children, and adolescents. He/she should be able to direct a surgical team in the performance of all current cardiac surgical procedures applicable to pediatric cardiology patients. The cardiac surgeon's training should include special emphasis in cardiovascular surgery in infants and children. If the American Board of Thoracic Surgery develops a special certificate of competence in pediatric cardiovascular and thoracic surgery in addition to the standard cardiovascular and thoracic board examination, at least one surgeon from the center should hold such a certificate.

D. **Other medical staff**. There should be physicians with recognized competence available to provide pediatric patients necessary services in hematology, nephrology, neurology, neonatology, pulmonology, endocrinology, genetics, surgery, infectious diseases, radiology, anesthesiology, intensive care, and pathology. It is preferable that these physicians have certificates of pediatric proficiency or board certification in their subspecialty if such certificates or boards exist.

E. **Nursing staff**. Nurses specially trained in managing specific age groups with heart disease are essential. They include cardiac nurse specialists, surgical, intensive care, and ward nurses. Frequent reassignment of nurses outside their area of special training is undesirable. Continuing in-service education must be incorporated into each nursing program.

F. **Support services**. Qualified medical social workers, or the equivalent, must be available within the institution to assist in dealing with the anxiety, fear, and worry common to the patients' families when cardiac diagnosis and treatment are being implemented. The case worker should be familiar with state and federal programs for the financial support and rehabilitation of cardiac patients.

Technicians may be trained to assist in invasive and non-invasive procedures for pediatric cardiac patients. Certification of these people by appropriate certifying agencies should be sought.

G. **Pediatric facilities**. The specific optimal criteria for hospital resources for the care of patients with heart disease described in the *Hospital Categorization Guidelines* of the Joint Commission on Accreditation of Healthcare Organizations are endorsed. There should also be readily accessible pediatric cardiology ambulatory services, supervised by a pediatric cardiologist. Emergency service must be continuously available.

1. **Inpatient services**. Comprehensive, specialized services for pediatric patients with heart disease should be provided in a hospital equipped to care for children as designated by the *Hospital Categorization Guidelines*. These units should be capable of providing comprehensive and optimal diagnostic and therapeutic services.

2. **Laboratory services** shall be available as described in the *Hospital Categorization Guidelines* of the Joint Commission on Accreditation of Healthcare Organizations.

3. **Non-Invasive procedures**. Available services should include electrocardiography, nuclear cardiology, ambulatory electrocardiographic monitoring, exercise testing, and echocardiography, with interpretation of each under the direction of a pediatric cardiologist.

   Exercise testing requires ECG and blood pressure monitoring, with possible special facilities for oxygen consumption and cardiac output determination. Studies should be performed with personnel able to recognize and treat medical emergencies in attendance. Emergency resuscitation equipment, including a cardiac defibrillator and ventilatory assistance devices, must be immediately available. A center dedicated to the care of patients with life-threatening arrhythmias should provide means for telemetry. Echocardiographic studies in the fetus, infant, child and adolescent require specialized equipment for complete M-mode, two-dimensional and Doppler examination. Utilization of color flow Doppler studies is a necessary facet of echocardiographic evaluation. Personnel should be available on continuous call. All echo-cardiographic examinations should be performed under the direction of a pediatric cardiologist. Physician staff review of each echocardiographic examination is mandatory.

4. **Intensive care unit**. One or more units must be available to provide constant and special care for infants and children with cardiovascular disease.

5. **Cardiac Catheterization Laboratory**.

   a. **Personnel**. Personnel should be available on continuous call. The physician directing or actively performing catheterizations in infants and children should fulfill the qualifications for a pediatric cardiologist. Pediatric cardiology trainees should perform cardiac catheterizations under the supervision of such a pediatric cardiologist.

      A graduate nurse or technician with special training in cardiovascular techniques and in the care of pediatric patients, plus two or more additional personnel to include physicians, nurses, or technicians, should be present for each procedure.

   b. **Equipment**. The equipment necessary for a catheterization laboratory includes:

      i. Multiple channel recording apparatus for the continuous display and recording of intracardiac pressures, ECGs, and other selected physiologic variables.

      ii. Equipment to measure oxygen consumption and to determine the cardiac output in patients of all ages.

      iii. Equipment to analyze hemoglobin-oxygen saturation and measure pH and blood partial pressure of carbon dioxide and oxygen. Results of these studies should be immediately available. Laboratories in which infants are cared for should be equipped with units able to use small samples of blood for analysis. A transcutaneous oximeter for continuous monitoring of tissue oxygenation is a necessity when performing invasive procedures on high-risk infants and children.

      iv. Image intensification x-ray apparatus capable of video and cine recording, biplane imaging equipment, and a pressure injector that permits rapid injection of controlled amounts of radiopaque contrast material are essential. Recently developed nonionic, or low ionic radio-opaque contrast materials should be available.

v. Intracardiac electrophysiologic studies represent a specialized area of cardiac catheterization requiring additional medical expertise and technical support. In centers without available expertise, these studies may be performed in conjunction with an adult electrophysiologist, or patients may be referred to a more specialized center. When performing electrophysiologic studies, the catheterization laboratory team should be particularly well versed and coordinated in performing cardioversion and cardiopulmonary resuscitation. Facilities for these specialized studies should include: 1) a physiologic recorder capable of displaying and recording at least three simultaneous ECGs, six intracardiac signals and a blood pressure; 2) a “freeze" oscilloscope; 3) a programmable stimulator capable of delivering three or more extrastimuli; and 4) electrophysiologic catheters designed for children.

vi. Interventional catheterization procedures represent a specialized area of cardiac catheterization requiring additional medical expertise and technical and surgical support. Specialized equipment for angioplasty, as well as equipment for catheter or prosthesis retrieval, are required. Immediate availability of surgical intervention in the same facility is necessary in the event of a major complication.

vii. Patient support devices should include resuscitation equipment and supplies available at all times for emergency use in the laboratory. At least two medical personnel trained in use of this equipment should be available in the laboratory. The equipment should be periodically checked for reliable performance and include: a defibrillator, capable of delivering energy at low doses and synchronized cardioversion; laryngoscopes with endotracheal tubes appropriate for all ages; an oxygen source; equipment for oxygen administration in assisted respiratory ventilation; a suction device; emergency drugs; capability for insertion of a transvenous pacemaker; a body temperature monitoring device; and a warming device for infants.

