AMERICAN ACADEMY OF PEDIATRICS

Section on Cardiology and Cardiac Surgery

Guidelines for Pediatric Cardiovascular Centers

ABSTRACT. Pediatric cardiovascular centers should aim to provide high-quality therapeutic outcomes for infants and children with congenital and acquired heart diseases. This policy statement describes critical elements and organizational features of centers in which high-quality outcomes have the greatest likelihood of occurring. Center elements include noninvasive diagnostic modalities, cardiac catheterization, cardiovascular surgery, and cardiovascular intensive care. These elements should be organizationally united in centers in which pediatric cardiac physician specialists and specialized pediatric staff work together to achieve and surpass existing quality-of-care benchmarks.

ABBREVIATIONS. AAP, American Academy of Pediatrics; ECMO, extracorporeal membrane oxygenator; ICU, intensive care unit; ICAEL, Intersocietal Commission for the Accreditation of Echocardiography Laboratories; VAD, ventricular assist device.

INTRODUCTION

This policy statement supersedes "Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers" published by the American Academy of Pediatrics (AAP) in 1991.[1] The objective of the 1991 statement was to describe the clinical and physical environment in which the pediatric patient with heart disease could undergo accurate and safe diagnostic and therapeutic procedures. Over the past decade, there have been changes in technology and clinical practice that render many aspects of the 1991 guidelines incomplete or obsolete. Recognizing the broadened scope of interaction between medical and surgical disciplines, this revised policy statement redesignates the pediatric cardiology center as the "pediatric cardiovascular center." The aim of this statement is to describe the configuration and critical elements of the pediatric cardiovascular center in which high-quality outcomes have the greatest likelihood of occurring.

CENTER CONFIGURATION

A pediatric cardiovascular center should be able to provide all of the sophisticated diagnostic services and the full range of treatments, interventions, and surgeries needed to produce high-quality outcomes in all pediatric patients with congenital and acquired heart diseases. Physicians and staff should function as a team and should include adequate numbers of qualified pediatric cardiologists, pediatric cardiovascular surgeons, pediatric cardiovascular anesthesiologists, pediatric intensive care physicians, and/or neonatologists with special expertise in the care of cardiac patients, and additional pediatric specialists required for the overall care of patients. Diagnostic elements should include a fully equipped pediatric echocardiography laboratory, a pediatric cardiac catheterization and electrophysiology laboratory, and appropriate additional facilities and capabilities for comprehensive laboratory and noninvasive diagnostic evaluations of critically ill children. Therapeutic components should include a pediatric cardiac catheterization laboratory equipped for interventional cardiology and transcatheter radiofrequency ablations, a cardiac operating suite suitable for surgical treatment of all pediatric cardiovascular patients, an extracorporeal membrane oxygenator (ECMO), and a cardiac intensive care unit (ICU) or pediatric ICU and/or neonatal ICU equipped and staffed to care for pediatric cardiovascular patients.

Pediatric cardiology practices, which do not have the configuration and the elements of a pediatric cardiovascular center, may provide triage and emergency care, care of strictly medical cardiovascular conditions, and ongoing joint management (together with a center) of patients after surgery or catheter interventions at the center. This statement does not make specific recommendations regarding such practices.

NONINVASIVE DIAGNOSTIC ELEMENTS

A pediatric echocardiographic laboratory is principal among a center's noninvasive diagnostic elements. Existing data suggest that pediatric patients are not optimally served in laboratories primarily geared for adult echocardiography[2,3]; thus, most pediatric cardiology programs should have dedicated pediatric echocardiography laboratories. The AAP endorses accreditation by the Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) and adherence to the guidelines promulgated by the American College of Cardiology and the American Heart Association[4] as means to ensure pediatric echocardiography laboratory standards are met. For ICAEL accreditation of pediatric transthoracic, transesophageal, or fetal echocardiography, a laboratory must show that it has state-of-the-art equipment and facilities suitable for children, follows good technique in recording and reporting examinations, and is staffed by physicians and technicians trained in pediatric echocardiography. The ICAEL mandates that the laboratory and its mobile or satellite locations are supervised by a medical

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

director (pediatric cardiologist) and a technical director (pediatric echocardiography technician) and sets standards for training and experience of these individuals. The medical director and other physicians who interpret echocardiograms and/or perform fetal or transesophageal echocardiography and technicians who staff the laboratory or its peripheral sites must meet the American Society of Echocardiography's guidelines for appropriate training[5–7] and must also satisfy ICAEL requirements for ongoing experience.

