Optimal Resources for Children’s Surgical Care
From the Committee on Children’s Surgery
American College of Surgeons
2014
The American College of Surgeons (ACS) Committee on Children’s Surgery has prepared these optimal resource standards.

The Committee on Children’s Surgery is derived from the ad hoc Task Force for Children’s Surgical Care which met on 3 occasions:

**April 30-May 1, 2012**
- Fizan Abdullah, MD, PhD, FACS, Baltimore, MD
- Marjorie Arca, MD, FACS, Milwaukee, WI
- Douglas Barnhart, MD, MSPH, FACS, Salt Lake City, UT
- Stuart Berger, MD, Milwaukee, WI
- Mary Brandt, MD, FACS, Houston, TX
- Laura Cassidy, PhD, Milwaukee, WI
- Clinton Cavett II, MD, FACS, Indianapolis, IN
- Li Ern Chen, MD, FACS, Dallas, TX
- Jacquelyn Evans, MD, Philadelphia, PA
- Keith Georgeson, MD, FACS, Spokane, WA
- Adam Goldin, MD, FACS, Seattle, WA
- David Hoyt, MD, FACS, Chicago, IL
- Bruce Kaufman, MD, FACS, Milwaukee, WI
- Jacqueline Kueser, Kansas City, KS
- Lynn Martin, MD, Seattle, WA
- R. Lawrence Moss, MD, FACS, Columbus, OH
- Keith Oldham, MD, FACS, Milwaukee, WI
- Shawn Rangel, MD, FACS, Boston, MA
- Thomas Ricketts, PhD, Chapel Hill, NC
- Marshall Schwartz, MD, FACS, Philadelphia, PA
- Thomas Tracy, MD, FACS, Providence, RI
- Mark Wietecha, Washington, DC

**May 30-31 2013**
- Rick Abbott, MD, Bronx, NY
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- Craig Derkay, MD, FACS, Norfolk, VA
- Jay Deshpande, MD, Little Rock, AK
- Jacquelyn Evans, MD, Philadelphia, PA
- Mary Fallat, MD, FACS, Louisville, KY
- Keith Georgeson, MD, FACS, Spokane, WA,
Constance Houck, MD, Boston, MA
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David Hoyt, MD, FACS, Chicago, IL
Bruce Kaufman, MD, FACS, Milwaukee, WI
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Lynn Martin, MD, Seattle, WA
R. Lawrence Moss, MD, FACS, Columbus, OH
Keith Oldham, MD, FACS, Milwaukee, WI
Shawn Rangel, MD, FACS, Boston, MA
Robert Sawin, MD, FACS, Seattle, WA
Mark Wietecha, Washington, DC

May 21-22, 2014
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Stuart Berger, MD, Milwaukee, WI
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Li Ern Chen, MD, FACS, Dallas, TX
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Craig Derkay, MD, FACS, Norfolk, VA
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Jacquelyn Evans, MD, Philadelphia, PA
Mary Fallat, MD, FACS, Louisville, KY
Randall Flick, MD, MPH, Rochester, MN
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Keith Georgeson, MD, FACS, Spokane, WA (not in attendance)
Adam Goldin, MD, FACS, Seattle, WA
BJ Hancock, MD, FACS, Winnipeg, MB, Canada
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Bruce Kaufman, MD, FACS, Milwaukee, WI
Mehwesh Khalid, Chicago, IL
Michael Klein, MD, FACS, Detroit, MI
Clifford Ko, MD, FACS, Chicago, IL
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Lynn Martin, MD, Seattle, WA (not in attendance)
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November 20, 2014

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104  Ramesh Sachdeva, MD, FAAP, Chicago, IL
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106  Marshall Schwartz, MD, FACS, Philadelphia, PA
107  Mark Wieteche, Washington, DC (not in attendance)
108
109
Executive Summary

The Task Force for Children’s Surgical Care, an ad hoc multidisciplinary group of invited leaders in relevant disciplines, assembled in Rosemont, IL initially April 30-May 1, 2012, and subsequently in 2013 and 2014 to consider approaches to optimize the delivery of children’s surgical care in today’s competitive national healthcare environment. Specifically, a mismatch between individual patient needs and available clinical resources for some infants and children receiving surgical care is recognized as a problem in the U.S. and elsewhere. While this phenomenon is apparent to most practitioners involved with children’s surgical care, comprehensive data are not available and relevant data are imperfect. The scope of this problem is unknown at present. However, it does periodically, and possibly systematically result in suboptimal patient outcomes. The composition of the Task Force is detailed above. Support was provided by the Children’s Hospital Association (CHA) and the American College of Surgeons (ACS). The group represented key disciplines and perspectives. Published literature and data were utilized when available and expert opinion when not, as the basis for these recommendations. The objective was to develop consensus recommendations that would be of use to relevant policy makers and to providers. Principles regarding resource standards, quality improvement and safety processes, data collection and a verification process were initially published in March 2014 [J Am Coll Surg 2014;218(3):479-487]. This document details those principles in a specific manner designed to inform and direct a verification process to be conducted by the American College of Surgeons and the ACS Committee on Children’s Surgery.

A summary of key recommendations follows.
LEVELS OF CARE

Table 1. Summary of Children’s Surgical Center Standards with Scope of Practice

<table>
<thead>
<tr>
<th>I</th>
<th>II</th>
<th>III</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>Any</td>
<td>&gt; 6 months</td>
</tr>
<tr>
<td>ASA</td>
<td>1-5</td>
<td>1-3*</td>
</tr>
<tr>
<td>Multidisciplinary management of co-morbidities</td>
<td>Multiple medical and surgical specialties; pediatric anesthesiology</td>
<td>Typically single surgical specialties; neonatology; pediatric anesthesiology</td>
</tr>
<tr>
<td>Operations†</td>
<td>Major congenital anomalies and complex disease including those that are uncommon or require significant multidisciplinary coordination</td>
<td>Common anomalies and diseases typically treated by most pediatric surgical specialists and that do not require significant multi-specialty coordination.</td>
</tr>
<tr>
<td>Ambulatory‡</td>
<td>ASA 1-3</td>
<td>ASA 1-3</td>
</tr>
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<td></td>
<td>Full term and preterm infants may be cared for as ambulatory patients based on written guidelines established by the pediatric anesthesiologist in charge of perioperative care. Institutional guidelines generally require full term infants &lt; 4 weeks or preterm infants &lt; 50 weeks PMA weeks to be monitored for at least 12 hours postoperatively.</td>
<td>Full term and preterm infants may be cared for as ambulatory patients based on written guidelines established by the pediatric anesthesiologist in charge of perioperative care. Institutional guidelines generally require full term infants &lt; 4 weeks or preterm infants &lt; 50 PMA to be monitored for at least 12 hours postoperatively.</td>
</tr>
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PMA = Post menstrual age

*Emergent procedures in some patients > ASA 3 may be appropriate in neonatal patients such as those with necrotizing enterocolitis.
†Types of anomalies and diseases that should have pediatric subspecialty care are further delineated in Appendix 1. Depending upon patient age, co-morbidities and need for multi-disciplinary surgical approach, these may be appropriate for either Level I or Level II centers. ‡Ambulatory sites of care are included in these recommended levels of institutional designation when the onsite provider team possesses the requisite pediatric training and experience. The site of care may be physically attached/integrated into the hospital or may be a component of a demonstrably integrated children’s health care delivery system that provides these defined resources.

Required access to subspecialty surgical and medical providers is defined and detailed subsequently within this document.

PEDIATRIC SURGERY

Level I Centers

Two or more pediatric surgeons must be on the medical staff (CD 2-7). These individuals should serve as the primary operating surgeon for children 5 years of age or younger undergoing relevant general and thoracic procedures (as defined by the Pediatric Surgery Board of the American Board of Surgery). A pediatric surgeon’s physical presence is required in the operating room for operative procedures for which he/she is the primary surgeon (CD 2-8). A pediatric surgeon is defined as an individual certified or eligible for certification in pediatric surgery by the Pediatric Surgery Board of the American Board of Surgery or equivalent body. A
pediatric surgeon must be available and respond to the bedside within 60 minutes 24/7 when required (CD 2-9). A relevant published call schedule must be readily available (CD 2-10).

Local criteria must be established to define conditions requiring the attending surgeon’s physical presence and a PIPS program must verify compliance (CD 2-11).

Level II Centers

Level II children’s surgical centers are required to have one or more pediatric surgeons available on a consultant basis to provide care within 60 minutes of such a request 24/7 (CD 2-59) and provide relevant care for children 5 years of age or less as for a Level I center. An appropriate published call schedule must be readily available (CD 2-60). Local criteria must be established to define conditions requiring the attending surgeon’s physical presence and a PIPS program must monitor compliance (CD 2-61).

Level III Centers

A Level III children’s surgical center must have continuous 24/7 availability within 60 minutes of general surgeons and anesthesiologists with pediatric expertise (CD 2-83). A general surgeon with pediatric expertise is defined as a surgeon either eligible for certification or certified by the American Board of Surgery or equivalent in general surgery. In addition, this individual will demonstrate ongoing clinical engagement and expertise in children’s surgery as evidenced by performing 25 or more procedures annually in patients less than 18 years of age, as well as completion of 10 or more relevant Category I CME credit hours annually. (CD 2-84)
Level I Centers

For Level I children’s surgical centers, two or more pediatric anesthesiologists must be on the medical staff (CD 2-12) and one must serve as the primary anesthesiologist for all children 5 years of age or less (CD 2-13). A pediatric anesthesiologist’s physical presence is required for procedures for which he/she is the primary credentialed provider (CD 2-14). A pediatric anesthesiologist is defined as an individual certified or eligible for certification in pediatric anesthesiology by the American Board of Anesthesiology or equivalent body. A pediatric anesthesiologist must be available to respond to the bedside and provide service within 60 minutes 24/7 when required (CD 2-15). A relevant published call schedule must be readily available (CD 2-16). Local criteria must be established to define conditions requiring the attending anesthesiologist’s physical presence and a patient improvement/patient safety (PIPS) program must verify compliance (CD 2-17).

Level II Centers

For Level II children’s surgical centers, one or more pediatric anesthesiologists must be on the medical staff (CD 2-62) and must be available 24/7 within 60 minutes to serve as the primary anesthesiologist for children 5 years of age or less (CD 2-63). A relevant published call schedule must be readily available (CD 2-64). Local criteria must be established to define conditions
requiring the attending anesthesiologist’s physical presence and a PIPS program must verify compliance (CD 2-65).

Level III Centers

A Level III children’s surgical center must have continuous 24/7 availability within 60 minutes of general surgeons with pediatric expertise and anesthesiologists with pediatric expertise (CD 2-83).

An anesthesiologist with pediatric expertise is defined as an anesthesiologist either eligible to certify or with a current certificate from the American Board of Anesthesiology or equivalent. He or she would demonstrate continuous experience with children < 24 months of age, defined as 25 patients per anesthesiologist per year. In addition, this individual will demonstrate ongoing pediatric clinical engagement in patients less than 18 years of age, and complete 10 or more relevant Category I CME credit hours annually. (CD 2-85)

DATA COLLECTION

Every verified children’s surgical center must collect and analyze its surgical outcome data and contribute it to the national collaborative effort (CD 7-1). For centers designated Level I or II this will be fulfilled by participation in the American College of Surgeons National Quality Improvement Program-Pediatric (NSQIP Pediatric) (CD 7-2). For Level III centers and
ambulatory surgical centers this requirement will be fulfilled by reporting of specific adverse events detailed in Appendix 3 (CD 7-3).

PERFORMANCE IMPROVEMENT AND PATIENT SAFETY (PIPS)

A children’s surgery Performance Improvement and Patient Safety (PIPS) program is an essential component of a high quality clinical surgical program. (CD 8-29) The unique elements of perioperative care of children with surgical diseases require a focused quality and safety construct that supplements existing hospital QI activities. The PIPS program for a Level I or Level II center must be a specific children’s surgical program (CD 8-30); Level III and ambulatory centers may utilize processes integrated within existing institution wide efforts to achieve these stated objectives. (CD 8-31) The programs for Level I and II centers must include the following elements:

- Shall be a confidential quality improvement activity that is protected by all pertinent state and federal statutes. (CD 8-32)
- Must be integrated with all appropriate hospital quality improvement and safety programs and with the Board of Trustees quality committee or equivalent. (CD 8-33)
- May be a dedicated sub-committee of a hospital’s existing PIPS program but must be focused on improving children’s surgical care within the institution. (CD 8-29, CD 8-30)
- Must be chaired or co chaired by the medical director of children’s surgery (MDCS) or her/his designee. (CD 8-34)
- Must include representatives of all surgical disciplines that provide care to children in the participating center, as well as pediatric anesthesiology and radiology. When within
scope of hospital surgical services, neonatology, pediatric intensive care, and emergency medicine representatives must also participate. (CD 8-35)

- Must meet at least quarterly. (CD 8-36)
- Members or designees must attend at least 50% of the PIPS meetings. (CD 8-37)
- Must establish criteria for care delivery by providers in each specialty, including individual providers’ credentials that document their validity as pediatric specialists in the respective disciplines. (CD 8-38)
- Must establish criteria for conditions that require physical presence of specific specialty providers. (CD 8-39)
- Must monitor the compliance of providers and the program with all criteria including physical presence of providers when indicated. (CD 8-40)
- Must review all surgical deaths, a significant cohort of surgical complications, and any serious safety events related to children’s surgical care. (CD 8-41)
- Should review the program’s quality performance metrics compared to national benchmarks and develop plans to address any significant outlying metrics.
- Must review all transfers to Level I programs for appropriateness, timeliness, and outcome. (CD 8-42)
- Will disseminate the reviews of the PIPS to all pertinent participants in the children’s surgical care program and the hospital leadership. (CD 8-43)

VERIFICATION

The American College of Surgeons has a long history of activities directed toward the improvement of surgical care. This new program defines the resources believed necessary to...
achieve optimal patient outcomes for children’s surgical care at designated centers and offers institutional consultation and/or verification. This program is administered by the American College of Surgeons (ACS) Committee on Children’s Surgery. This document, *Optimal Resources for Children’s Surgical Care* is to be used as a guide for the development and verification of centers throughout the United States. It is the basis upon which centers will evaluated by ACS approved site surveyors.
Introduction

The American College of Surgeons (ACS) was founded in 1913 on the basic principles of improving the care of surgical patients and strengthening the education of surgeons. With this in mind, the ACS Committee on Children’s Surgery was created in 2014 to continue on a permanent basis within the ACS the work of the ad-hoc Task Force on Children’s Surgical Care. This group was first convened in 2012 and has worked continuously since that time, including assemblage as an entire group on three occasions for in person discussion. The recommendations of this Task Force have been disseminated [J Am Coll Surg 2014;218(3):479-487].

The ACS Committee on Children’s Surgery was established with the goal of improving the care of children with surgical needs. This process includes defining optimal resource standards and matching these prospectively to an individual child’s needs. Achievement of this goal requires an appropriately designed system of care and includes verification that these standards are met in individual children’s surgical centers. We intend to continuously review and improve this document as new information and more data are developed that can be applied to its content. Our intent is to use evidence-based scientific methods to support recommendations. We used existing data where possible and combined this with expert opinion to establish consensus and formulate these current standards. Multiple research efforts are underway to strengthen the evidence base as well.

We believe that these standards reflect a realistic assessment of our current resource capability while emphasizing the goal of providing the highest quality patient care. We recognize that these standards will certainly challenge our existing models of children’s surgical care. We are
confident that the objective of improving children’s surgical care is correct and that it is a collective professional responsibility. It is an expectation of the public as well. These standards are meant to be positive and constructive. We believe they are likely to improve clinical outcomes for children. This effort is envisioned to provide impetus for a broad based initiative that includes process improvement of systems of care as well as research and provider education. It is a multidisciplinary effort undertaken with specialty societies and representatives who speak for those across the entire continuum of children’s surgical care. This initial standards document will be subject to evolution and revision as practice continues to change and improve.

Few individual facilities can provide all resources to all children in all situations. Ultimately, all patients who require the resources of the Level I center should have access to it. This reality requires the development of systems of care for children with surgical needs, not simply the development of children’s surgical centers.

An ideal children’s system includes all of the components identified to be optimal for children’s surgical care. Elements include considerations such as appropriate access, high quality developmentally appropriate acute hospital care and ambulatory care, rehabilitation and relevant research and education activities. Although the focus of this document is children’s surgical center consultation and verification, it also emphasizes the need for various levels of children’s surgical centers to cooperate to meet children’s surgical needs in order to avoid poor use of precious medical resources. In an era where value is a public demand, we must strive not only for optimal care, but we must provide this care in a cost effective manner.
Emphasis has been placed on identifying criteria that are judged essential for each level of children’s surgical center designation. These criteria are referenced in each chapter by terms such as “must”, “essential”, “required”, and so forth and are delineated by number identifying the criterion and chapter; for example (CD 5-2) is the second criterion in Chapter 5. The authors recognize that some criteria will change or be added or deleted as more knowledge is obtained based on data that become available. These current standards represent expert consensus on resource standards judged most likely to yield optimal clinical outcomes for patients. We are hopeful they will supplement rather than supplant various state and other existing administrative processes such as Certificate of Need (CON) regulations.

**Definitive Care Facilities**

Essential to the development of a children’s surgical care system is the designation of definitive children’s surgical care facilities. The children’s surgical care system is ideally a network of definitive care facilities that provides the spectrum of care necessary for all children with surgical needs. Ideally, every center that provides surgical services to children would define its scope of practice and provide appropriate resources as defined by the level designations described in this document. Some population dense areas may have multiple Level I centers as well as Level II and III centers. A Level I facility will provide support for centers with less intensive children’s resources. This should be determined locally to insure appropriate use of available resources. In less densely populated and rural areas, Level II and III hospitals will be essential. Likewise, cooperative relationships with other centers are needed. Because a large proportion of children with surgical needs receive care in an outpatient environment, ambulatory
surgery must also be considered in this discussion. In any such system, determining the anticipated number and character of children with surgical needs and assessing available resources to determine the optimal number and level of children’s surgical centers in a given area is essential.