6. **Operating room**. Operating room and surgical support facilities should be available and equipped as outlined in the report of the *Intersociety Commission for Heart Disease Resources*. This support should include a physician with training in pediatric/cardiovascular anesthesia who must be available to help manage the delivery of anesthesia to pediatric cardiac patients.

V. Case Load

A. **Minimum case loads**. A minimum case load is essential to stimulate and maintain the quality of support necessary for safe and effective diagnostic procedures and cardiac surgery. An optimum population base for a comprehensive pediatric cardiology center would include 30,000 live births per year. The following case loads are considered minimum numbers for centers providing complete comprehensive care.

1. **Cardiac Catheterization**.

a. Laboratories should perform a minimum of 100 cardiac catheterizations on infants and children per year. For purposes of this section a cardiac catheterization is defined as all procedures performed in the cardiac catheterization laboratory on a patient during a single visit to that laboratory. Each cardiologist with privileges to perform pediatric cardiac catheterizations should perform at least 25 catheterizations per year.

b. Records of procedures shall be maintained and shall identify the physician performing the procedure.

2. **Surgery**.

a. In institutions performing pediatric cardiac surgery, a minimum of 100 operations on infants and children should be performed per year, of which 75 should be open heart procedures (i.e., employing extra corporeal circulation).

B. **Permissible Variances In Case Loads**

1. Each currently approved Center will be expected to have achieved the above specified minimum case loads within 24 months of the date of implementation of these revised standards. New applicants for Center status should meet the specified minimum case loads by the date of application. Programs functioning as a principal teaching affiliate of a medical school in Illinois or which provide accessible services to an otherwise underserved geographic region of Illinois may be recommended by the DSCC Advisory Board for up to a 20% variance in case load standards when:

a. The program satisfies all of the other standards specified in section IV; and

b. A review of the experience of the institution over the preceding 24 months reveals case fatality rates, morbidity rates, and quality of care standards comparable to those of established approved Centers.

VI. Approval of Additional Centers

A. Additional DSCC Cardiac Centers may be approved by the DSCC Director upon the recommendation of the DSCC Advisory Board. Programs desiring Center status must apply to the Division of Specialized Care for Children in writing, providing sufficient information to demonstrate compliance with the standards contained in this document. All sufficiently supported applications will be presented to the DSCC Advisory Board for discussion and recommendation at the time of a regularly scheduled meeting. A representative from the applying program may be invited to attend that meeting to clarify any issues raised during consideration of the application.

B. Applicants fulfilling all of the criteria noted in sections IV and V will be recommended for approval by the DSCC Advisory Board. Applicants not able to meet minimum case load standards may be recommended for an exception if they meet the criteria noted in section V, paragraph B-1. above.

VII. Quality Control Programs

A. Each approved Center will maintain detailed records concerning case numbers, fatality rates, complications, average length of stay, and outcome. Records will also be maintained concerning patients referred to other institutions for treatment and their outcome.

B. Participating Centers will be responsible to provide the above information to DSCC annually, the date to be determined by the hospital in agreement with DSCC.

C. Each approved Center will develop ongoing quality assurance procedures, as mandated by the JCAHO, which will be available for review by the Division.

D. At least once every three years, review of each Pediatric Cardiology Center approved by the Division will be carried out by a team of consultants recommended by the DSCC Medical Advisory Board. This review may include a site visit.

E. As an alternative to a site visit which would evaluate both process and outcome parameters, if available, a Center may choose to participate in a regional data system which statistically evaluates outcome of cases. The Center must submit all cases to such a system; the data should be analyzed so that statistical comparisons can be made to the experience of other centers. The data system should provide a format for discussion of the data and qualify of care, and provide a method to assess improvement in care.

F. Centers failing to meet or maintain compliance with these standards will be considered for removal from the list of approved DSCC Cardiac Centers upon the recommendation of the DSCC Advisory Board. All available information relating to staffing, services, case numbers and patient outcomes will be presented to the Board for discussion and recommendation at the time of a regularly scheduled meeting. A representative of the program under review will be invited to attend the meeting to clarify any issues raised by the Board.

VIII. Hospitals Affiliated with DSCC Cardiac Centers

A. Hospitals with pediatric cardiology programs unable to meet the criteria specified in sections IV and V for designation as DSCC Cardiac Centers may participate with DSCC through development of an affiliation with an established Center, thereby creating a regionalized and, when appropriate, stratified system of health care delivery for children with cardiac impairments served by DSCC.

B. The affiliation must be defined in a written *Memorandum of Understanding* (MOU) between the Center and the affiliate which has the concurrence of the DSCC Advisory Board. The MOU must define the level of care and types of diagnostic and/or interventional services permitted in the affiliated program, and the manner by which the Center will monitor and assure the quality of pediatric cardiac services provided to DSCC clients by the affiliate. A copy of the MOU must be on file with DSCC.

C. These *Memoranda of Understanding* must be reviewed by all parties at least once every three years, and at any time that the Center has reason to believe that a significant change in the capabilities of the affiliated program has occurred.

Approved: (original signed) ____________________________
Director
Division of Specialized Care for Children
University of Illinois at Chicago

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