Pediatric cardiovascular centers should adhere to American Heart Association guidelines for exercise testing in pediatric patients.[8] Because equipment and expertise appropriate for pediatric patients are needed, in most clinical settings, establishment of a pediatric exercise laboratory separate from existing adult laboratories is appropriate. Pediatric exercise laboratories must have a knowledgeable physician director and staff with competence in exercise testing and interpretation in young patients with disorders of varying severity.[9] Pediatric resuscitative equipment must be immediately available to the laboratory.

Additional essential noninvasive elements of a pediatric cardiovascular center, which should be directed by a pediatric cardiologist, include electrocardiography, holter monitoring, transient arrhythmia monitoring, and pacemaker evaluation. Proper application of these tests requires appropriate physician expertise and personnel familiar with the unique requirements of pediatric patients.

Pediatric cardiovascular centers should also have access to tilt-table testing and additional imaging capabilities, such as magnetic resonance imaging and computed tomography. This equipment may be shared with adult patient departments. However, if shared, a pediatric cardiologist with expertise in the pediatric cardiovascular applications of these modalities should collaborate with other specialists to ensure diagnostic-quality pediatric cardiovascular studies.

CARDIAC CATHETERIZATION

The American College of Cardiology and the Society for Cardiac Angiography and Interventions have developed catheterization laboratory standards (including recommendations for pediatric catheterization laboratories).[10] The AAP endorses these standards with respect to the recommendations regarding pediatric cardiac catheterization laboratories.

Cardiac catheterization continues to be a definitive diagnostic modality that provides hemodynamic, anatomic, and electrophysiologic data critical for patient care. Transcatheter therapeutic interventions have become common but more complicated.[11,12] Furthermore, transcatheter radiofrequency ablation has become the standard definitive treatment of pathologic tachycardias. Because of the expanded role of cardiac catheterization, high-quality catheterization services are more important than they were in the past.

A number of factors help to ensure high-quality pediatric cardiac catheterization care. A board-certified pediatric cardiologist who has additional fellowship training (or qualifying experience) in pediatric catheterization and interventional procedures should direct the pediatric catheterization laboratory. The pediatric catheterization laboratory director should have responsibility for all aspects of the administration and function of the laboratory (including quality assessment and quality improvement activities). In addition to technicians trained in pediatric catheterization, staffing of every procedure should include a minimum of 1 board-certified (or board-eligible) pediatric cardiologist and 1 pediatric nurse with training and experience in pediatric airway management and sedation.

The pediatric catheterization laboratory should have biplane imaging equipment with a moveable C-arm, immediate replay capabilities (preferably digital), a physiologic recorder, a blood gas analyzer, a pulse oximeter, an infant warming device, pacing catheters and an external pacemaker, a defibrillator and an emergency cart, and a comprehensive inventory of pediatric catheters, devices, and expendables. There should be an appropriate ICU available to care for patients before and after cardiac catheterization, and interventional procedures require the availability of in-hospital pediatric cardiac surgery backup.

Each cardiac catheterization program should strive to achieve high-quality outcomes with low morbidity and mortality. Data should be gathered prospectively to document quality of care. There should be systematic review of all case outcomes and procedural complications at regular catheterization quality assurance conferences. Recent studies of pediatric catheterization demonstrate that catheterization-related mortality rates much less than 1% are achievable (with mortality essentially confined to emergency cases in neonates and high-risk interventional cases). In addition, an incidence of major complications (defined as potentially life-threatening events) less than 3% is also attainable.[13,14] Another study showed that fewer than 4% of transcatheter interventional procedures should require surgical intervention because of complications.[15] Furthermore, in radiofrequency ablation procedures, data show that permanent complete heart block rates less than 2% are common.[16] All pediatric cardiac catheterization laboratories should strive to achieve and exceed these benchmarks.

In pediatric cardiac catheterization and intervention, data relating outcomes and laboratory or operator case volume are not currently available. However, data indicate that coronary interventional outcomes are improved if operators exceed a certain number of individual cases annually.[17] Given the wide range of procedures performed and the variety of rare diagnoses treated in pediatric cardiology, pediatric cardiology centers performing a small number of catheterizations should restrict the activity to 1 or 2 cardiologists so that operators maintain their clinical skills.

CARDIOVASCULAR SURGERY

In 1991, the American College of Surgeons published guidelines for minimal standards in cardiac

surgery, including recommendations with respect to hospitals operating on children with congenital heart disease.[18] These recommendations are outdated.