In most children’s health care systems, a combination of levels of designated centers will coexist with other facilities. The children’s surgical care system must establish relevant facility and personnel standards. This document is the initial effort to establish these standards. We have attempted to emphasize resource differentiation between centers. We do not view our classification scheme as a ranking of medical quality. We expect the commitment to quality care to be the same regardless of resources.

We hope that one of the outcomes of this initiative is that all children who require health care services including surgical care will receive the appropriate care regardless of ability to pay. The Emergency Medicine Treatment and Labor Act imposes obligations on Medicare participating hospitals that offer emergency services to provide medical screening examination or treatment for an emergency medical condition, regardless of ability to pay. Hospitals are required legally and ethically to provide stabilizing treatment for a child, as well as appropriate transfer when required.
Level I

The Level I children’s surgical center is a regional resource that is a tertiary care facility central to the children’s health care system. This facility must have the capability of providing leadership and comprehensive care for all aspects of children’s surgical needs. In this central role, the Level I center must have adequate depth of resources and personnel.

In addition to acute care responsibilities, Level I children’s centers have the major responsibility of providing leadership in education, research and system planning. This responsibility includes the expectation of cooperation and prospective planning with all hospitals caring for children with surgical needs in their region. Recognizing that they will need to provide care for young families with few resources who may be far from home and local support systems, Level I centers also have responsibility for assisting the families with managing travel burden as well as psychological, spiritual, and social support.

Research and education programs, as defined in this document, are essential for Level I children’s surgical center verification. Medical education programs require relevant residency program support and postgraduate training in children’s surgical care for physicians, nurses and other providers. Education can be accomplished through a variety of mechanisms including related fellowship training programs, continuing medical education (CME), preceptorships, personnel exchanges and other approaches appropriate to the local situation.
Level II

The Level II children’s surgical center is a hospital that is expected to provide initial children’s surgical care regardless of the complexity of the need and definitive care when appropriate. Depending on geographic location, patient volume, personnel and resources, the Level II center will not be able to provide the same comprehensive care as a Level I children’s surgical center. Therefore, patients with more complex, particularly multidisciplinary needs may require transfer to a Level I center. In some areas where a Level I center does not exist, the Level II center will take on the responsibility for education and regional leadership.

Level III

The Level III children’s surgical center serves communities that do not have immediate access to a Level I or II institution. These Level III children’s surgical centers can provide prompt assessment, resuscitation, emergency operations and stabilizations and also arrange for possible transfer to a facility that can provide definitive surgical care. Additionally, Level III children’s surgical centers may provide a limited scope of services in areas where there is a Level I or II institution. Procedures that are less complex for patients who are generally low risk may be definitively cared for in this environment. General surgeons with pediatric expertise and anesthesiologists with pediatric expertise are required at a Level III children’s surgical center. Ideally these centers provide these services as part of an organized system of care in coordination with Level I or II centers. Planning for care of children with surgical needs at these hospitals requires transfer agreements and standardized treatment protocols. Level I and II children’s
surgical centers have an obligation to extend their educational activities to rural areas in the form of professional education, consultation, or community outreach. A process should exist to provide feedback about individual patient care and outcome analysis to the referring hospital.

**Children’s Ambulatory Surgical Centers**

These standards were developed because a large proportion of children’s surgical needs are managed on an outpatient basis in a contemporary environment; this may be half or more of all children who undergo surgical procedures. While these children are generally healthy and do well, the uncommon consequences of perioperative problems, particularly related to anesthesia, may be life threatening. These standards have been developed in an effort to minimize this risk.

Children’s ambulatory surgery centers must have treatment protocols for resuscitation, transfer protocols, data reporting and participate in systems performance improvement. Children’s ambulatory centers must have good working relationships and be fully integrated with a Level I, II or III inpatient children’s surgical center. This relationship is vital to the development of a children’s surgical system in which realistic standards must be based on available resources.

Optimal ambulatory children’s surgical care in rural areas can be provided by skillful use of existing professional and institutional resources supplemented by guidelines that result in enhanced education, resource allocation, and appropriate designation for all levels of providers.

It is essential for the children’s ambulatory surgical center to have the involvement of one or more committed and appropriately trained health care providers to provide leadership and sustain the integration with other relevant centers.
No ambulatory surgical facility without a defined relationship demonstrating integration with a Level I, II or III children’s surgical center will be verified by the ACS. This relationship requires a plan to facilitate expeditious transfer of seriously ill children who require a higher level of care. Exchange of medical personnel between Level I, II and III inpatient and ambulatory surgical centers may be an excellent way to develop this relationship.

Consultation and Verification Process

An obvious corollary for this type of document defining resource standards for children’s surgical needs is the development of a consultation and verification process whereby a hospital or health system can be evaluated to determine whether ACS criteria are being met. This verification process for children’s surgical centers is now available through the American College of Surgeons. This document was developed to aid the process of consultation and verification of children’s surgical centers. Attention is given to defining resources available within an inclusive system for children’s surgical care. As this verification process matures, it will yield better definitions and new standards for many of the assessed areas within the hospital.

Principles for this 1st Edition

This is the first edition of the ACS-Committee on Children’s Surgery document entitled Optimal Resources for Children’s Surgical Care. It is intended to establish resource standards that assure that individual patient needs are matched prospectively with available institutional resources in an effort to provide the safest and highest quality care possible. It will, over time, undergo substantial change. Many individuals volunteered a significant amount of their time, energy,
experience and knowledge drafting this document. The individuals involved include those
delineated as Task Force members and also participants from all of the surgical disciplines
represented within the American College of Surgeons, with much additional multidisciplinary
input from other individuals and professional organizations relevant to children’s surgical care.
This document attempts to define the resources needed at various types of facilities to provide
optimal care. The authors were guided by a number of principles that are worth mentioning.

**Emphasis on a Children’s Health System Rather Than the Children’s Surgical Center**

Optimal care of children with surgical needs requires a systems approach. No one children’s
center can do everything alone. Thus, a systems approach is necessary within a community
regardless of its size. In some cases, the system may encompass a region or even an entire state.
If resources for optimal care of children’s surgical needs are to be used wisely, then some
concentration of resources should occur. This type of resource distribution should allow patients
to move to the appropriate level of available care and, ideally, match to a child’s individual
perioperative needs. This should avoid excessive, inadequate or inappropriate resource
expenditure in a time of limited resources.

**Difference in External Environment**

It is recognized that we provide surgical care to children in urban and rural environments that
are often very different. Rural environments often, but not always, have fewer clinicians and less
complex facilities and technology. Although a perfect definition cannot be found for these
environments, an attempt is made to recognize the needs of these different settings. However, in either environment, the matrix is predicated on the fact that children with the most complex needs must be treated at more resource-intense facilities. Facilities must interact with one another to optimize care within and across both environments.

**Differentiation Between Levels of Care**

A sincere attempt was made to clearly differentiate resource needs between the defined levels of care. Although the quality of care is expected to be similar at all levels of care, the complexity and volume of children with surgical needs were accepted as the drivers of resource needs and level designation. As complexity and volume increase, more human and capital resources are required to ensure optimal care. Hopefully, the differences in resource requirements will allow each facility at each level to allocate acceptable resources based on the needs of the patient population served. Our resource standards have been developed with an effort to be pragmatic given the current medical economic environment.

**Human Resource Commitment**

The capacities and skill sets of pediatric surgeons, specialty children’s surgeons, pediatric anesthesiologists and others with specialized pediatric training have been defined elsewhere. Defining their roles in teams related to systems of children’s surgical care is a point of emphasis in this document. Individuals from these specialties who intend to care for children must take an active role in the children’s surgical program in any system providing care to children. As the
level of care increases, these physicians must become more involved and be part of the resource
commitment for a successful children’s surgical program. The role of the administrative support
team is defined as well.

**Involvement of Surgeons and Physicians**

Resources necessary for optimal children’s surgical care include human capital, facilities,
technology and the organization of care. The optimal care goal assumes that the human
resources include the most highly trained and qualified medical professionals available to treat
our children. This document establishes the level of responsibility for surgeons,
anesthesiologists and others involved in the perioperative care of children with surgical needs.
These individuals must be readily available 24 hours a day in facilities providing the highest
level of care.

**Neonatology and Critical Care Services**

The need for access to perioperative critical care services for infants and children undergoing
surgery is evident. Resource requirements defining and delineating these are provided in this
document. It is required that critically ill patients of any age have appropriate and immediate
physician and nursing coverage when needed.
Available data emphasize the critical role of specialty trained pediatric anesthesiology providers for infants and young children undergoing surgery. For several decades, it has been apparent that the highest perioperative risk for anesthesia is in neonates and infants, and furthermore that this risk can be diminished by the deployment of individuals with the unique skills acquired in pediatric anesthesiology specialty training. In October 2013, the American Board of Anesthesiology administered for the first time a certifying examination leading to a certificate of added qualification in pediatric anesthesiology. This standard is incorporated into this document.
CHAPTER 1

Responsibilities of Regional Systems of Care

More than 5 million infants and children undergo a surgical procedure in the United States annually. Some are relatively simple; some are quite complex. Patient risk factors that influence outcome include a host of medical and surgical comorbidities; notably young age is an important one of these. Optimal anesthesia and airway management in infants and children require specific training and skills; infrequently encountered problems may be life threatening. Neonatal and other pediatric critical care capacity may be necessary to provide appropriate perioperative care. The volume of surgical care and the potential complexity are enormous. Given the large number of infants and children involved, uncommon negative events are certain to occur. Given the potential consequences to an individual patient, optimal care of a population requires a planned system of care for children’s surgical services. All verified children’s surgical centers must participate in state and/or regional system planning/development or operation. (CD 1-1)

As a means for further assisting the development of state and regional children’s surgical systems, the ACS-Committee on Children’s Surgery will initiate a program for system consultation. Unlike center verification, this program is purely consultative and designed to be applied to a system at any stage of development. The consultative process for a children’s surgical system involves a site visit by a multidisciplinary team and a comprehensive analysis of all of the components and the functionality of the state or regional system.
Role of Designated Children’s Surgical Centers in the Development of Regional Systems

As the scope of activity for the provision of children’s surgical care expands from single centers to multifaceted systems, it becomes increasingly important that designated centers be effectively engaged in all aspects of system planning, implementation and evaluation within their region.

Designated centers are a key element in a system and the focal point for treatment. Centers typically contribute administrative leadership, medical leadership and academic expertise to a state or regional system. Lead facilities in a given region (Level I or II) have the additional challenge of engaging all other acute care facilities, designated centers and nonspecialty hospitals in the performance improvement process for an inclusive children’s surgical system.

Meaningful participation in state and regional system planning, development and operation is essential for all designated facilities within a region (CD 1-1). This participation will be dependent on local administrative structures, history, vision and the state of system development.

Examples of participation by center staff include the following:

- Participation in state and regional advisory committees
- Leadership in state and regional medical committees responsible for children’s medical and surgical care
- Regular collaboration with regional committees, or other relevant entities to promote development of state and regional systems
- Participation in media and legislative education to promote and develop children’s care systems
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- Participation in state and regional needs assessment or surveillance
- Participation in the development of a state or regional plan or registry
- Provision of technical assistance and education to regional hospitals and providers for the purposes of improving system performance
- Leadership in development of regional transport systems for infants and children
CHAPTER 2

Children’s Surgical Center Levels and Their Roles in a System of Care

An ideal children’s health system provides all of the elements of optimal care, including prompt and appropriate access, high quality acute hospital and ambulatory care, rehabilitation, health maintenance and relevant research and education activities. Our focus here is children’s surgical care and central to an ideal system is a relatively large, resources-rich center. The need for resources is based primarily on the patient centered concept of being able to provide the right medical care to an individual patient at the right time.

Optimal resources at a Level I children’s surgical center includes immediate availability of board-certified or board eligible pediatric specialty anesthesiologists, pediatric surgeons, subspecialty children’s surgeons, neonatologists, pediatric intensivists and pediatric emergency physicians. Other board-certified pediatric specialists would be similarly available, within a short time, to all patients who require their expertise. To assure adequate experience, this center would require a certain volume of patients to be admitted each year and would include the most complex and high-risk patients from the system. In addition, certain needs that occur infrequently should be concentrated in this special center to ensure that these patients are properly treated and studied. Research activities are necessary to enhance our knowledge of the care of children with complex surgical needs. Research in areas relevant to children’s surgical care should be present. This center would have an integrated, concurrent performance improvement and patient safety (PIPS) program to ensure optimal care and continuous improvement in care. This center would be responsible not only for assessing care provided
within its surgical program, but also for helping to organize the assessment of care within the entire system or region. This center should serve as a comprehensive resource for all entities dealing with children’s surgical patients in the system and potentially the region. Verified centers should demonstrate commitment toward reaching this ideal.

Surgeon commitment is essential for a properly functioning children’s surgical center (CD 2-1). In fact, without surgical leadership, the program will not be able to meet all the requirements outlined in *Optimal Resources for Children’s Surgical Care*. Although this commitment may be difficult to measure objectively, it can be recognized in a number of ways, including a children’s surgeon who is the medical director of the program, surgeons who take an active role in all aspects of caring for surgical infants and children, active surgical participation in the PIPS program, and surgeons who take an advocacy role for patients. The PIPS program must be inclusive of relevant medical and surgical providers actively participating in children’s surgical care (CD 2-2). Surgical leaders who promote the program to the community, hospital, and other colleagues also should be easily recognized. Therefore, surgical commitment is a valuable resource that is integral to a successful children’s surgical program.

The ACS supports children’s surgical center and system development and related public health policies, including needs assessment, policy development and quality assurance. Each community should assess its true needs for children’s surgical care, emphasizing a system approach. The center classification scheme (Level I, Level II, Level III, and Ambulatory) is intended to assist communities in the development of their system for children’s surgical care. Centers developed should match the medical and access needs of the pediatric population which
is reasonably expected to require and use these surgical services. Every community of providers should ensure that resources are used appropriately to achieve the stated goal of optimal care for children undergoing surgery. The goal of every system is to match the needs of patients to the capabilities of the facility. Proper triage is a critical feature of a good system and is necessary to achieve this goal. Transport to appropriate facilities will optimize outcome and utilization of resources. Although payor status is an important feature of the U.S. health care system, medical necessity is paramount. Children’s surgical centers at all levels of verification must accept referrals of all medically appropriate patients within their region from centers without the necessary children’s surgical capacity regardless of payor (CD 2-3). To properly function, the system requires proper communication systems and clear, well-defined protocols for triage and transport. In addition, well-designed systems facilitate the acquisition of new knowledge through effective clinical research.

Objective, extramural verification of a hospital’s resources, commitment, and capability is an important early step in the development of a regional system. Owing to the inherent differences in population density, geography, and health care resources, each regional system will be individualized to achieve optimal patient care.

Regardless of the size of an area, each system should have an identified lead hospital. Ideally, one hospital, typically a Level I center, would be looked upon as the resource leader within a given region. This hospital would serve as a resource to all other hospitals within the system. Outside major population centers, Level II centers may serve as the lead hospital for extended geographic areas. In some rural areas, where population densities are low and distances great, a
Level III center may be the only resource for miles. Ambulatory surgery centers are considered separately, but in any system will have clearly identified relationships and demonstrable integration with one or more verified Level I, II or III children’s inpatient facilities (CD 2-4).

Description of Children’s Surgical Center Levels

Children’s surgical centers must be able to provide on their campuses the necessary human and physical resources to properly provide children’s surgical care consistent with their level of verification. (CD 2-5)

Level I

A Level I children’s surgical center should be a regional resource center and generally serve large cities, population-dense or large catchment areas. This institution will usually serve as the lead hospital for the system. In larger population-dense areas, more than one Level I designated center may be appropriate. This institution is expected to manage large numbers of patients. A Level I children’s surgical center must perform surgical procedures for at least 1000 patients less than 18 years of age annually. (CD 2-6)

A Level I children’s surgical center is expected to provide optimal care to neonates, infants, children and adolescents regardless of age and medical and surgical comorbidities. This requires access to a comprehensive portfolio of medical and surgical subspecialists on the medical staff who are readily available 24/7 to provide bedside care. The scope of service includes care for
major congenital anomalies and complex diseases including those that are uncommon or require significant multidisciplinary coordination.

Two or more pediatric surgeons must be on the medical staff (CD 2-7). These individuals should serve as the primary operating surgeon for children 5 years of age or younger undergoing relevant general and thoracic procedures (as defined by the Pediatric Surgery Board of the American Board of Surgery). A pediatric surgeon’s physical presence is required in the operating room for operative procedures for which he/she is the primary surgeon (CD 2-8). A pediatric surgeon is defined as an individual certified or eligible for certification in pediatric surgery by the Pediatric Surgery Board of the American Board of Surgery or equivalent body. A pediatric surgeon must be available and respond to the bedside within 60 minutes 24/7 when required (CD 2-9). A relevant published call schedule must be readily available (CD 2-10). Local criteria must be established to define conditions requiring the attending surgeon’s physical presence and a PIPS program must verify compliance (CD 2-11).

For Level I children’s surgical centers, two or more pediatric anesthesiologists must be on the medical staff (CD 2-12) and one must serve as the primary anesthesiologist for all children 5 years of age or less (CD 2-13). A pediatric anesthesiologist’s physical presence is required for procedures for which he/she is the primary credentialed provider (CD 2-14). A pediatric anesthesiologist is defined as an individual certified or eligible for certification in pediatric anesthesiology by the American Board of Anesthesiology or equivalent body.
A pediatric anesthesiologist must be available to respond to the bedside and provide service within 60 minutes 24/7 when required (CD 2-15). A relevant published call schedule must be readily available (CD 2-16). Local criteria must be established to define conditions requiring the attending anesthesiologist’s physical presence and a PIPS program must verify compliance (CD 2-17).

In a Level I center, all surgical specialists require institutional credentials for specific privileges for operative procedures to be done in children (CD 2-18).

A Level I children’s surgical center must maintain appropriate neonatal and pediatric critical care services with demonstrable surgical leadership participating in their operational management. (CD 2-19) Children’s surgeons must participate in the care of surgical patients specific to their surgical fields, including planning and implementation of major therapeutic decisions (CD 2-20), presence at major resuscitations (CD 2-21), presence at operative procedures (CD 2-22), and involvement in the critical care of all infants and children receiving perioperative care (CD 2-23). A Level I children’s surgical center must participate in the training of surgical residents (CD 2-24), be a leader in surgical education and outreach activities (CD 2-25), and conduct surgical research (CD 2-26).

A Level I children’s surgical center is required to provide resources consistent with Level IV NICU designation (CD 2-27). Neonatal Intensive Care Unit (NICU) designations are those

Level I children’s surgical center designation requires 24/7 neonatologist availability when a neonatologist is not on site. (CD 2-28) This must be verified in the PIPS process (CD 2-29). A neonatologist is defined as an individual who is either sub-board eligible or certified by the American Board of Pediatrics in Neonatal-Perinatal Medicine or equivalent. Level IV NICUs must maintain a full complement and range of pediatric medical subspecialists, children’s surgical subspecialists and pediatric anesthesiologists on site (index institution is the primary site of practice). (CD 2-30)

A Level I children’s surgical center must have a dedicated pediatric intensive care unit (CD 2-31). A dedicated pediatric intensive care unit requires pediatric intensivist availability 24/7 with individuals certified in critical care medicine by the American Board of Pediatrics, the American Board of Anesthesiology or the American Board of Surgery or equivalent organizations. (CD 2-32) This must be verified in the PIPS process (CD 2-33). This unit must be fully dedicated to pediatric patients (CD 2-34) and support staff must have demonstrable relevant pediatric training and expertise (CD 2-35). Appropriate pediatric equipment must be available for the scope of service (CD 2-36).

Two or more pediatric radiologists must be on the medical staff of a Level I children’s surgical center (CD 2-37) and one must be available to provide appropriate service within 60 minutes 24/7 (CD 2-38). A pediatric radiologist is defined as an individual certified by the American Board of Radiology or equivalent in addition to being certified or eligible for certification in
pediatric radiology by the American Board of Radiology or equivalent. Remote electronic image analysis is a permissible adjunct, however individuals trained and skilled in hands on pediatric imaging such as fluoroscopy must be physically available within 60 minutes. (CD 2-39) This must be verified in the PIPS process (CD 2-40). In addition to 24/7 pediatric radiologist coverage, interventional radiology physicians and support personnel must be available 24/7 for designation as a Level I children’s surgical center. This must be verified in the PIPS process (CD 2-41).

Level I children’s surgical centers must have pediatric emergency physician coverage 24/7 (CD 2-42). A pediatric emergency physician is an individual who is Board certified or eligible either in pediatrics or emergency medicine with ACGME-approved or equivalent pediatric fellowship training for this specialized designation. In addition, children’s specific emergency department resources must be in place to support Level I designation, including dedicated facilities (CD 2-43), pediatric appropriate equipment (CD 2-44) and nonphysician personnel with specific pediatric training (CD 2-45).

Level I children’s surgical centers must have pediatric medical and surgical specialists promptly and readily available for consultation; these specialists must be on the medical staff and available within 60 minutes, 24/7 to provide care at the bedside (CD 2-46). A portion of this 24/7 coverage may be provided by appropriately trained specialists who lack pediatric certification. In this case the medical director of children’s surgery and institutional surgical subspecialty leaders must prospectively define the scope of practice of these providers. (CD 2-47) There must be a plan for provision of pediatric subspecialty care outside this limited scope of practice if needed during
periods when call coverage is provided by surgeons without pediatric certification. (CD 2-48)
The medical director of children’s surgery and institutional subspecialty leaders must monitor compliance with this plan (CD 2-49). Here and elsewhere in this document, pediatric medical and surgical specialists are defined as those who are either eligible for or Board certified after relevant children’s specialty fellowship training (either medical or surgical) and recognized by the appropriate Board of the American Board of Medical Specialties or equivalent. Relevant children’s surgical specialists will be available to support the entire scope of institutional surgical practice in infants and children. (CD-50) Where providers with pediatric specific training and experience are designated as “available”, the requirement is that patient care will be demonstrably provided by these specialized children’s medical and surgical providers (CD 2-51).

A pediatric rapid response and/or resuscitation team is required for Level I designation (CD 2-52). This requires 24/7 physical presence of a pediatric specialty physician or surgeon to include PALS certification, in the leadership role. (CD 2-53)

Level I centers are required to participate in a data collection program which yields peer performance assessments against which an individual program may be externally measured (CD 2-54). This should include the ability to assess clinical outcomes at an individual level as well as for the population served. This requirement is detailed in Chapter 7.

It is appropriate to include ambulatory sites of care in Level I institutional designation if a fully integrated or onsite ambulatory surgery care team possesses pediatric training and experience consistent with the above requirements, and the site of care is a component of a demonstrably
integrated children’s health care delivery system that does provide resources appropriate for the scope of practice. (CD 2-55)

Level II

A Level II children’s surgical center provides comprehensive surgical care in two distinct environments that are recognized in the verification program sponsored by the ACS. The first environment is a population-dense area where a Level II children’s surgical center may complement the clinical activity and level of resources of a Level I institution to serve the needs of a broad regional population. In this scenario, the Level I and II children’s surgical centers should work together to optimize resources expended to care for all children with surgical needs in their area. This implies a cooperative environment between institutions that allows patients to flow between hospitals, depending on resources and clinical expertise.

The second Level II environment occurs in less population-dense areas. The Level II hospital serves as the lead children’s facility for a geographic area when a Level I institution is not geographically close. This may be the best model for many rural areas. This lead hospital should have an outreach program that incorporates smaller institutions in the same service area.

In either environment, children’s surgeons must participate in the care of surgical patients specific to their surgical fields, including planning and implementation of major therapeutic decisions (CD 2-56), presence at major resuscitations (CD 2-57), presence at operative
procedures (CD 2-58), and involvement in the critical care of all infants and children receiving perioperative care (CD 2-59).

The scope of service for Level II children’s surgical centers potentially includes definitive care for neonates, infants, children and adolescents; it may be limited to neonates or other specific populations (i.e. Women’s and Children’s centers or military hospitals). Generally, the surgical care will include children with low risk or moderate comorbidities (ASA 1-3), although it may include infrequent emergency procedures in higher risk patients. Typically the procedures involve a single specialty treating common anomalies and diseases typically treated by most pediatric surgical specialists in that discipline, and that do not require significant multispecialty coordination.

Level II children’s surgical centers are required to have one or more pediatric surgeons available on a consultant basis to provide care within 60 minutes of such a request 24/7 (CD 2-60) and provide relevant care for children 5 years of age or less, as in a Level I center. An appropriate published call schedule must be readily available (CD 2-61). Local criteria must be established to define conditions requiring the attending surgeon’s physical presence and a PIPS program must monitor compliance (CD 2-62).

For Level II children’s surgical centers, one or more pediatric anesthesiologists must be on the medical staff (CD 2-63) and must be available 24/7 within 60 minutes to serve as the primary anesthesiologist for children 5 years of age or less (CD 2-64). A relevant published call schedule must be readily available (CD 2-65). Local criteria must be established to define conditions...
requiring the attending anesthesiologist’s physical presence and a PIPS program must verify compliance (CD 2-66).

A Level II children’s surgical center is required to have a Level III or higher NICU as delineated in Appendix 1 (CD 2-67). Level III NICUs must provide prompt and readily available access to a full range of pediatric medical subspecialists and neonatologists, pediatric surgeons, pediatric anesthesiologists and pediatric ophthalmologists (CD 2-68) (this requirement may be fulfilled by on site specialists or by individuals at a closely related institution by prearranged consultative agreement). Level II centers that limit the scope of practice to neonatal patients are not required to have ICU services beyond that of the Level III NICU. Pediatric ICU service must be available to correspond with the scope of service offered (CD 2-69). For example, infrastructure and providers would be in place in a Level II center to provide mechanical ventilation to an infant or a child following a surgical procedure if necessary (CD 2-70). Critical care physicians, respiratory therapists, nurses and others with demonstrable pediatric training and experience are required (CD 2-71).

A Level II children’s surgical center is required to have an appropriate radiologist available to provide service within 60 minutes 24/7 (CD 2-72). In a Level II center, coverage for this immediate availability requirement may be provided by a combination of pediatric radiologists supplemented by radiologists with pediatric expertise. A radiologist with pediatric expertise is defined as a radiologist with certification by the American Board of Radiology or equivalent, demonstrable pediatric experience to support the scope of actual practice, and 10 or more relevant Category 1 CME hours annually. Here and throughout this document, annual CME
requirements may be averaged over a 3 year period. Local policy will define credentials, the need for physical presence and this will be monitored by PIPS (CD 2-73).

A Level II children’s surgical center must have 24/7 emergency department capability to care for children with surgical needs within the scope of practice (CD 2-74). This may be provided by emergency physicians with pediatric expertise. An emergency physician with pediatric expertise is defined as an individual certified by the American Board of Emergency Medicine, the American Board of Pediatrics or equivalent and who has demonstrable pediatric experience to support the actual scope of emergency medicine practice, as well as 10 hours annually of relevant Category I CME. Children’s specific emergency department resources must be in place to support the level of designation including facilities, equipment and nonphysician personnel (CD 2-75). Level II centers that limit the scope of practice to neonatal patients are not required to meet these emergency department requirements.

For Level II children’s surgical center verification, medical and surgical specialists within the scope of practice must be available for consultation within 60 minutes, 24/7 (CD 2-76). Where providers with pediatric specific training and experience are designated as “available”, the requirement is that the care of patients will be demonstrably provided by these children’s specialists. (CD 2-77) Here and elsewhere, pediatric medical and surgical specialists are defined as those who are either eligible for or have current certification after relevant pediatric specialty fellowship training (either medical or surgical) recognized by the appropriate Board of the American Board of Medical Specialties or equivalent. This requirement is met by holding or
being eligible to hold a certificate with added qualification for pediatric patients when offered.

This requirement must be monitored by PIPS (CD 2-78).

A pediatric rapid response and/or resuscitation team is required for Level II center designation (CD 2-79). This requires 24/7 physical presence of a pediatric provider to include PALS certification, in a leadership role. (CD 2-80)

Level II centers are required to participate in a data collection program that yields peer performance assessments against which an individual program may be externally measured (CD 2-81). This is detailed in Chapter 7.

It is appropriate to include ambulatory sites of care in Level II institutional designation if a fully integrated or on site ambulatory surgical care team possesses the requisite pediatric training and experience as defined in this document, and the site of care is a component of a demonstrably integrated children’s health care delivery system that provides resources appropriate for the scope of practice. (CD 2-82)

Performing procedures outside the defined scope of practice for a Level II center should be uncommon.
<table>
<thead>
<tr>
<th>Requirement</th>
<th>Children’s Level I</th>
<th>Children’s Level II</th>
<th>Children’s Level II (neonatal scope of service only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freestanding children’s hospital or comprehensive pediatric care unit within general hospital organization</td>
<td>E</td>
<td>E</td>
<td>-</td>
</tr>
<tr>
<td>Children’s Surgical Service</td>
<td>E</td>
<td>E</td>
<td>-</td>
</tr>
<tr>
<td>Pediatric surgeons</td>
<td>E</td>
<td>E</td>
<td>E</td>
</tr>
<tr>
<td>Pediatric anesthesiologists</td>
<td>E</td>
<td>E</td>
<td>E</td>
</tr>
<tr>
<td>Pediatric emergency medicine physicians</td>
<td>E</td>
<td>D</td>
<td>-</td>
</tr>
<tr>
<td>Pediatric pulmonary and gastroenterology specialists</td>
<td>E</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>Other surgical specialists</td>
<td>E</td>
<td>E</td>
<td>E</td>
</tr>
<tr>
<td>Other pediatric medical specialists</td>
<td>E</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>Surgery specific children’s continuing medical education for children’s surgery medical director and liaisons</td>
<td>E</td>
<td>E</td>
<td>E</td>
</tr>
<tr>
<td>Neonatal intensive care unit</td>
<td>Level IV</td>
<td>Level III or greater</td>
<td>Level III or greater</td>
</tr>
<tr>
<td>Neonatologists</td>
<td>E</td>
<td>E</td>
<td>E</td>
</tr>
<tr>
<td>Pediatric emergency department area</td>
<td>E</td>
<td>E</td>
<td>-</td>
</tr>
<tr>
<td>Pediatric intensive care unit</td>
<td>E</td>
<td>D</td>
<td>-</td>
</tr>
<tr>
<td>Pediatric critical care medicine physicians</td>
<td>E</td>
<td>D</td>
<td>-</td>
</tr>
<tr>
<td>Pediatric acute care unit</td>
<td>E</td>
<td>E</td>
<td>-</td>
</tr>
<tr>
<td>Pediatric resuscitation equipment in all appropriate patient care areas</td>
<td>E</td>
<td>E</td>
<td>E</td>
</tr>
<tr>
<td>Children’s surgical program manager or coordinator</td>
<td>E</td>
<td>E</td>
<td>E</td>
</tr>
<tr>
<td>Surgical data collection</td>
<td>E</td>
<td>E</td>
<td>E</td>
</tr>
<tr>
<td>Child life and family support programs</td>
<td>E</td>
<td>E</td>
<td>E</td>
</tr>
<tr>
<td>Pediatric social work and child protective services</td>
<td>E</td>
<td>E</td>
<td>E</td>
</tr>
<tr>
<td>Community outreach programs</td>
<td>E</td>
<td>E</td>
<td>-</td>
</tr>
<tr>
<td>Children’s education programs</td>
<td>E</td>
<td>E</td>
<td>-</td>
</tr>
<tr>
<td>Surgical research</td>
<td>E</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>Minimum No. of annual surgical procedures of children younger than 18 years</td>
<td>1,000</td>
<td>500</td>
<td>-</td>
</tr>
<tr>
<td>Children’s surgical performance improvement and patient safety program (PIPS)</td>
<td>E</td>
<td>E</td>
<td>E</td>
</tr>
</tbody>
</table>

*E indicates essential; and D, desired.
For many areas, a Level III children’s surgical center will be an important part of the health care system. A Level III center will potentially provide definitive care for well children greater than 6 months of age. Generally these will be children without comorbidities (ASA 1-2), without the need for multidisciplinary care, and the procedures will generally be common, low risk procedures typically performed by a single specialty. A Level III center will have transfer agreements with a Level I or Level II center for patients whose needs exceed their resources (CD 2-83). A Level III children’s surgical center must have continuous 24/7 availability within 60 minutes of general surgeons and anesthesiologists with pediatric expertise (CD 2-84). A general surgeon with pediatric expertise is defined as a surgeon either eligible for certification or certified by the American Board of Surgery or equivalent in general surgery. In addition, this individual will demonstrate ongoing clinical engagement and expertise in children’s surgery as evidenced by performing 25 or more procedures annually in patients less than 18 years of age, as well as completion of 10 or more relevant Category I CME credit hours annually. (CD 2-85) An anesthesiologist with pediatric expertise is defined as an anesthesiologist either eligible to certify or with a current certificate of the American Board of Anesthesiology or equivalent. He or she will demonstrate continuous experience with children < 24 months of age, defined as 25 patients per anesthesiologist per year. In addition, this individual will demonstrate ongoing pediatric clinical engagement in patients less than 18 years of age, and complete 10 or more relevant Category I CME credit hours annually (CD 2-86). General surgeons and anesthesiologists must remain knowledgeable regarding children’s surgical care whether treating patients locally or transferring them to a center with more resources, therefore 10 relevant category I CME credit hours are required annually. Here and throughout this document, the annual CME requirement
may be averaged over 3 years. (CD 2-87) General surgeons and anesthesiologists with pediatric expertise are required to participate in children’s surgery performance review activities (CD 2-88). Through the PIPS program and hospital policy, the medical director of children’s surgery must have responsibility for performance review and authority for determining each general surgeon’s ability to participate on the children’s panel based on an annual review (CD2-89).

A radiologist with pediatric expertise must be available to provide care at the bedside within 60 minutes 24/7 at Level III centers (CD 2-90). This is an individual defined as a radiologist with certification by the American Board of Radiology or equivalent, demonstrable ongoing pediatric experience to support the scope of actual practice, and 10 or more relevant Category 1 CME hours annually. (CD 2-91) The PIPS process will monitor services provided by these individuals (CD 2-92).

Level III centers may treat patients who ultimately need to be transferred to a higher level of care. Transfer guidelines approved by the medical director of children’s surgery that define appropriate patients for transfer and retention are required (CD 2-93) and these must be monitored by the PIPS program. (CD 2-94).

<table>
<thead>
<tr>
<th>Indications for transfer of infants and children with surgical needs to Level I or II Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 60 weeks post menstrual age</td>
</tr>
<tr>
<td>Patient less than 6 months of age</td>
</tr>
<tr>
<td>High level of acuity, need for ICU</td>
</tr>
</tbody>
</table>

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Outreach activities to the local community and education programs for nurses, physicians, and allied healthcare workers involved with children are also functions of a Level III children’s surgical center.