In the current era, hospital mortality rates less than 1% are achievable for simpler forms of congenital heart disease (eg, atrial septal defect, ventricular septal defect, coarctation of the aorta), and significant postoperative morbidity among such patients has been rare.[19–22] For more complex lesions, risks are greater. However, for lesions such as tetralogy of Fallot, complete atrioventricular canal defect, and transposition of the great arteries without additional complicating defects or conditions, hospital mortality rates less than 5% are attainable.[19,23–25] Patients who have more complex disease or who are more ill experience higher morbidity and mortality but have usually been best served in experienced surgical environments with consistent excellent outcomes among patients with more complicated illness. Furthermore, to offer patients a full range of surgical treatments, centers have offered pediatric cardiac transplant (as centers certified by the United Network for Organ Sharing) or have been closely affiliated with a certified transplant center. All pediatric cardiovascular centers should strive to achieve and surpass these benchmarks and should provide or have available heart replacement services.

A major objective of this statement is to describe the surgical environment associated with high-quality outcomes. Surgical outcomes are enhanced by early patient referral, definitive anatomic and physiologic diagnosis, and optimal preoperative and postoperative care. Parental counseling and planning of the timing and nature of surgical intervention should be accomplished by a team skilled in the care and treatment of pediatric heart disease and responsible for the care of the patient. Team members should include cardiac surgeons, cardiologists, anesthesiologists, intensive care physicians, neonatologists, nurses, and perfusionists.

Expert, experienced congenital heart surgeons are required for staffing a pediatric cardiovascular surgical program. Surgical training (after cardiac surgery residency) requires 2 years of pediatric cardiac surgery fellowship and additional years working as a junior staff surgeon in a pediatric and congenital heart program with high volume and demonstrated high-quality outcomes.

A dedicated team of anesthesiologists, perfusionists, operating room nurses, and technicians should be available to support all pediatric cardiovascular surgical procedures. Anesthesiologists should have pediatric and pediatric cardiac anesthetic training and experience with expertise in dealing with the problems arising from complicated interactions between the cardiac pathophysiology, surgical procedures, and anesthetic techniques. Perfusionists should be dedicated to the pediatric cardiovascular surgery program and have training, knowledge, and experience with small body perfusion, ECMO, and ventricular assist devices (VADs), including set up, delivery, and maintenance of these systems. Operating room nurses should be dedicated pediatric cardiovascular operating room nurses with training, knowledge, and experience in pediatric cardiac operative techniques and requirements. Likewise, technicians should be appropriately trained and experienced permanent members of the operating team.

One or more operating rooms should be specifically designated and designed for pediatric cardiovascular procedures. Each room should be large and should include a positive-pressure climate control system capable of maintaining humidity at 55% and changing room temperature by 20°F within 15 to 20 minutes. The operating room is best located near the postoperative ICU. The operating room should be equipped with a cardiopulmonary bypass machine, which can deliver precise volumes at low flows against varying impedance with minimal blood trauma. Anesthetic equipment should be suitable for the smallest patients and appropriate also for adult patients.

Clinical data on patients who undergo cardiac surgery should be recorded prospectively in a comprehensive database. A quality assurance program responsible for monitoring and evaluating surgical outcomes should be in place. This program should also review individual deaths and major complications.

CARDIOVASCULAR INTENSIVE CARE

Although cardiac intensive care may be required for patients before surgery, before or after cardiac catheterization, and for medical conditions, the highest level of care is most often required for patients after cardiac surgery. Thus, the ICU providing care for cardiovascular patients should be a cardiac unit organized specifically to provide postoperative care for pediatric heart patients or it should be a pediatric ICU that satisfies AAP guidelines for level I pediatric ICUs[26] (currently being revised) and/or a subspeciality neonatal ICU that satisfies guidelines for perinatal care.[27] Pediatric ICUs and subspeciality neonatal ICUs should be organized to routinely provide postoperative care for pediatric heart patients.

The ICU should be equipped and staffed to provide the following services 24 hours a day, 7 days a week: respiratory support, using the full range of mechanical ventilators and gases (such as nitric oxide and carbon dioxide); complete hemodynamic and cardiac rhythm monitoring and recording; cardiac pacing; open- and closed-chest resuscitation and operating; and ECMO and VADs. Blood gas and basic biochemistry laboratory determinations, radiologic services, echocardiography, and cardiac catheterization should also be available 24 hours a day, 7 days a week.

The ICU staff should include a medical director who should have fellowship training, experience, and specific expertise in the postoperative care of pediatric heart patients. Physicians with primary responsibility for cardiovascular patient care should provide in-house supervision of the unit 24 hours a day, 7 days a week. Coverage by pediatric cardiac surgeons and pediatric cardiologists capable of performing complete echocardiographic assessments

and cardiac catheterization should be available 24 hours a day, 7 days a week. In addition, pediatric subspecialty physicians and surgeons with expertise in critical disease of all other organ systems should be readily available for consultation. ICU nurses should have training and experience in the postoperative intensive care of pediatric heart patients. The nursing staff should be dedicated to the ICU and sufficient to provide 1-to-1 coverage of all high-acuity patients. Appropriate additional staff, such as respiratory therapy technicians, should also be available 24 hours a day, 7 days a week.