Performing procedures outside the defined scope of practice in Level III centers should be uncommon.
Table 1. Summary of Children’s Surgical Center with Scope of Practice

<table>
<thead>
<tr>
<th>Age</th>
<th>I</th>
<th>II</th>
<th>III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Any</td>
<td>Any</td>
<td>&gt; 6 months</td>
</tr>
<tr>
<td>ASA</td>
<td>1-5</td>
<td>1-3*</td>
<td>1-2</td>
</tr>
<tr>
<td>Multidisciplinary</td>
<td>Multiple medical and surgical specialties; pediatric anesthesiology</td>
<td>Typically single surgical specialties; neonatology; pediatric anesthesiology</td>
<td>None</td>
</tr>
<tr>
<td>management of co-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>morbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operations†</td>
<td>Major congenital anomalies and complex disease including those that are uncommon or require significant multidisciplinary coordination</td>
<td>Common anomalies and diseases typically treated by most pediatric surgical specialists and that do not require significant multi-specialty coordination.</td>
<td>Common, low-risk procedures typically performed by a single specialty.</td>
</tr>
<tr>
<td>Ambulatory‡</td>
<td>ASA 1-3</td>
<td>ASA 1-3</td>
<td>Otherwise healthy (ASA 1-2)</td>
</tr>
<tr>
<td></td>
<td>Full term infants and preterm infants may be cared for as ambulatory patients based on written guidelines established by the pediatric anesthesiologist in charge of perioperative care. Institutional guidelines generally require full term infants &lt; 4 weeks or preterm infants &lt; 50 weeks PMA weeks to be monitored for at least 12 hours postoperatively.</td>
<td>Full term and preterm infants may be cared for as ambulatory patients based on written guidelines established by the pediatric anesthesiologist in charge of perioperative care. Institutional guidelines generally require full term infants &lt; 4 weeks or preterm infants &lt; 50 PMA to be monitored for at least 12 hours postoperatively.</td>
<td>Age &gt; 6 months</td>
</tr>
</tbody>
</table>

PMA = Post menstrual age

*Emergent procedures in some patients > ASA 3 may be appropriate in neonatal patients such as those with necrotizing enterocolitis.
Types of anomalies and diseases that should have pediatric subspecialty care are further delineated in Appendix 1. Depending upon patient age, co-morbidities and need for multidisciplinary surgical approach, these may be appropriate for either Level I or Level II centers.

†Ambulatory sites of care are included in these recommended levels of institutional designation when the onsite provider team possesses the requisite pediatric training and experience. The site of care may be physically attached/integrated into the hospital or may be a component of a demonstrably integrated health care delivery system that provides these defined resources.

The ability to stabilize and transfer critically ill children must be demonstrated at all levels of designation (CD 2-95). This includes critically ill children and neonates whose care may be initiated at an internal site, such as radiology or the emergency department distinct from definitive care, or at another institution for which a formal transfer agreement is in place.

Congenital heart centers are not specifically verified or designated in this program, although it is relevant to note that resource standards for this have been developed by the American Academy of Pediatrics [Bricker JT, Fraser CD, Fyfe DA, et al. AAP Section on Cardiology and Cardiac Surgery: Guidelines for Pediatric Cardiovascular Centers. Pediatrics 2002; 109(3):544-549.]
Ambulatory Surgical Centers

The American College of Surgeons does recognize the critical role of ambulatory surgical centers (ASCs) in the care of infants and children. Ambulatory surgery centers that meet the resource standards for children delineated and which are demonstrably integrated with a Level I, II or III Children’s Surgery Center will be so verified. The safety of performing outpatient surgical procedures in children is substantially dependent upon the provision of a safe anesthetic, but is enhanced by having appropriate high quality surgical equipment with operating room personnel experienced in its use. The major postoperative risk is apnea. Risk factors for postoperative apnea are prematurity, history of apnea, and anemia. In general, the risk of postoperative apnea is highest among infants born at younger gestational and post-conceptual ages. The most relevant data are found in Cote’s analysis of 255 preterm infants undergoing inguinal herniorrhaphy under general anesthesia [Cote CJ, Zaslavsky A, Downes JJ, et al. *Postoperative apnea in former preterm infants after inguinal herniorrhaphy. Anesthesiology* 1995; 82: 809-821]. In the non-anemic child with a gestational age of 32 weeks and a post-menstrual age (PMA) of 56 weeks, the probability of apnea was <1%. With a gestational age of 35 weeks, a post-menstrual age of 54 weeks was the threshold for apnea to be <1%.

It is widely accepted that one can safely administer anesthesia on an ambulatory basis for preterm infants with a post-menstrual age > 50 weeks and who are without other risk factors. (www.asahq.org) Ambulatory surgery in infants born before 37 weeks gestation may be safely done after 50 weeks post-menstrual age as long as there is no anemia, prior apnea or coexisting
disease. Institutional guidelines generally require full term infants less than 4 weeks or preterm infants < 50 post-menstrual weeks to be monitored for at least 12 hours postoperatively.

Optimal ambulatory children’s surgery should be performed in facilities with specific children’s resources and policies as described below:

- A pediatric anesthesiologist, pediatric surgeon or other specialty trained and certified children’s surgeon must serve as medical director (CD 2-96).
- A pediatric anesthesiologist or anesthesiologist with pediatric expertise must administer or directly oversee the administration of a general anesthetic and/or sedation to all patients less than two years of age undergoing a surgical procedure. (CD 2-97).
- The preoperative preparation and post-operative recovery of children must occur in an area appropriate for pediatric patients. (CD 2-98)
- The special needs of a child’s social and emotional comfort must be considered in the construction and protocols of a pediatric ambulatory surgery center. (CD 2-99)
- Anesthesia and other equipment including resuscitation devices and appropriate pharmacologic supplies and drug doses for all sizes of children must be readily available in the operating room and recovery areas. (CD 2-100)
- One or more persons certified in pediatric advanced life support (PALS) must be present and available to the pediatric patient who is sedated, anesthetized, recovering from anesthesia, or receiving perioperative opioids. (CD 2-101)
- Healthy full term infants > 4 weeks and less than 6 months of age should be monitored at least 2 - 4 hours after surgery and should be scheduled early in the day. Prolonged
postoperative monitoring should be provided for infants less than 3 months who receive perioperative opioids.

- Full term infants less than 4 weeks of age and preterm infants younger than 50 weeks post-menstrual age are not appropriate for surgery on an ambulatory outpatient basis.

- Formal transfer agreement must be in place to allow planned processes and prompt transfer to an appropriate (Level I, II or III) inpatient children’s facility when medically necessary. (CD 2-102)
Chapter 3

Triage and Transfer for Seriously Ill Infants and Children

The system is driven by the goal of getting the child with surgical needs to the right place at the right time. Imprecision results in overtriage and undertriage. In general, priority is given to reduction of undertriage because this may result in preventable mortality or morbidity for a seriously ill child. Although overtriage has minimal or no adverse consequences for the patient, it can result in excessive costs and burden for higher level centers in the routine care of patients as well as a travel burden for families. The medical community needs to be more concerned about undertriage and the medical consequences that result from inadequate use of a system.

The system’s performance improvement program should evaluate triage (referral) and transfer criteria to provide the best quality care to patients.

Interhospital Transfer

The development of agreements for transfer of seriously ill patients between institutions is an essential part of a system. These agreements should be made well in advance of the need to implement them and should define which patients should be transferred and the process for doing so. Once the need for transfer or referral is recognized, the process should not be delayed for laboratory or diagnostic procedures that have no impact on resuscitation, immediate needs or the transfer process. Minimizing the time to appropriate definitive care can have a
positive influence on outcome. Regional systems facilitate transfer and referral processes and improve the efficiency of patient movement through the system by designing and implementing plans that deal with transfer and referral issues before the acute patient need.

Written agreements between hospitals help ensure the consistent, timely, proper, and efficient movement of seriously ill children between institutions, allow for review of the structure of transfer and referral processes with the goal of performance improvement, and result in mutual educational benefit for both originating and recipient institutions. An example is provided in Appendix 2. The value of these agreements is to design a process before it is necessary that allows patients to receive the specialty care needed. This process avoids delays that prolong the time to definitive care. The transferring and receiving hospitals benefit by having predetermined the needs and expectations of both institutions and resolving problematic areas before the actual transfer process. The best plans are carefully considered, mutually approved, written and frequently reviewed.

Once the decision for referral or transfer has been made, it is the responsibility of the referring physician to initiate resuscitation and any needed stabilization measures within the capabilities of the local hospital. The referring physician should select a mode of transport for the patient’s needs so that the level of care is appropriate during transport. Effective communication between the referring center and receiving center is essential (CD 3-2). Specifically, the accepting physician should review the current physiologic status of the patient and discuss the initial management and the optimal timing of transfer.
There are identifiable needs and combinations of needs that result in high mortality, even when patients are managed in Level I centers. Patients with these critical needs should be considered for early transfer. Physicians in community hospitals should develop specific guidelines for the identification of patients who would benefit from early transfer based on available local resources. Written agreements for transfer of patients between hospitals have their greatest utility in establishing a system in which patients can be moved expeditiously to an institution that has been identified by prior agreement to be capable and willing to provide needed children’s specialty surgical services.

The decision to transfer a patient to a children’s specialty care facility in an acute situation must be based solely on the needs of the patients and not on the requirements of the patient’s specific provider network (such as health maintenance organization or preferred provider organization) or the patient’s ability to pay (CD 3-3). Subsequent decisions regarding transfer to a facility within a managed care network should be made only after stabilization of the patient’s medical/surgical condition.

Obligations of the referring physician and facility include the following:

1. Identifying an appropriate children’s facility with available space and qualified surgical personnel that has agreed to accept the patient before beginning the transfer.
2. Not transferring patients with physiologic instability, except for medical necessity and only after providing medical treatment within the facility’s capacity that minimizes the risks to the patient’s health.
3. Providing appropriate transportation with a vehicle augmented with infant and child specific life-support equipment and staff to meet the anticipated contingencies that may arise during transportation.

4. Sending all records, test results, radiologic studies, and other relevant reports or data with the patient to the recipient facility unless delay would increase the risks of transfer, and then sending the information as soon as possible.

5. Issuing a physician transfer summary and consent for transfer to accompany the patient.

Receiving hospitals also have obligations. Hospitals that have specialized children’s care capabilities or facilities are obligated to accept the appropriate transfer of patients requiring such services if they have the capacity to treat them.

Another important aspect of interhospital transfer is an effective performance improvement and patient safety program that includes evaluating transport activities. These activities can be accomplished in a number of ways depending on the transport service. Regardless of how the process is accomplished, the receiving hospital should have input and feedback with the personnel responsible for the transport process to ensure that problems occurring during and associated with transport are addressed in a timely manner. The input, feedback, and communication also should allow recognition of transportation efforts that are consistent with optimal care.
Guidelines for Transferring Patients

1. Transferring physician responsibilities
   a. Identify patients needing transfer.
   b. Initiate the transfer process by direct contact with the receiving surgeon.
   c. Initiate appropriate resuscitation and stabilization measures within the capabilities of the facility.
   d. Determine the appropriate mode of transportation in consultation with the receiving surgeon.
   e. Transfer all records, test results, and radiologic evaluations to the receiving facility.

2. Receiving physician responsibilities
   a. Ensure that resources are available at the receiving facility.
   b. Provide consultation regarding specifics of the transfer, additional evaluation, or resuscitation before transport.
   c. Once transfer of the patient is established, clarify medical control
   d. Identify a performance improvement and patient safety process for transportation, allowing feedback from the receiving surgeon to the transport team directly or at least to the medical director for the transport team. (CD 3-4)

3. Management during transport
   a. Children’s specific personnel and equipment should be available during transport to meet anticipated contingencies.
b. Sufficient supplies should accompany the patient during transport, such as intravenous fluids, blood, and medications, as appropriate for age and size of the patient.

c. Vital signs should be monitored frequently.

d. Vital functions should be supported.

e. Records should be kept during transport.

f. Communication should be maintained with online medical direction during transport.

4. System responsibilities

a. Ensure prompt transport once a transfer decision is made.

b. Review all hospital transfers for performance improvement and patient safety as well as overtriage and undertriage. (CD 3-5)

c. Ensure transportation commensurate with the patient’s need.

5. Information to accompany patient

Appropriate family members and available patient demographic information should accompany the seriously ill child. Information about the nature of the medical problem andprehospital care constitute important facts that can influence subsequent treatment. A summary of evaluation and care provided at the transferring facility should include the results of laboratory tests and radiologic evaluations, the needs identified, the patient’s response to treatment, and a chronologic record of the patient’s vital signs. Additional information that is helpful includes the medical history, current medications, medications and immunizations administered, and
allergies. The name, address, and phone number of the referring physician is important. The name of the surgeon who accepted the patient at the receiving hospital also should be indicated.

**Transport Teams**

A Level I children’s surgical center is required to have a dedicated transport team for neonatal and pediatric patients (CD 3-6). The complement of personnel, mode of transport and medical control policies will vary by location, but performance must be monitored by PIPS (CD 3-7). Written policies must address personnel, mode of transport and medical control at a minimum (CD 3-8). Quality improvement efforts require data documenting timeliness and appropriateness of response as well as missed transports (CD 3-9). Level II centers are not required to provide their own transport team but must have a relationship with and use pediatric specific transport teams when transferring infants and children to or from their center. (CD 3-10)
CHAPTER 4

Hospital Organization and the Children’s Surgical Program

A decision by a hospital to become a children’s surgical center requires the commitment of the institutional governing body and the medical staff (CD 4-1). The commitment and collaboration of these two bodies are necessary to facilitate the allocation of resources and the development of programs designed to improve the care of children with surgical needs. Elements include the following: (1) hospital organization, (2) medical staff support, (3) the surgical program, (4) the medical director of children’s surgery (MDCS), (5) the children’s surgery program manager (CSPM), (6) data collection, and (7) the children’s surgery performance improvement and patient safety (PIPS) program.

Hospital Organization

The administrative structure must support the children’s surgical program. Written commitment by the hospital’s governing body and the medical staff is necessary (Table 1). This support must be reaffirmed continually (every 3 years) and must be current at the time of verification (CD 4-2). Administrative support of the surgical program helps provide adequate resources for the optimal care of children with surgical needs. The responsible administrator works closely with the medical director to establish and maintain the components of the children’s surgery program. Participation of an administrator helps ensure that the written commitment to the surgery program is implemented to ensure optimal multidisciplinary surgical care.
The administrative structure of the hospital should demonstrate institutional support and commitment and must include an administrator, medical director of children’s surgery and the children’s surgical program manager. (CD 4-3) Sufficient authority for the surgery program to achieve all programmatic goals should be reflected in the organizational structure.

Administrative support includes human resources, educational activities, and community outreach activities to enable community cooperation and a systematic approach to the care of children with surgical needs. Adequate funding of the children’s surgery program is the direct responsibility of the institution.

Medical Staff Support

The medical staff commitment ensures that the members of the medical staff support the children’s surgery program by their professional activities. This support includes a current written commitment acknowledging the medical staff’s willingness to provide appropriate specialty care to support the optimal care of children with surgical needs (Table 1). This support must be reaffirmed continually (every 3 years) and must be current at the time of verification (CD 4-4).
Table 1. Sample Commitment and Support Statements

<table>
<thead>
<tr>
<th>Hospital Commitment</th>
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<tr>
<td>Resolved, that the XYZ Hospital Board of Directors (or other administrative governing authority) approves the establishment of a Level ____ children’s surgical center (or “applies for verification or reverification of a Level ____ children’s surgical center”). The Board commits to maintain the high standards needed to provide optimal care of children with surgical needs.</td>
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<tr>
<th>Medical Staff Support</th>
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<tr>
<td>Resolved, that the Medical Staff or Executive Committee of XYZ Hospital (or other governing body of the medical staff) supports the establishment of a Level ____ children’s surgical center (or “supports verification or reverification of a Level ____ center”). This statement acknowledges the commitment to provide appropriate specialty care as required to support optimal care of children with surgical needs.</td>
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The Children’s Surgical Program

The children’s surgery program involves multiple disciplines that transcend normal departmental hierarchies. Because optimal care extends from diagnosis of a surgical need through the acute care setting to discharge and outpatient convalescence, the program should have appropriate specialty representation from all phases of care. Representatives of all disciplines provide the appropriate skills as team members working in concert to implement treatment based on a prioritized plan of care. To ensure optimal and timely care, a multidisciplinary program must continuously evaluate its processes and outcomes (CD 4-5).
The Medical Director of Children’s Surgery (MDCS)

The medical director of children’s surgery (MDCS) is the surgeon who leads the multidisciplinary activities of the children’s surgery program. This individual may have a title such as Surgeon-in-Chief or others, but the following are requirements for this program. For Level I and II centers, the director must be a surgeon with current board certification (or equivalent) with special interest and qualifications in children’s surgical care (CD 4-6) and participate in surgical call. (CD 4-7) The MDCS must maintain an appropriate level of extramural continuing medical education to meet American Board of Medical Specialties (ABMS) maintenance of certification requirements in his/her discipline (CD 4-8). Membership and active participation in appropriate regional or national children’s organizations is essential for the MDCS in Level I and II centers (CD 4-9) and desirable in Level III facilities.

The MDCS’s responsibilities extend far beyond the technical skills of surgery. The MDCS should have the authority to manage the surgery program. The MDCS participates in the credentialing of surgeons with children’s privileges, works in cooperation with nursing administration to support the nursing needs of children with surgical needs, develops treatment protocols along with the surgical teams and coordinates the performance improvement and peer review process. The surgery director must have the authority to correct deficiencies in surgical care (CD 4-10). In partnership with the hospital administration and the children’s surgery program manager, the MDCS should participate in coordination and management of the budgetary processes for the surgery program. The MDCS should identify representatives from
appropriate disciplines to determine which physicians from individual disciplines are qualified to be members of the children’s surgery program.

The Surgical Service

A children’s surgical service represents a structure of care for children with surgical needs. The service includes personnel and other resources necessary to ensure appropriate and efficient provision of surgical care. The precise character and composition of a service will vary based on specific needs of the medical facility, available personnel and other resources. In a Level I or II children’s surgery center, infants and children with primary surgical problems must be admitted to or evaluated by an identifiable surgical service staffed by credentialed children’s surgical providers (CD 4-11). Sufficient infrastructure and support to ensure adequate provision of care must be provided for this service (CD 4-12). To be sufficient, the infrastructure and support may require additional qualified physicians, residents, nurse practitioners, physician assistants, or other allied health professionals. The number and type of individuals required for a surgery service should be determined by the volume of patients requiring care and the complexity of their conditions. In teaching facilities, the relevant requirements of the Accreditation Council for Graduate Medical Education (ACGME) and appropriate Residency Review Committees also must be met (CD 4-13).
The Children’s Surgical Program Manager (CSPM)

The CSPM is fundamental to the development, implementation, and evaluation of the surgery program. In addition to administrative ability, qualified candidates must show evidence of educational preparation and clinical experience in the care of children with surgical needs (CD 4-14). The CSPM works in close collaboration with the medical director of children’s surgery and complements the director’s efforts. A constructive, mutually supportive relationship between these key leaders is important to the success of the program.

The CSPM, usually a full-time registered nurse, is responsible for the organization of services and systems necessary for a multidisciplinary approach to providing care to children with surgical needs. The CSPM, in particular, assumes day-to-day responsibility for process and performance improvement activities as they relate to nursing and ancillary personnel and assists the MDCS in carrying out the same functions for the physicians. Accountability for all activities of the surgery program resides with the medical director. The role of the CSPM in the educational, clinical, research, administrative, and outreach activities of the surgery program is determined by the needs of the MDCS and institution. (Various responsibilities of CSPMs are detailed in Table 2).

Administrative and budgetary support needed for the CSPM depends on the size of the program. Relevant data collection is required and must be appropriately staffed (CD 4-15). A comparable level of administrative assistant and clinical nursing personnel helps fulfill needs for outreach,
concurrent case review, and discharge planning. The data collection personnel, administrative assistant, and surgical nurse clinician(s) should be supervised by the CSPM.

The Surgery Data Collection Personnel

The individuals responsible for surgery data collection are important members of the team. These individuals may come from a background such as nursing, medical records, computer science, medical informatics, and other fields. Ideally, he/she should work directly with the surgical team and report to the CSPM. This children’s surgery data collection leader must receive initial training when starting the job. (see Chapter 7) (CD 4-16) He/she also should complete at least 4 hours of registry specific continuing education per year. Technical support, locally and from relevant national vendors or agencies, should be available to assist with these training requirements.

It is important to acknowledge that high quality data begin with high quality data entry, and it is the children’s surgery data collection leader who is responsible to perform this task.

Performance Improvement and Patient Safety Program

Level I and Level II centers must have a multidisciplinary peer review committee chaired by the medical director of children’s surgery or designee, with representatives from all surgical services, anesthesiology, radiology (CD 4-17), and emergency medicine, neonatology and critical care physicians if within scope of service (CD 4-18). The purpose of the committee is to
improve surgical care by reviewing all deaths, selected complications, and sentinel events with objective identification of issues and appropriate responses. The aforementioned representatives or designees must attend at least 50% of these multidisciplinary peer review committee meetings (CD 4-19). The frequency of meetings is to be determined by the medical director of children’s surgery based on the needs of the performance improvement and patient safety program, but must be at least quarterly (CD 4-20).

Evidence for participation and acceptable attendance must be documented. (CD 4-21) The medical director of children’s surgery must ensure and document dissemination of information and findings from the peer review meetings (CD 4-22).

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Table 2. The Children’s Surgery Program Manager

<table>
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<tr>
<th>Qualifications of the Children’s Surgery Program Manager (CSPM)</th>
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<tr>
<td>The CSPM, usually a registered nurse, must show evidence of educational preparation, with a minimum of 16 hours (internal or external) of surgery-related continuing education per year and clinical experience in the care of children with surgical needs (CD 4-23). There should be a written job description that defines sufficient authority to do the job and clearly outlines the responsibilities of the individual. Qualifications and activities should include the following:</td>
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<td>Clinical Activities</td>
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<td>Education Responsibilities</td>
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<td>Performance Improvement</td>
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<td>Administration</td>
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<tr>
<td>Supervision of Data Collection</td>
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<td>Consultant and Liaison</td>
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<td>Research</td>
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<td>Community and National Engagement in Children’s Surgical Care Systems</td>
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**Children’s Operating Room Committee**

Efficient and safe children’s surgical practice requires an operating room environment tailored to specifically meet children’s needs. Although the personnel and processes will vary with the local environment, Level I and II centers are required to have a dedicated children’s operating room committee charged with oversight of day to day OR operations and which insures that
November 20, 2014

children’s surgical needs are met (CD 4-24). This group must meet regularly and it should be
chaired by the medical director of children’s surgery or designee (CD 4-25). Members (or
designees representing each surgical service) as well as anesthesiology, nursing and
administrative representatives must attend 50% of meetings (CD 4-26). Agendas and minutes
must be distributed to members and be available for review at site visitation (CD 4-27). Level III
and ambulatory children’s surgical centers must demonstrate similar oversight and support
specific to children’s surgical needs, although the operating room committee structure may be
integrated into a larger institutional body. (CD 4-28)
CHAPTER 5  Clinical Functions-Surgeons

Qualifications

Surgeons caring for children must meet certain requirements as described herein. (CD 5-1) These requirements may be considered in 4 categories: board certification or equivalent, clinical involvement, education, and regional or national commitment. The medical director of children’s surgery (MDCS) must have the responsibility and authority to ensure compliance with these requirements (CD 5-2).

Board Certification

Basic to qualification for any surgeon is board certification by the American Board of Surgery, other relevant Board of the American Board of Medical Specialties (ABMS), or an equivalent organization such as the Bureau of Osteopathic Specialists and Board of Certification, or the Royal College of Physicians and Surgeons of Canada. Board certification is essential for surgeons who take call and provide care in Level I, II, III and ambulatory children’s surgical centers (CD 5-3). It is acknowledged that many boards require a practice period and that completion of certification may take 3 to 5 years after completing a residency approved by the Accreditation Council for Graduate Medical Education (ACGME), the American Board of Osteopathic Specialties or equivalent entity. A surgeon is specifically permitted to meet these program requirements during this period of eligibility for certification if credentialed by the applicant organization. If a physician has not been certified within 5 years after successful completion of an ACGME or Canadian residency, the physician usually is not eligible for
inclusion on the children’s surgical team. A physician may be included when given recognition by a major professional organization in his or her specialty. On a case by case basis, alternative training and certification may be judged equivalent by the applicant organization and the American College of Surgeons. The credentialing body of the hospital will assure that qualifications of the practicing providers are current and relevant to the care of children. (CD 5-4)

Clinical Involvement

In a hospital committed to children’s surgical care, surgeons with demonstrable expertise should be identified. Specifically, qualified children’s surgeons must be involved in the care of all infants and children. (CD 5-4) Participation in the organization of protocols, teams, call rosters and rounds are clear indicators of commitment to excellence in children’s surgical care. It is important for children’s surgeons to maintain their surgical skills. Surgeons must have privileges in children’s surgery (CD 5-5). To maintain operative skills, surgeons must remain actively involved in clinical surgery. (CD 5-6) One of the ways that this is demonstrated is participation in elective surgery and emergency surgery.

In Level I children’s surgical centers, the pediatric surgeons and pediatric anesthesiologists on call must be dedicated to the center while on duty and available to provide care at the bedside 24/7 within 60 minutes of such a request. (CD 5-7) A published call schedule for pediatric and subspecialty surgeons and pediatric anesthesiologists must be available (CD 5-8). A Level II center is required to have a pediatric surgeon available on a consultant basis to care for a patient
in the relevant institution within 60 minutes of such a request (CD 5-9). In Level III centers this requirement may be met by general surgeons or general anesthesiologists with pediatric expertise (CD 5-10).

Performance Improvement and Patient Safety

In Level I, II, III and ambulatory children’s surgical centers, there must be a multidisciplinary peer review process with leadership by the medical director of children’s surgery or designee and representatives from anesthesiology and all surgical and medical specialties relevant to level of verification and scope of service (CD 5-11). The purpose is to improve surgical care by reviewing all deaths, selected complications and sentinel events with the objective of identifying issues and developing appropriate responses. Each member must attend at least 50% of the multidisciplinary peer review committee meetings (CD 5-12).

Education

It is important that all members of the surgical team are knowledgeable about current practices in children’s surgical care. In Level I and II centers, external CME is the recommended method of keeping current. The medical director of children’s surgery must accrue an average of 16 hours annually or 48 hours in the 3 years prior to site visit of relevant children’s surgical Category I external CME (CD 5-13). Programs given by visiting professors or invited speakers are considered outside education. It is important that other surgeons who take children’s surgical call be knowledgeable and current in the care of children with surgical needs. In Level I and II centers, this requirement must be met by acquisition of 16 hours of children’s surgical CME per
year on average as above, or by demonstrating participation in an internal educational process conducted by the program based on the principles of practice-based learning and the performance improvement and patient safety program (CD 5-14).

Regional or National Commitment

Membership and active participation in regional or national organizations relevant to children’s surgery is essential for the medical director of children’s surgery in Level I or II centers and desirable in Level III facilities (CD 5-15).
Children’s specialists should be promptly available and qualified in their areas of expertise.

**A) Anesthesiology**

Specialist pediatric anesthesiology services are critical in the management of infants and children with surgical needs and must be promptly available for elective and emergency operations (CD 6-1) and for managing airway problems (CD 6-2). These needs must be fulfilled in Level I and Level II centers by pediatric anesthesiologists and may be fulfilled in Level III centers by an anesthesiologist with pediatric expertise as defined below. Although anesthesia services are often based primarily in the operating room, the responsibilities of the anesthesiology team extend beyond the operating room. Examples include airway management, assisting with resuscitation, providing preoperative and postoperative cardiorespiratory support, and assisting with pain management.

**Level I and II Centers**

The anesthetic care of children with surgical needs in a Level I or II center must be organized and overseen by a pediatric anesthesiologist who is highly experienced and devoted to the care of infants and children. (CD 6-3) A pediatric anesthesiologist medical director for the children’s surgical program must be designated for both Level I and II centers (CD 6-4).
Pediatric anesthesia services in Level I centers must be immediately available on site 24 hours a day (CD 6-5). This requirement may be fulfilled by anesthesiology residents in their final year of training, pediatric anesthesiology fellows or certified registered nurse anesthetists (CRNAs) who are capable of assessing emergency situations in children and of providing any indicated treatment, including airway management and initiation of surgical anesthesia. When anesthesiology chief residents, pediatric fellows or CRNAs are used to fulfill availability requirements, the staff pediatric anesthesiologist on call must be advised of clinical activities, promptly available at all times (able to respond to the bedside within 60 minutes of request) (CD 6-6), and be physically present for all operations (CD 6-7). The availability of appropriate pediatric anesthesia services and the absence of delays in airway control or operations must be documented by the hospital performance improvement and patient safety (PIPS) process (CD 6-8).

In a Level II children’s surgical center, a pediatric anesthesiologist must be available 24 hours a day to respond within 60 minutes to bedside (CD 6-9). Protocols must be in place to ensure the timely arrival of a pediatric anesthesiologist at the bedside at the time of need (CD 6-10). The attending pediatric anesthesiologist on call must be promptly available at all times and present for all operations (CD 6-11). The onsite presence of a physician or allied health professional with demonstrable pediatric airway management skills is required 24 hours a day. (CD 6-12) The availability of pediatric anesthesia services and the absence of delays in airway control or operations must be documented by the hospital PIPS process (CD 6-13).
Level III Centers

At Level III children’s surgical centers, anesthesiologists or CRNAs with expertise in pediatrics must be promptly available 24 hours a day to respond to the bedside within 60 minutes (CD 6-14). Local criteria must be established to allow the anesthesia provider to take call from outside the hospital, but with the clear commitment that the provider will be immediately available and provide airway and operative management for children (CD 6-15). Under these circumstances, the presence of a physician or allied health professional demonstrably skilled in emergency airway management for children within the scope of service must be documented (CD 6-16). In Level III facilities, operative pediatric anesthesia may also be provided by a CRNA with pediatric expertise under the supervision of an anesthesiologist with pediatric expertise (defined below). The availability of pediatric anesthesia services and the absence of delays in airway control or operations must be documented by the hospital PIPS process (CD 6-17).

Qualifications

In Level I and II children’s surgical centers, anesthesiologists taking call for infants and children must be board certified in anesthesiology and either possess or be eligible for a certificate of added qualifications in pediatric anesthesiology (CD 6-18). Furthermore, in Level I and Level II facilities, at least 1 anesthesiologist should put forth a specific effort and commitment to education in pediatric related anesthesia and educate other anesthesiologists and the entire team. In Level III centers, call obligations may be met by anesthesiologists with pediatric expertise as defined below (CD 6-19).
- Pediatric anesthesiologist is defined as an individual certified in anesthesia by the American Board of Anesthesiology or equivalent, in addition to being certified or eligible for certification in pediatric anesthesia by the American Board of Anesthesiology or equivalent organization. Such an individual must demonstrate adequate ongoing engagement in the practice of pediatric anesthesia in patients less than 18 years of age.

- Anesthesiologist with pediatric expertise is defined as an anesthesiologist either eligible to certify or with a current certificate of the American Board of Anesthesiology, or equivalent. He or she would demonstrate continuous experience with children < 24 months of age, defined as 25 patients per anesthesiologist per year. In addition, this individual will demonstrate ongoing pediatric clinical engagement in patients less than 18 years of age, as well as 10 relevant Category 1 CME credit hours annually.

- A CRNA with pediatric expertise is defined as a credentialed CRNA provider with continuous supervised experience with children < 24 months of age, defined as 25 patients per practitioner per year. In addition, this individual will demonstrate ongoing pediatric clinical engagement in patients less than 18 years of age, as well as 10 relevant Category 1 CME credit hours annually.

The above continuing education credit hours may be averaged over 3 years to achieve the annual requirement, here and elsewhere in this document.
Performance Improvement and Patient Safety

In Level I, II, III and ambulatory children’s surgical centers an anesthesiology medical director or liaison to the children’s surgical performance improvement and patient safety program must be identified (CD 6-20). In all centers, participation in the PIPS program by this anesthesiology representative is essential (CD 6-21). The anesthesiology representative to the program must attend at least 50% of the multidisciplinary peer review meetings with documentation by the PIPS program (CD 6-22).

B) Operating Room

Personnel

A dedicated children’s operating room must be adequately staffed and immediately available in a Level I children’s surgical center (CD 6-23). This criterion is met by having a complete operating room team in the hospital at all times, so if a patient requires emergency operative care, the patient can receive it in the most expeditious manner. This criterion cannot be met by individuals who also are dedicated to other functions within the institution. Their primary function must be the operating room (CD 6-24). If the first operating room becomes occupied in a Level I center, a mechanism for providing additional staff must be in place to staff a second room (CD 6-25).
In Level II and III centers, a children’s operating room with appropriate and adequate children’s staff must be readily available in a medically appropriate and timely manner (CD 6-26). This criterion can be met by a team on call from outside the hospital, depending on the patient population served, prehospital communications, the volume of urgent cases, and other relevant factors. In Level I and II centers, prompt and appropriate OR response times, both provider and institutional, must be demonstrable for emergencies such as critical airway foreign bodies, malrotation with midgut volvulus, and others of similar life or limb threatening medical urgency (e.g. less than 60 minutes from diagnosis to OR (CD 6-27).

Availability of children’s specialty operating room personnel and timeliness of starting operations must be evaluated by the hospital PIPS process for Level I, II and III centers and measures implemented as required to ensure optimal response times which yield optimal care (CD 6-28).

Equipment

Level I, II, III, and ambulatory children’s surgical centers must have age and size appropriate operating room equipment for the patient populations they serve (CD 6-29). All centers must have pediatric specific equipment for the scope of service to include airway management, vascular access, thermal control, surgical instruments, intraoperative imaging capabilities, equipment for endoscopic evaluation (airway and gastrointestinal endoscopy) and minimally invasive surgery (CD 6-30). In addition, age appropriate resuscitation fluids, medications and pharmacy support must be available to support the operative services provided. (CD 6-31)
C) Postanesthesia Care Unit

Postoperative care of infants and children may be provided in a postanesthesia care unit (PACU), depending on the patient’s needs. At Level I, II, III and ambulatory children’s centers, a designated PACU or other unit with dedicated personnel and functional capacity, including qualified pediatric nurses, must be available 24 hours per day to provide care for the patient if needed during the recovery phase (CD 6-32). If this availability requirement is met with a team on call from outside the hospital, absence of delays must be documented by the PIPS program (CD 6-33). The PACU or other unit utilized must have the necessary equipment to monitor and resuscitate pediatric patients within the scope of services offered, consistent with the processes of care designated by the institution and monitored by the PIPS program (CD 6-34). The PIPS program must, at a minimum, address the need for appropriate personnel, postoperative pulse oximetry, end-tidal carbon dioxide detection, arterial pressure monitoring, patient rewarming, and intracranial pressure monitoring (CD 6-35).

D) Radiology

Specialized radiology services are critical in the management of infants and children with surgical needs. Qualified pediatric radiologists must be promptly available in person when requested for the interpretation of diagnostic imaging studies or interventional procedures in Level I centers (CD 6-36). Teleradiology is a permissible adjunct, but is not alone sufficient to
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meet this requirement. This need may be met in Level II and III centers by radiologists with pediatric expertise as defined below.

Diagnostic information from imaging studies must be communicated in a written form and in a timely manner (CD 6-37). Critical information that is deemed to immediately affect patient care must be verbally communicated to the surgical team (CD 6-38). The preliminary report should be permanently recorded. The final report must accurately reflect the chronology and content of communications with the surgical team, including changes between the preliminary and final interpretation (CD 6-39). Changes in interpretation must be monitored through the PIPS program (CD 6-40).