RELATIONSHIP OF THE PEDIATRIC CARDIOVASCULAR CENTER TO THE HEALTH CARE ENVIRONMENT

Pediatric cardiovascular centers are established and constituted to provide high-quality cardiac care for pediatric patients. Centers are usually components of pediatric tertiary health care systems. As such and by definition, centers should support and complement related tertiary pediatric programs and centers.

Even more importantly, pediatric cardiovascular centers serve patients within family, school, and community environments. To deliver high-quality cardiac care, centers should partner with primary health care systems and practitioners in cardiovascular disease. Center physicians, particularly pediatric cardiologists, should maintain ongoing dialogue with pediatricians and other primary care practitioners regarding individual patient care plans and problems; case management should be a joint project. In addition, center physicians, in cooperation with the primary care practice team, should be responsible for education of and communication with families and school and community authorities regarding all aspects of patients' cardiovascular care. Other personnel in pediatric cardiovascular centers, such as nurse practitioners, social workers, and patient care representatives, may also be instrumental in these relationships and activities.

QUALITY OF CARE

Existing evidence suggests that certain practices promote high-quality outcomes. Thus, pediatric cardiovascular centers should strive to 1) participate in a regional health care network, 2) use modern information technology, and 3) maintain adequate case volumes to achieve and demonstrate high-quality therapeutic outcomes.

Early experience with regional networks for perinatal and neonatal care and pioneering efforts in regionalizing infant cardiac care by 11 pediatric cardiac centers in 6 states (the New England Regional Infant Cardiac Program) suggest that participation in a regional network of health care providers results in improved outcomes for mothers, infants, and children with heart disease.[28–30] Furthermore, the Northern New England Cardiovascular Disease Study Group has shown that regional intervention, including feedback of outcome data, training in continuous quality improvement techniques, and site visits to other medical centers, improves hospital mortality rates associated with coronary artery bypass surgery.[31] In pediatric cardiology, the Pediatric Cardiac Care Consortium has demonstrated the feasibility of quality improvement as the result of participation in a physician-directed clinical database.[32] Moreover, in many areas of health care, regionalization has been shown to improve access while decreasing costs, numbers of hospital beds, and inpatient days and average length of stay.[33–35]

Improvements in quality of care have been linked to information technology and automated information and decision support systems. There is evidence to suggest that the number of preventable errors can be decreased by use of better information systems that disseminate knowledge about drugs and make drug and patient information readily accessible in a timely manner.[36] Furthermore, computerized drug order entry systems have been shown to decrease the number of errors[37]; computerized laboratory data can alert clinicians to abnormal lab values[38]; and the use of a computerized physician order entry, in which physicians enter and transmit medication orders online, can prevent medication errors attributable to misinterpretation of handwritten orders.[39]

Finally, pediatric heart surgery is one of several classes of procedures for which lower mortality rates have been demonstrated at high-volume hospitals.[40] The relation of in-hospital mortality rates to case volume for congenital heart surgery has been examined in studies using statewide administrative data.[41–44] All have shown a significant correlation between improvement in severity-adjusted mortality rate and increasing institutional case volume. However, institutional case volume explains only a relatively small fraction of the variability in outcomes among pediatric heart surgery programs, and uncommon outcomes such as mortality are difficult to measure with statistical precision for smaller programs. Thus, although "high volume" ensures a certain degree of quality, there is no consistent relationship between quality and "low volume." It is probable that a number of low-volume centers have consistent and excellent results, but the identifiers of these centers have not been elucidated. Quality indicators other than in-hospital mortality rates must be developed to aid in the validation of quality, especially in smaller centers.

CONCLUSION

The quality of outcomes in pediatric cardiovascular centers is the most important measure of center activity. Although outcome assessment in pediatric cardiovascular surgery and intervention is currently rudimentary, basic outcome benchmarks are available and have been incorporated into the guidelines in this statement. Additional outcomes research is ongoing, and future guidelines will require modification to accommodate the results of this research. Nevertheless, the AAP recommends that pediatric cardiovascular centers document and analyze their individual outcomes, strive to achieve and surpass existing quality benchmarks, and commit to contin-

uous quality improvement methodology in all of their programs.

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Section on Cardiology and Cardiac Surgery

Pediatrics 2002;109;544
DOI: 10.1542/peds.109.3.544

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Pediatrics 2002;109;544
DOI: 10.1542/peds.109.3.544