Collaboration between the children’s radiology team and the children’s surgical program is important. In Level I and II facilities, a pediatric radiologist must be appointed as liaison to the surgical program (CD 6-41). The pediatric radiology liaison or designee should attend peer review meetings and should educate and guide the entire surgical team in the appropriate use of radiologic services. The most important imaging process and outcome measures to support the PIPS program should be defined collaboratively and should include system or individual case factors that materially affect time to diagnosis and/or treatment, patient morbidity or mortality, and efficient resource use. In Level I and II centers, participation in the PIPS program process by the pediatric radiology liaison is essential (CD 6-42). At a minimum, a pediatric radiologist must be involved in protocol development and trend analysis that relates to diagnostic imaging (CD 6-43). In Level III centers, it is desirable for radiologists with pediatric expertise to be involved in the PIPS program.
Radiology Support Services

Level I and II children’s surgical centers must have policies designed to ensure that infants and children who may require resuscitation and monitoring are accompanied by appropriately trained providers and relevant children’s specific support equipment during transportation to and from the department, and while in the radiology department (CD 6-44).

Conventional radiography and computed tomography (CT) at radiation dosing suitable for infants and children and within the scope of services must be available in Level I and II centers 24 hours per day (CD 6-45). This includes both equipment and personnel. This requirement can be fulfilled with a combination of technicians, residents, fellows, allied health professionals and teleradiology (CD 6-46). The PIPS process must document appropriate and timely availability (CD 6-47). An in-house CT technologist is required at Level I centers (CD 6-48). In Level II and III centers, if the CT technologist takes call from outside the hospital, the PIPS program must document the technologist’s response time (CD 6-49). Interventional radiology and ultrasonography must be available 24 hours per day at Level I centers (CD 6-50). Magnetic resonance imaging capability must be available 24 hours per day at Level I centers (CD 6-51). Technologists and others relevant may respond from outside the hospital, but appropriate timeliness of arrival must be documented by PIPS program (CD 6-52).
Qualifications

- In Level I, II, III and ambulatory children’s surgical centers, all staff radiologists providing imaging services must have successfully completed a radiology residency program approved by the Accreditation Council for Graduate Medical Education, and should either have or be eligible for board certification by the American Board of Radiology; or have completed equivalent residency training either in a foreign radiology residency, or a program approved by the American Board of Osteopathic Specialties (Radiology) and have equivalent certification and/or credentials (CD 6-53). Level I centers are required to have a pediatric radiologist (defined below) available within 60 minutes 24 hours a day (CD-6-54) and PIPS verification of appropriate and timely response is required (CD 6-55). Electronic image analysis is a permissible adjunct, however individuals trained and skilled in hands on imaging such as fluoroscopy must be physically available within 60 minutes (CD-6-56). In a Level II center, coverage for this immediate availability may be provided by a combination of pediatric radiologists and radiologists with pediatric expertise (CD 6-57). In addition to 24/7 pediatric radiologist coverage, interventional radiology availability 24/7 is required for designation as a Level I children’s surgical center (CD 6-58).

Level II and III centers may meet similar requirements for 60 minute response with radiologists with pediatric expertise as defined below (CD 6-59).
- Pediatric radiologist is defined as an individual certified by the American Board of Radiology or equivalent in addition to being certified or eligible for certification in pediatric radiology by the American Board of Radiology or equivalent.

- Radiologist with pediatric expertise is defined as a radiologist with certification by the American Board of Radiology or equivalent, demonstrable pediatric experience to support the scope of actual practice, and 10 or more relevant Category 1 CME hours annually.

E) Critical Care

In Level I and II children’s surgical centers the surgical services will remain clinically involved and maintain responsibility for the care of infants and children with primary surgical problems throughout their admission to an intensive care unit, including both NICU and PICU (CD 6-60).

ICU Organization

In a Level I children’s center, an ICU physician team with direct surgeon involvement in the day to day management of the patient is essential for the care of surgical infants and children (CD 6-61). This team provides continuous in-house coverage by appropriately trained physicians and advanced practice providers for all infants and children in an ICU environment. This team can be staffed by critical care trained physicians from different specialties. A pediatric intensive care unit with pediatric intensivists requires coverage 24/7 with individuals certified in critical care.
medicine by the American Board of Pediatrics, the American Board of Anesthesiology or the American Board of Surgery or equivalent. (CD 6-62)

In Level I and Level II children’s surgical centers, there must be a children’s surgeon that serves within the medical leadership body of the PICU (may be designated as the “Surgical Director”) and is responsible for setting policies and defining administrative needs related to pediatric ICU patients with surgical needs (CD 6-63). In Level III centers, a surgeon must remain responsible for the surgical issues of the patients while in the ICU (CD 6-64). In Level I and II centers, pediatric specialty physician and surgeon coverage of critically ill surgical infants and children must be promptly available 24 hours a day (CD 6-65). These physicians must be capable of rapid response to deal with urgent problems as they arise (CD 6-66). Generally, Level III centers transfer most critically ill patients, but when patients are treated locally, there must be documentation of medical decision making and a process in place to ensure prompt availability of ICU physician coverage 24 hours a day (CD 6-67).

In a Level I children’s surgical facility, it is strongly recommended that the surgical critical care director will have obtained critical care training during residency or fellowship. He/she must have expertise in the perioperative care of infants and children who are surgical patients (CD 6-68). This expertise may be demonstrated by having board certification or a certificate of added qualification in surgical critical care from the American Board of Surgery, or other ABMS board which offers critical care certification (Pediatrics or Anesthesiology). In a Level I children’s surgical center, critical care qualifications of the surgical director require documentation of active participation in ICU administration specifically as it pertains to children’s surgical care
and PIPS activities (CD 6-69); and direct involvement in the ICU care of surgical infants and children during the preceding 12 months (CD 6-70). In Level I, II and III centers surgeons who are credentialed by the hospital to care for infants and children in the ICU must participate in the PIPS process (CD 6-71).

Surgeon Responsibility for Infants and Children with Surgical Needs in the ICU.

The surgical service that assumes initial responsibility for the care of an infant or child with surgical needs in an ICU should maintain that responsibility and involvement either throughout the acute care phase of hospitalization or until formal transfer to another service upon adequate resolution of acute surgical issues. For centers of all levels, the children’s surgeon must remain involved with the surgical needs of the patient while in the ICU (CD 6-72), the surgical service must retain responsibility for the surgical needs of the patient and be involved in the therapeutic decisions (CD 6-73). The structure designed to care for critically ill ICU patients will differ between hospitals, but the concept of the surgeon retaining responsibility for the surgical needs of the patient is essential (CD 6-74). Many of the daily care requirements can be managed by a dedicated ICU team, but the surgeon must be kept informed, participate in and concur with major therapeutic and management decisions made by the ICU team (CD 6-75). Infants and children in Level 1 surgical centers must have on site specialty pediatric provider coverage for intensive care at all times (CD 6-76).

The children’s surgeon in Level II centers must also retain responsibility for the surgical aspects of patient care, although it is recognized that the surgeon will seek daily input from physicians
with critical care credentials consistent with the medical staff privileging process of the
institution (CD 6-77). This coverage may be provided by the patient’s primary surgical service
or by physicians credentialed in critical care by the hospital. This coverage is not intended to
replace the primary children’s surgeon in caring for the patient in the ICU; it is to ensure that the
patient’s immediate needs are met while the primary surgeon is being contacted. The PIPS
program must document that surgical responsibility is appropriate (CD-78).

ICU Support Services

At Level I, II, and III children’s surgical centers, a qualified nurse with relevant children’s
specialty training must be available 24 hours per day to provide care for infants and children with
surgical needs during any ICU phase of care (CD 6-79). The nurses caring for pediatric patients
must maintain current certification in PALS or document similar proficiency in pediatric specific
life support knowledge and skills annually. (CD 6-80) The patient/nurse ratio must be
consistent with institutional ICU standards depending on the severity of illness of the patient (CD
6-81). The ICU must have necessary equipment to monitor and resuscitate infants and children
within the scope of service (CD 6-82). This equipment includes that appropriate for airway
management, vascular access, pulse oximetry, end-tidal carbon dioxide detection, arterial
pressure monitoring, intracranial pressure monitoring and patient rewarming. Respiratory
therapy (CD 6-83) and pharmacy services (CD 6-84) must have demonstrable expertise in the
care of pediatric patients.
F. Neonatal Intensive Care Unit (NICU)

Neonatal Intensive Care Unit (NICU) designations in this document are consistent with current American Academy of Pediatrics recommendations in Appendix 1. [American Academy of Pediatrics Committee on Fetus and Newborns. Level of Neonatal Care. Pediatrics 2012; 130(3): 579-587.]. Facilities, nonphysician personnel and equipment are detailed. Surgeon engagement with neonates with surgical problems who require the NICU environment must be as delineated above for surgical critical care in a PICU. (CD 6-85) Level IV NICU resources are required for designation as a Level I children’s surgical center (CD 6-86). Level III or higher NICU resources are required for Level II children’s surgical center designation (CD 6-87).

A Level I children’s surgical center requires 24/7 neonatologist coverage (CD 6-88). A neonatologist is defined as an individual who is either sub-board eligible or certified by the American Board of Pediatrics in Neonatal-Perinatal Medicine or equivalent. Level IV NICUs must maintain a full range of pediatric medical subspecialists, children’s surgical subspecialists, and pediatric anesthesiologists on site; (index institution is the primary site of practice) (CD 6-89). Level III NICUs must provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgeons, pediatric anesthesiologists and pediatric ophthalmologists (this can be done at the site or at a closely related institution by prearranged consultative agreement) (CD 6-90).
G) Emergency Services

The ability to rapidly evaluate, respond to and resuscitate an infant or child is essential when caring for surgical patients of all ages. Level I, II or III designation requires that pediatric specific rapid response and/or resuscitation teams with experience and training to support the scope of service must be in place 24/7 to respond to any site within a designated facility (CD 6-91). 24/7 physical presence of a certified pediatric provider to include PALS certification in the leadership role for such a team is required for Level I, II or III designation (CD 6-92).

Level I children’s surgical center designation requires on site pediatric emergency medicine coverage 24/7 (CD 6-93). In addition to pediatric emergency physician coverage 24/7, children’s specific emergency department resources must be present to support the entire scope of emergency care for infants and children including facilities, equipment and nonphysician personnel (CD 6-94).

Level II and III children’s surgical centers are required to have emergency coverage by physicians with pediatric expertise (CD 6-95) and to have emergency department resources in place to support the scope of practice, including facilities, equipment and nonphysician personnel (CD 6-96). Level II centers that limit the scope of practice to neonatal patients are not required to have emergency physicians with pediatric experience or pediatric emergency physicians.
H) Primary Care Physicians and Pediatricians

The patient’s personal physician or pediatrician is important to infants and children of any age. The primary care physician or pediatrician is helpful in providing information about the patient’s history, dealing with long-term problems, and meeting the family’s psychosocial health needs. Primary care physicians and pediatricians are also important to provide continuity of care throughout the patient’s home recovery period and return to health. The immediate presence of the primary care physician or pediatrician is not a requirement.

When a committed surgeon has assumed responsibility for an infant or child with a surgical problem in a Level I, II or III children’s surgical center, he/she should recognize the primary care physician or pediatrician as a valuable resource. Depending on the local circumstances, a primary care physician may serve as a member of the care team or may provide continuity of care and act as a liaison with the family. Children with surgical needs should not be admitted or transferred by the primary care physician without the knowledge and active involvement of the surgical service.

Hospitalists have become important members of the acute care team in many institutions. A Level I, II or III children’s surgical center should have a pediatric trained hospitalist or general pediatrician available 24/7 if acute hospital care for perioperative infants and/or children is provided outside of NICU and PICU environments.
1) Other Surgical Specialists

Many surgical subspecialists are needed to properly serve a population of infants and children. Level I facilities must be prepared to manage the most complex patients and must have available a full spectrum of children’s surgical specialists beyond pediatric surgeons and pediatric anesthesiologists. (CD 6-97) Pediatric orthopedic surgery, pediatric neurosurgery, pediatric cardiac surgery, pediatric plastic surgery, pediatric ophthalmology, pediatric otolaryngology, and pediatric urology are required in Level I children’s surgical centers (CD 6-98). Level II centers may not have the local resources to provide all of these specialists, but must have appropriate children’s surgical specialists to match the scope of services offered. (CD 6-99).

Here and elsewhere children’s surgical specialists are defined as those who are either eligible for or board certified after relevant specialty fellowship training and recognized by the appropriate board of the American Board of Medical Specialties or equivalent.

For Level I and Level II verification, children’s surgical specialists must be on the medical staff and readily available (within 60 minutes) 24/7 to provide care at the bedside (CD 6-100).

Where individuals with pediatric specific training and experience are designated above as “available”, it is required that the care of infants and children will be demonstrably provided by these specialized providers (CD 6-101).
J) Medical Consultants

Contemporary management of many infants and children with surgical needs requires support from pediatric medical specialists as well. In a Level I children’s surgical center, pediatric medical specialists on staff must be available from the following disciplines: cardiology, hematology/oncology infectious disease, gastroenterology, pulmonary medicine, neurology and nephrology. (CD 6-102) Available is defined as a 24/7 response to the bedside within 60 minutes of request with care demonstrably provided by the pediatric specialist. (CD 6-103) In addition, their respective children’s specific support teams (for example, children’s respiratory therapy, pediatric dialysis team and pediatric nutrition support team) must be readily available. (CD 6-104). A multidisciplinary cancer program is highly recommended for a Level I children’s surgical center.

In a Level II facility, providers from pediatric medical specialties appropriate for the scope of services must be available on staff (CD 6-105). In Level II facilities, specialty consultations for problems related to pediatric pulmonary medicine, cardiology, gastroenterology, neurology, hematology/oncology and infectious disease must be available (CD 6-106). A multidisciplinary cancer program is highly recommended for a Level II facility.

In a Level I, II or III facility, a general pediatrician or pediatric hospitalist must be readily available within 60 minutes 24/7 if perioperative acute hospital care beyond the NICU or PICU is within the scope of service. (CD 6-107)
As for “available” surgical specialists above, children’s medical specialists must demonstrably provide needed bedside care and this must be monitored by the PIPS program (CD 6-108).

K) Support Services

Specialized support services are required to care optimally for infants and children with surgical needs. In Level I and II centers, a respiratory therapist with pediatric expertise must be available in-house 24/7 to care for patients within the scope of institutional service (CD 6-109). Acute pediatric dialysis must be available in Level I centers (CD 6-110). If a Level II center does not have pediatric dialysis capability, it must have a transfer agreement in place (CD 6-111). Pediatric nutrition support must be available in Level I and II centers (CD 6-112).

L) Child Life

A child life support program is required at Level I and II children’s surgical centers (CD 6-113).

M) Clinical Laboratory

Pediatric laboratory services to support the scope of service offered must be available 24/7 for the standard analyses of blood, urine, and other body fluids, including microsampling when appropriate, in Level I, II and III children’s surgical centers (CD 6-114). Likewise, coagulation studies, blood gases, and microbiology must be available 24/7 (CD 6-115). The blood bank must be capable of blood typing and cross-matching (CD 6-116) and must have an adequate supply of

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red blood cells, fresh frozen plasma, platelets, cryoprecipitate, and appropriate coagulation factors to meet the needs of infants and children within the scope of services. (CD 6-117)

The department of laboratory services in Level I centers should have a dedicated pediatric component that meets the needs of the patients and their caregivers. The anatomic pathology component should be represented by one or more anatomic pathologists fully committed to children’s issues. The best indicator of achieving this will be the children’s surgeons’ confirmation that the patients’ needs in this area are being met. (CD 6-118)

The department of laboratory services in Level II centers (including anatomic pathology) should have a dedicated pediatric component that meets the needs of the patients and their caregivers. The best indicator of achieving this will be the children’s surgeons’ confirmation that the patients’ needs in this area are being met. (CD 6-119)

N) Transfer of Patients

The ability to stabilize and transfer critically ill infants and children must be demonstrated all levels of designation (CD 6-120). This must include processes to safely move patients from one location to another either within or between institutions (CD 6-121).
CHAPTER 7  Data Collection and Reporting

Participation in data collection

An overarching principle of this *Optimal Resources for Children’s Surgical Care* document is to support the program using evidence based information to the maximum extent possible. While many core recommendations in this document are evidence based, a large proportion of the recommendations are guided by expert opinion and consensus. Expansion of the existing evidence base is not only necessary for improvement in the program, it is a critical mission of the Optimal Resources for Children’s Surgical Care initiative. Institutions providing optimal care for children have an obligation to participate in collection of data locally, to contribute these data to the program for collation and distribution, and to use the data to improve the care of children. Every verified children’s surgical center must collect and analyze its surgical outcome data and contribute it to the national collaborative effort (CD 7-1). For centers seeking Level I or II verification this requirement will be fulfilled by participation in the American College of Surgeons National Quality Improvement Program-Pediatric (NSQIP Pediatric) (CD 7-2). For Level III centers and ambulatory surgical centers this will be fulfilled by reporting specific safety events detailed in accompanying Appendix 3 (CD 7-3). Level I and II centers are also required to report the events detailed in Appendix 3. (CD 7-4)
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These data should be directly viewed by the medical director of children’s surgery and the children’s surgery program manager. It is essential that programs demonstrate that these individuals receive both institution-specific and national aggregate data on a regular basis (CD 7-5) and that these data are used to guide specific quality improvement initiatives within the institution (CD 7-6).

The relationship with the medical center’s electronic medical record and other data collection systems continues to evolve. The ACS supports efforts to reduce redundancy in data collection efforts. However, it is imperative that the data populating the NSQIP-Pediatric and Children’s Surgery Safety Report databases be as accurate as possible. It is expected that participating institutions be actively engaged in using the electronic resources within the institution to optimize accuracy of data and efficiency of collection. Institutions must be able to demonstrate engagement in this effort (CD 7-7). The outcome data collected via NSQIP-Pediatric will be guided by the NSQIP-Pediatric sampling algorithm [Saito JM, Chen LE, Hall BL, et al. Risk-adjusted hospital outcomes for children’s surgery. Pediatrics, 2013 Sep; 132(3):e677-88]. The data regarding safety events is expected to include all such events at the center, verified centers will be able to demonstrate the effectiveness of their data collection process at capturing all relevant events (CD 7-8).

**ACS-NSQIP-Pediatrics**

The NSQIP Pediatric is the first comprehensive risk adjusted peer reviewed outcomes program in children’s surgery. The program has demonstrated the ability to create valid risk adjusted
models that discriminate performance between participating institutions for all-cause combined morbidity, morbidity in neonatal surgery, specific morbidities (i.e. surgical site infections, pneumonia etc.), and for morbidity in specific specialties (i.e. spine surgery, pediatric abdominal surgery, others). The incidence of mortality in the pediatric surgical population is generally insufficient for this to be a discriminating variable.

Experience with the adult NSQIP program, which has been in existence for about 20 years has conclusively demonstrated that the program has produced a marked reduction in surgical morbidity and mortality in the United States. This benefit was observed in essentially all participating institutions to varying degrees. While NSQIP provides periodic reports of an institution’s adverse event rates compared to peer institutions, there is conclusive data showing that the baseline incidence of these events has progressively declined after implementation of the program. This clear demonstration that the adult NSQIP program has directly benefited patients is the basis for requiring participation in the pediatric program by Level I and II centers.

ACS-NSQIP-Pediatrics is an entity that is independent of but closely aligned with the Optimal Resource for Children’s Surgical Care initiative. Currently the program is focused on measuring system wide events such as infections, renal failure, and pulmonary complications among others. The NSQIP pediatric program is evolving to examine complications that are more operation and specialty specific and to address resource utilization. For example, a pilot project is examining the use of ionizing radiation in the diagnosis of appendicitis in children. Another project is examining functional outcomes after spinal surgery.
ACS-NSQIP-Pediatrics seeks to provide a sample of surgical practice that allows assessment of key relevant issues in children’s surgery at participating institutions and provide national comparable data to identify opportunities for improvement at the institutional level. The specific data collected by NSQIP-Pediatric is determined by the ACS-NSQIP-Pediatric steering committee composed of leaders in children’s surgery and an experienced staff of investigators and statisticians. It is expected that institutions that participate in ACS-NSQIP-Pediatric and actively utilize the information will have created a culture that is in the best interest of all patients undergoing surgery at the institution, not only those with procedures or diagnoses currently being assessed by ACS-NSQIP-Pediatrics.

Major Adverse Perioperative Events

An important but not sole focus of the Optimal Resources for Children’s Surgical Care initiative is to insure that the operating room and immediate proximate care is provided in the safest manner possible. Much of this care is provided or strongly influenced by non-surgeon members of the surgical team. This team includes but is not limited to anesthesiologists, CRNAs, nurses, technicians, and operating room support staff. It is imperative that every verified children’s surgical center accurately track and report 100% of the major adverse events that occur in the center (CD 7-9) and address them in a systematic manner with a culture of improvement and prevention (CD 7-10).

These safety events to be monitored in all surgical patients ≤ 18 years are detailed in Appendix 3. ACS-NSQIP-Pediatrics has historically not collected these types of data. Children’s surgical centers at all levels of verification will report these data directly to the American College of
Surgeons as part of the Optimal Resources for Children’s Surgical verification program. All levels of verified children’s surgical centers will be expected to develop detection and reporting processes for these events and to articulate this process for the ACS verification team at the time of site visit. (CD 7-11) This will allow better understanding of the strengths, limitations, and cost of detection methods so that detection may be improved as the program evolves.

Use of the data

There are two primary purposes for collecting data as described above. The first is for the American College of Surgeons Committee on Children’s Surgery to better understand the processes and outcomes of children’s surgical care in the United States and to develop benchmarks, standards, and expectations that will guide the evolution of the Optimal Resources for Children’s Surgical Care program. The second is to give the institutions providing the care the information and tools to develop and execute meaningful and impactful quality improvement initiatives that directly improve the quality of care for children at the facility. Verified centers will receive regular reports from the American College of Surgeons providing aggregate and institution specific data and will be expected to demonstrate the presence of ongoing quality improvement projects that derive directly from analysis of collected data (CD 7-12). Further, they will be able to provide evidence of the manner in which these projects have improved care of patients. This information must be quantitative and specific (CD 7-13). The institutions will also be able to demonstrate that these improvements have been sustained or that there is a plan in place for sustainability (CD 7-14).
Public Health

The Optimal Resources for Children’s Surgical Care program and ACS-NSQIP-Pediatrics are part of a comprehensive data system needed to describe the current status of children’s surgery in the United States. These data will provide important information about the safety, quality, cost, and outcomes of the system. They can be further stratified and analyzed by age, gender, race, ethnicity, and socioeconomic status. In combination with other public health data, this information can provide a crucial resource to governments, policy makers, and agencies interested in the health and welfare of children. These data may also be used to inform public officials about major opportunities for improvement in children’s surgical care, thus serving as a basis for legislative and regulatory efforts.

Research

Generation of new knowledge is an effective means of advancing the quality of care provided to children. This requires reliable, accurate and available data. The data collected by participation in this program can be a rich source of information to answer research questions or provide background data for new studies. All children’s surgical centers are encouraged to use their own data and national pooled data for research. Level I centers should demonstrate active research efforts utilizing the data collected, ideally resulting in peer-reviewed publication of findings.

Data entry and maintenance

High quality data begins with high quality data entry and requires ongoing maintenance to insure the quality endures. For Level I and II centers, the primary individual responsible for data entry and quality will be the Surgical Clinical Reviewer (SCR) for the institution’s NSQIP-Pediatric
program. These individuals undergo a rigorous and closely monitored period of training that is well described elsewhere. [Saito JM, Chen LE, Hall BL, et al. Risk-adjusted hospital outcomes for children’s surgery. Pediatrics, 2013 Sep; 132(3):e677-88] For children’s surgical safety reports a process must be developed and implemented that insures the data collection staff are appropriately trained and monitored to insure high quality data. (CD 7-15) The medical director of children’s surgery and children’s surgery program manager will be responsible for insuring this(CD 7-16).

**Confidentiality**

Hospitals are responsible for ensuring patient and hospital confidentiality. The passage of the Health Insurance Portability and Accountability Act (HIPAA) by Congress in 1996 brought about major changes in the way internal and external data are handled at health institutions. The children’s surgery program must ensure that appropriate measures are in place to meet the confidentiality requirements of the data (CD 7-17). All reasonable means should be used to protect against threats, hazards, and unauthorized uses or disclosures of these data. The responsible parties should ensure that all persons dealing with these data are trained in protecting the confidentiality of patients. Actions to protect confidentiality should be firmly integrated in the administration of the data collection effort at all levels so that identifying information is available only to people who have a need to know. Facilities that submit data to the ACS-NSQIP-Pediatrics or Optimal Resources for Children’s Surgical Care program or that are participating in children’s surgery center verification must have a current and fully executed business associate agreement with the American College of Surgeons (CD 7-18).
Data Collection

In the planning stages of a data collection effort, it is useful to consider the mechanisms for data collection and entry from medical records and the hospital information system. Data downloading from hospital information systems is expanding. The use of portable computers and handheld devices for data extraction and data entry is popular. It allows SCRs and data collectors to work concurrently from the medical record and interviews. Alternatively, a paper data form may be designed to record patient information for subsequent batch data entry. The least desirable method is post-discharge data extraction from the medical record. Once collected, these data are downloaded to the central registry. Provisions should be made to ensure timely and complete availability of pre-hospital care reports, operative notes, medical examiner reports, and other documents that may not always be present in the active medical record.

The amount of time and effort that will be necessary to maintain the data collection process should not be underestimated. A designated and well-trained SCR is critical to the success of a registry. The ACS-NSQIP-Pediatrics program has a track record of effective training and support of SCRs and further information is available from this program. At Level I and II centers one full-time equivalent employee dedicated to the SCR duties must be available to process the data (CD 7-19). At Level III centers and children’s ambulatory surgery centers, appropriate staffing must be demonstrated(CD 7-20). This staffing need increases if additional data elements are collected. Hospitals must also take into account the additional tasks, above the abstraction and entry of patient data, which are assigned to the data collecting staff. (CD 7-21) Processes such as report generation, data analysis, research assistance, and meeting various submission requirements will decrease the time dedicated to the meticulous collection of patient data.
Electronic downloads into the system also create additional tasks, as does ongoing data validation prior to data acceptance. Additional staff will be required to perform these tasks to ensure the integrity and quality of registry data that are used for prevention, quality improvement, and other essential aspects of the children’s surgery program.
CHAPTER 8 - Performance Improvement and Patient Safety

This chapter describes the concept of monitoring, evaluating and improving the performance of a children’s surgical program. Although there is no consensus prescription for performance improvement and patient safety (PIPS), the American College of Surgeons Committee on Children’s Surgery requires a structured effort by the program to demonstrate a continuous process for improving care for children with surgical needs at all levels of verification. (CD 8-1)

Current health care imperatives emphasize the value proposition; demonstrably high quality care delivered in a cost effective manner. Although this may be difficult to translate to the care of some infants and children, an evidence-based rather than an empiric approach presents more meaningful criteria against which our care can be measured. A standardized approach to recurring problems minimizes unnecessary variation, allows better outcome assessment and makes changes in care easier to implement and more uniform. Coordination of the PIPS children’s surgical program into a hospital-wide program offers a reduction in labor while producing more impact on quality.

Patient safety is a core focus of the PIPS process and underscores an important program goal. Safety in medical practice once was considered a “given,” but it is now recognized as an issue that clearly requires monitoring and focused attention to achieve. The patient safety process directs its efforts at the environment in which care is given, and the performance improvement process is directed at the care itself. The boundary between the performance improvement and patient safety processes is indistinct and overlap is common. A combined PIPS program is necessary to ensure optimal outcomes.
The PIPS method, which involves guideline development, process assessment, process correction, and monitoring for improvement, may seem unnecessary to surgeons who are highly motivated and work hard at providing good patient care. However, health care experts believe that individual physicians simply trying harder will not result in better quality and safer patient care. Contemporary care processes are complex and require an entire multidisciplinary team, so responsibility for a patient’s safety and optimal outcome should be shared by all involved. In centers with residency programs, residents should be exposed to the PIPS process. This exposure is valuable training and may be used to demonstrate compliance with Accreditation Council for Graduate Medical Education core competency requirements (Table 1).
<table>
<thead>
<tr>
<th>ACGME Competency</th>
<th>Related Program Areas-Examples:</th>
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<tbody>
<tr>
<td>Patient Care</td>
<td>Patient-centered emphasis on all aspects of children’s surgical program</td>
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<td>Ease of patient access to children’s surgical care</td>
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<td>Medical knowledge</td>
<td>Board-certification requirements of physician care providers</td>
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<td>Mandatory children’s surgery-related continuing education requirements for team</td>
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<td>Local, regional and national educational conferences</td>
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<tr>
<td>Professionalism</td>
<td>Commitment by the surgeons to accountability for dutiful action on behalf of patients in the framework of a public contract for care</td>
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<tr>
<td>System-based practice</td>
<td>Design of the health care system as a coordinated system of care from diagnosis to operation through patient recovery</td>
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<td>Development, use and periodic reevaluation of standardized care processes</td>
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<td></td>
<td>Use of electronic medical record and physician order entry systems when available</td>
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<tr>
<td>Practice-based learning and improvement</td>
<td>Development, use and assessment of evidence-based practice guidelines</td>
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<td></td>
<td>Data Collection/Outcomes Assessment</td>
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<td></td>
<td>Emphasis placed on performance improvement and patient safety process</td>
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<td>Children’s surgical center committee activities</td>
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<tr>
<td>Interpersonal and communication skills</td>
<td>Multidisciplinary team approach to care (rounds, conferences)</td>
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<td>Communication training related to patients, families, other professional staff</td>
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<td></td>
<td>Conflict resolution training</td>
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ACGME indicates Accreditation Council for Graduate Medical Education; and ACS, American College of Surgeons
Operational Concepts

Children’s surgical care should be efficacious, safe and cost-effective. All hospitals and providers in the United States are expected to measure, evaluate and improve their performance.

Quality assurance began with retrospective chart reviews by nonphysicians looking for documentation of predetermined criteria thought to reflect acceptable quality of physician performance. Quality assurance evolved through concepts known as total quality management and continuous quality improvement to what is known today as performance improvement.

Performance improvement emphasizes a continuous, multidisciplinary effort to measure, evaluate and improve the processes of care and the related outcomes. A major objective of PIPS is to reduce inappropriate variation in care and to improve patient safety. All children’s surgical centers (Levels I, II, III and children’s ambulatory surgical centers) must demonstrate a clearly defined PIPS program for their populations that should be coordinated with an institution wide program (CD 8-2).

The traditional use of empiric “audit filters” or “indicators” to measure the effectiveness of the process of care has had limited value because many of these resource-intense tools do not correlate with outcome. However, some filters, such as those readily available in registries or hospital-wide PIPS programs (for example, unplanned readmissions) are reasonable for trending, especially when comparative risk-adjusted benchmarking data are available. The development of expectations from evidence-based guidelines, pathways and protocols presents an alternative for measuring the process, expected outcomes and consistency of care. This model also allows for assessment of the cost-effectiveness of care.
Modern performance improvement and patient safety in surgical care is a continuous cycle of monitoring, assessment and management (Figure 1). Performance improvement must be supported by a reliable method of data collection that consistently obtains valid and objective information necessary to identity opportunities for improvement (CD 8-3). At a minimum, the program must be able to demonstrate that the data collection relevant to the children’s surgical program supports the PI process (CD 8-4). The process of analysis must include multidisciplinary review (CD 8-5) and must occur at regular intervals to meet the needs of the program (CD 8-6). The results of analysis must define corrective strategies (CD 8-7) and must be documented (CD 8-8). The effect of this change then is evaluated as the cycle repeats itself.

A patient safety program evaluates the overall care process to see whether it minimized risk of harm related to the care process itself. Various agencies concerned with patient safety have proposed specific program initiatives to improve safety of care that is often complex and delivered by multiple providers.

An effective PIPS program is characterized by a certain number of elements: (1) authority and accountability for the program; (2) a well-defined organizational structure; (3) appropriate, objectively defined standards to determine quality of care; and (4) explicit definition of outcomes derived from relevant standards.
Because it crosses many traditional specialty lines, the surgical program must be empowered to address issues that involve multiple disciplines (CD 8-9). The program, including PIPS, should be approved by the hospital governing body as part of its commitment to optimal care of children with surgical needs. This commitment must include adequate administrative support and defined lines of authority that ensure comprehensive evaluation of all aspects of surgical care for infants and children (CD 8-10). The children’s surgical program must have a medical director with the authority and administrative support to lead the program (CD 8-11). A children’s surgery program manager is a critical component of a surgery program. Although the physician director remains responsible for the overall function of the program, the surgery program manager usually is responsible for logistic information, coordination of daily data processing and
monitoring of the effectiveness of interaction of all involved services, including case
management and resource utilization.

Surgery Privilege Assessment

The medical director of children’s surgery must review the qualifications for the children’s
surgical service members (CD 8-12) and have sufficient authority to recommend changes based
on performance review (CD 8-13). This review may include evaluation of the practitioners’
continuing education, resource utilization, complications, mortality rates and participation in
evidence-based guidelines, pathways and protocols.
The granting of privileges and credentialing are departmental and medical staff functions.

Categories of Performance

General Principles

The meaning of outcome measurement varies depending on the perspective from which it is
viewed. The patient and family anticipate a complete and rapid recovery; the administrator and
payer focus upon the cost of care; and the surgeon emphasizes the quality of care, most often
based upon morbidity and mortality. Regardless of individual perspective, most would agree
with a goal of improving the value of surgical care. The spectrum of performance evaluation can
extend from institution-wide assessment to measures of individual practitioner performance.
Determinants of patient outcomes include modifiable variation in care as well as factors not so
readily managed (for example, patient comorbidities and systems performance). Another useful
method of viewing performance is through the “value equation” concept:
Value = \frac{\text{Quality of Process} + \text{Quality of Outcome}}{\text{Cost}}

Value can be increased by improving the quality of process or outcome or by decreasing cost. However, a modest increase in cost that significantly improves quality also can add value. This perspective can help prioritize performance improvement initiatives. It is clear that high quality care in the United States can be delivered at lower cost.

Process Measures (Examples)

The following categories of process variables require defined criteria (expectations), which can be determined from consensus, institutional guidelines, or, ideally, nationally derived, evidence-based guidelines. Some require peer review for determination. It is practical to monitor several rather than all of the following examples:

- Compliance with guidelines, protocols and pathways
- Appropriateness of prehospital and emergency department triage/referral
- Delay in assessment, diagnosis, technique or treatment
- Error in judgment, communication or treatment
- Appropriateness of documentation
- Timeliness and availability of imaging reports
- Timely participation of subspecialists
- Availability of operating room
- Professional behavior
- Availability of family services
- Consistency of outpatient follow-up
Care processes should be evaluated to determine if they are adequate to achieve the desired outcome. Ineffective processes should be identified, revised and reevaluated to determine if the revisions are effective.

Outcome Measures (Examples)

Clinical outcomes as well as those that reflect patient and/or family perspective are fundamental to a children’s surgical program. These examples may reflect quality of patient care:

- Mortality
- Morbidity (complications)
- Length of stay – intensive care unit and total
- Patient safety initiatives
- Cost
- Quality of life
- Functional outcomes
- Patient satisfaction
The goals of multidisciplinary review are as follows: (1) review the performance of the surgical program, (2) review the safety of the program, (3) provide focused education and (4) provide peer review. These activities can be accomplished in a variety of formats depending on the volume of patients. Patient care may be evaluated initially by individual specialties within their usual departmental PIPS review structures; however, identified problem trends must undergo multidisciplinary peer review by a dedicated children’s surgical peer review committee in Level I and II centers (CD 8-14). This function may be integrated into existing institution wide processes for Level III and ambulatory centers. The center must be able to demonstrate that specific patient populations can be identified for separate review regardless of the institutional PIPS processes (CD 8-15). This identification usually is done through a registry or similar monitoring process. Risk adjusted outcomes assessment using NSQIP-Pediatrics data is required for Level I and II children’s surgical center verification. (Chapter 7)

Program Operational Process Performance Committee

There must be a process to address children’s surgical program operational issues (CD 8-17). Typically, this function is accomplished by a multidisciplinary committee that examines related hospital operations and includes representatives from all phases of care provided to surgical patients. This is often the operating room committee or surgical authorities committee, but may take other forms. Besides physicians, this committee may include, nurses, technicians, administrators and other relevant personnel. In Level I and II centers this committee must be
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dedicated to the children’s surgical services; in Level III and ambulatory centers, this may be
integrated into existing institution wide processes. (CD 8-18) This committee should meet at
least quarterly, but may need to meet more often as necessary, to review operational performance
issues. Documentation (minutes) must reflect the review of operational issues and, when
appropriate, the analysis and proposed corrective actions (CD 8-19). This process must identify
problems (CD 8-20) and must demonstrate problem resolutions (loop closure) (CD 8-21).

**Peer Review Committee**

Center staff should be familiar with state laws governing peer review. Most peer review
activities are protected from discovery. Minutes from peer review activities should be written
carefully but document a candid discussion.

There must be a dedicated multidisciplinary children’s peer review committee in Level I and II
centers chaired or co-chaired by the medical director of children’s surgery or designee and with
participation of representatives from pediatric anesthesiology, radiology, and other children’s
surgical specialties; as well as neonatology, critical care medicine and emergency medicine if
within the scope of service. The committee will improve surgical care by reviewing all deaths,
selected complications and sentinel events with the objectives of identifying issues and
developing appropriate responses (CD 8-22). Participation must include attendance by the
aforementioned representatives (or designees) at a minimum 50% of the multidisciplinary peer
review committee meetings (CD 8-23). The medical director of children’s surgery must ensure
dissemination of information with documentation (CD 8-24). Dissemination of information
typically is achieved by attendance at peer review meetings and by letter or minutes. Evidence for appropriate participation and acceptable attendance must be documented in the PIPS process (CD 8-25). The frequency is to be determined by the medical director of children’s surgery based on the needs of the PIPS program, but must be at least quarterly (CD 8-26).

All deaths of infants and children occurring within 30 days of an operative procedure must be systematically reviewed and categorized as unanticipated mortality with opportunity for improvement, mortality without opportunity for improvement or anticipated mortality with opportunity for improvement through a peer review process (CD 8-27). Likewise, these will be characterized as patient, system or provider related.

**Corrective Action**

Monitoring and evaluation may determine that performance meets or exceeds expectations. It may be useful to monitor trends continuously or periodically. When a consistent problem or inappropriate variation is identified, corrective actions must be taken and documented (CD 8-28).

Examples of corrective actions include the following:

- Guideline, protocol or pathway development and revision
- Targeted education (for example: rounds, conferences, journal clubs)
- Enhanced resources, facilities or communication
- Process improvement/team implementation
- Counseling
- Peer review presentations
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Change in provider privileges or credentials

External review

Closing the Loop (Result)

Performance improvement entails demonstrating that a corrective action has the desired effect as determined by continuous evaluation. As the definition of quality is neither exact nor constant, improvement cannot always be demonstrated with compelling data; however, systematic use of a defined PIPS process can do so. Although some process loops may never be completely closed, all children’s surgical centers (Levels I, II, III and ambulatory) should demonstrate the continuous pursuit of performance improvement and patient safety.

Summary of Performance Improvement and Patient Safety (PIPS) Program

A children’s surgery Performance Improvement and Patient Safety (PIPS) program is an essential component of a high quality clinical surgical program. (CD 8-29) The unique elements of perioperative care of children with surgical diseases require a focused quality and safety construct that supplements existing hospital QI activities. The PIPS program for a Level I or Level II center must be a specific children’s surgical program (CD8-30); Level III and ambulatory centers may utilize processes integrated with institution wide efforts to achieve these stated objectives. (CD8-31)
The programs for Level I and II centers must include the following elements:

- Shall be a confidential quality improvement activity that is protected by all pertinent state and federal statutes. (CD 8-32)
- Must be integrated with all appropriate hospital quality improvement and safety programs and with the Board of Trustees quality committee. (CD 8-33)
- May be a dedicated sub-committee of a hospital’s existing PIPS program but must be focused on improving children’s surgical care within the institution. (CD 8-29, CD 8-30)
- Must be chaired or co chaired by the medical director of children’s surgical care (MDCS) or her/his designee. (CD 8-34)
- Must include representatives of all surgical disciplines that provide care to children in the participating center, as well as pediatric anesthesiology and radiology. When within scope of hospital surgical services, neonatology, pediatric intensive care, and emergency medicine representatives must also participate. (CD 8-35)
- Must meet at least quarterly. (CD 8-36)
- Members or designees must attend at least 50% of the PIPS meetings. (CD 8-37)
- Must establish criteria for participation of providers in each specialty, including individual providers’ credentials that document their validity as pediatric specialists in the respective disciplines. (CD 8-38)
- Must establish criteria for conditions that require physical presence of specific specialty providers. (CD 8-39)
- Must monitor the compliance of providers and the program with all criteria including physical presence of providers when indicated. (CD 8-40)
• Must review all surgical deaths, a significant cohort of surgical complications, and any serious safety events related to children’s surgical care. (CD 8-41)

• Should review the program’s quality performance metrics compared to national benchmarks and develop plans to address any significant outlying metrics.

• Must review all transfers to Level I programs for appropriateness, timeliness, and outcome. (CD 8-42)

• Will disseminate the reviews of the PIPS to all pertinent participants in the children’s surgical care program and the hospital leadership. (CD 8-43)
CHAPTER 9: Optimal Resources For Children’s Surgical Care Verification/Consultation

Program for Hospitals - Research and Scholarship Requirements

Research and Scholarship

Research and scholarly activity are some of the activities which distinguish a Level I children’s surgical center from other centers. Research, the process to advance knowledge, is essential to optimize the care of patients. The unique combination of a large volume of complex and/or severely ill infants and children, a core of experienced specialty pediatricians and pediatric surgeons, pediatric anesthesiologists, other children’s specialty surgeons and an academic infrastructure enable Level I children’s surgery centers to be effective and productive in research and scholarly activity. The research portfolio of a Level I children’s surgery center seeking American College of Surgeons verification should be balanced to reflect the diverse aspects of children’s surgical care. Mechanistic questions regarding pathophysiology and clinical care are answered using rigorous scientific methods, whereas evidence-based clinical investigations use large relational databases and other tools to evaluate standard operating procedures and patient outcomes, including cost-effectiveness. Either basic or clinical investigative approaches meet the requirements delineated herein. This chapter outlines the fundamental components of a successful research program in a Level I children’s surgical center. It also may serve as a template for research endeavors in other centers and is desirable for Level II centers.
The concept of scholarship entails the following elements.

1. Discovery
2. Leadership in major children’s surgery related organizations
3. Extramural funding
4. Dissemination of information
5. Application of clinical knowledge
6. Participation in clinical discussions and conferences
7. Support of trainee participation in scholarly activities
8. Mentorship of junior faculty, residents, and fellows

There are 2 alternatives to fulfill the research and scholarship criteria for Level I verification:

1. For a Level I children’s surgery center at the minimum, a program must have 20 peer-reviewed articles published in journals in PubMed in the most recent 3-year period (CD 9-1). These publications must result from work related to the center (CD 9-2). Of the 10 publications, at least 1 must be authored or coauthored by members of the children’s general pediatric surgery team (CD 9-3). Related articles authored by members of other disciplines or work done in collaboration with the surgical services and/or with other centers and participation in multicenter investigations may be included in the remainder.

Or

2. A Level I program must meet requirements A and B below (CD 9-4):

A. The center must have 10 peer-reviewed articles in journals included in PubMed in the most recent 3-year period. (CD 9-5) These publications must result from work related to the center. (CD 9-6) Of the 10 articles, at least 1 must be authored or
coauthored by members of a children’s specialty surgical service. (CD 9-7) Related articles authored by members of other disciplines or work done in collaboration with surgical services and/or with other centers and participation in multicenter investigations may be included in the remainder.

And

B. Of the 7 following related scholarly activities, 4 must be demonstrated: (CD 9-8)

(1) Leadership in major organizations relevant to children’s surgical care. Evidence includes membership in committees of any of the regional and national organizations.

(2) Peer-reviewed funding for related research. There should be demonstrated evidence of funding of the center from a recognized government or extramural private agency or organization.

(3) Evidence of dissemination of knowledge to include review articles, book chapters, technical documents, Web-based publications, editorial comments, training manuals, and related course material

(4) Display of scholarly application of knowledge as evidenced by case reports or reports of clinical series in journals included in PubMed

(5) Participation as a visiting professor or invited lecturer at relevant national or regional conferences
(6) Support of resident participation in institution-focused scholarly activity, including laboratory experiences, clinical trials, or resident paper competitions at the state, regional, or national level

(7) Mentorship of residents and fellows, as evidenced by the development of a children’s surgical fellowship program or successful matriculation of graduating residents into such fellowship programs

**Research Infrastructure**

There is renewed emphasis on translational research in recent years. Discoveries in basic science require engagement of enlightened clinicians to make them applicable at the bedside, and queries at the bench are not relevant to patients until pursued form a clinical perspective. Capitalizing on the unique coexistence of expert children’s surgeons and committed basic and social scientists benefits a structured research program. It is likely that most Level I centers will be housed in academic medical centers.

Perhaps the most important resource is a core of children’s surgeons with interests and dedicated training in research methodology. Specifically, the Level I center medical director of children’s surgery (MDCS) should have a record of established basic science or clinical research productivity with regular participation in academic forums. A children’s surgeon who remains clinically active in patient care should direct formal, regularly scheduled research meetings with documentation of the ongoing activities. Basic or social scientists should participate in the regularly scheduled research meetings, but the majority of the attendees should be surgeons and
surgical residents or research fellows. Finally, the administration of the Level I children’s
surgical center must demonstrate support for the research program, such as by providing basic
laboratory space, research equipment, advanced information systems, biostatistical support,
salary support for basic and social scientists, research support personnel, or seed grants for less
experienced faculty (CD 9-9).

**Research Activity**

Every children surgery center should continually evaluate its own outcomes and compare these
with regional and national benchmarks. Trend analyses of morbidity and mortality and
assessment of pertinent selected events to monitor the quality of care often raise important
research questions. In addition to morbidity and mortality, outcome assessment should include
age appropriate functional outcome and quality of life measures.

Nurse coordinators and registrars are an integral part of the research team for ensuring the
collection of complete and accurate data and regularly providing clinical outcomes reports.
Clinical research nurses and clinical specialists are also valuable for the research program by
coordinating patient selection, adherence to protocols, timely specimen acquisition, and ongoing
surveillance of patient outcomes. All of these personnel should be involved in the research effort
and should participate in the presentation and publication of reports and major meetings and in
the peer-reviewed literature.
The more sophisticated the performance improvement process the more likely it will generate appropriate research questions. The distinguishing quality of a Level 1 children’s surgery center is development of timely research questions well beyond established national standards.

Because of the fortuitous combination of expert children’s surgeons and patients with complex illness in a scholarly environment, Level I centers are ideal settings to generate novel study hypotheses that explore clinical dilemmas from a unique perspective. Furthermore, Level I centers are positioned to engage the collaboration of qualified basic and social scientists to design studies to address these complex issues.

Residents and fellows in surgical training are another key component of research activity in a Level I children’s surgery center. Involving them in research projects, presentations at major meetings, and publications are important elements in the mentorship function of centers and a valuable part of surgical education that fosters development of the next generation of children’s surgeons. The Level I children’s surgery center should demonstrate resident participation and authorship in related publications.

**Research Productivity**

Level I children’s surgery centers have a responsibility to disseminate their research findings in a timely and effective manner. The best measure of research productivity is peer-reviewed publication. In addition, currently, the most effective means to convey novel and provocative research findings is by presentations at meetings of national and regional academic societies. Level I centers should be presenting their research results at these venues annually. The medical
director of children’s surgery and other children’s surgeons in each discipline should be
presenting their research work regularly as well. The medical director of children’s surgery and
surgeons participating in patient care at a Level I center should be actively engaged in research
and coauthor peer-reviewed articles. Furthermore, because Level I children’s surgery centers
provide comprehensive care for severely ill infants and children with multidisciplinary needs,
other key team members also are expected to be academically productive. Each of these groups
should have peer-reviewed articles and presentations at their respective national academic
society meetings.

Research Funding

The administration of a Level I children’s surgery center should contribute substantively to the
research program, but extramural funding may be necessary to conduct and sustain meaningful
research. Level I centers should be competitive for extramural research funds.

Research Role Models

The leadership in surgery should continue to demonstrate, by personal example, that quality
research is an integral and gratifying part of the discipline. Implicitly, the medical director of
surgery of a Level I children’s center ideally should have an established record of research
productivity and continue to be an active participant and a spokesperson for children’s surgical
research at the national level. For example, Level I centers should participate in large
collaborative research programs sponsored by the National Institutes of Health, the Department
of Health and Human Services, ACS or other professional societies. Research is important to
advance the field of children’s surgical care and train the future generation of children’s
surgeons. The Level I center serves as the role model within the community. Research is an
opportunity and an obligation.
CHAPTER 10  Outreach and Education

Children’s surgical centers are important community and regional resources. In addition to the patient care services they provide, these centers are sources of information, expertise, and public leadership. Programs to strengthen and foster community engagement are an integral part of children’s surgical center services designed to help improve outcomes through the public and professional dissemination of information and by facilitating access to clinical and educational resources. The components of an outreach program may include public awareness and education or professional education through course offerings, lectures, conferences, visitation programs, web sites, newsletters, and other means. The scope of educational and outreach programs will depend on many factors in a given region, including population size, type and level of the center, and regional needs and resources. All verified children’s surgical centers, however, must engage in public and professional education (CD 10-1). Level I and II centers also must provide some means to facilitate referral and access to children’s surgical center resources (CD 10-2).

Professional Education and Training

Principles of children’s surgical care are introduced in medical school, nursing school, prehospital provider programs, and other allied health training programs. Graduate medical education (GME) in the form of relevant residency and fellowship training programs is highly desirable within a children’s health care system. The ACS recognizes that residency programs provide service to surgical centers, but the educational experience should be the prime focus. The residency training programs should emphasize direct supervision and teaching of residents by dedicated attending surgeons who have demonstrated interest and expertise in children’s
surgery. Centers that support residency training programs and fellowships in children’s surgery should have a clear written curriculum for the development of trainee expertise and appropriate trainee supervision within the program. In addition, residents should be given an introduction to the surgical services and meet the ACGME educational requirements for their respective programs. At a minimum, a Level I children’s surgical center must have a continuous rotation in surgery for senior residents that is part of an Accreditation Council for Graduate Medical Education-accredited program in at least one of the following disciplines: general surgery, orthopedic surgery, urology, neurosurgery or otolaryngology. (CD 10-3)

Continuing medical education (CME) programs are important to maintain and enhance the knowledge and skills to care for children with surgical needs. Cooperative arrangements with other institutions may enhance available educational programs. Postgraduate education courses for nurses are available. Some nurse practitioners may choose to specialize in pediatric care. Nurses and other allied health professionals who are involved in the children’s surgical program should have their educational needs identified and served. In Level I, II, III and ambulatory centers, the hospital must provide a mechanism to offer relevant children’s surgical education to nurses and other allied health professionals who are part of the children’s surgical team (CD 10-4).

Multidisciplinary education should be ongoing in all children’s surgery centers. Performance improvement programs should be an important part of educational activities. Intramural educational programs are an efficient means of providing information to the surgical team.
Children’s surgery centers should expend financial resources to facilitate intramural and extramural educational programs.

It is important that all members of the children’s surgical team are knowledgeable about current practices in children’s surgical care. External CME is the recommended method of keeping current. The medical director of children’s surgery, the liaison representatives from each of the surgical subspecialties performing children’s surgery, as well as the liaison or medical director of pediatric anesthesiology, emergency medicine and radiology, must accrue an average of 16 hours annually or 48 hours in 3 years of related external Category I CME (CD 10-5). Programs given by visiting professors, invited external speakers, and teaching done by children’s surgeons elsewhere are considered external CME.

All members of children’s surgical specialties who take call also must be knowledgeable and current in the care of children’s with surgical needs (CD 10-6). This requirement may be met by documenting acquisition of 16 hours of relevant CME per year on average as above or by demonstrating participation in an internal educational process conducted by the children’s surgical program and the specialty liaison based on the principles of practice-based learning and the performance improvement and patient safety program.

Medical specialists and other providers involved in children’s surgical care are encouraged to participate in related CME activities on a regular basis.
Outreach: Engaging the Center in Regional Care and Education

Outreach is the act of providing center expertise, information, and leadership to institutions, agencies, and individuals within a region for the purpose of improving the care of infants and children with surgical needs. A good outreach program allows the verified center to serve as a regional resource for the benefit of patients and providers. The goals of an outreach program are as follows:

- To improve regional outcomes for children’s surgery by the dissemination of knowledge and expertise regarding the care of infants and children
- To participate with regional agencies, organizations, and providers in improving the care within the geographic region
- To facilitate access to center resources (such as educational programs, performance improvement, consultation, and referral)
- To support educational programs of regional facilities and health care personnel

Regional hospitals, including pediatric and non-pediatric center facilities, should have access to consultation by staff members from larger children’s centers for a variety of purposes: (1) to improve and facilitate care on a case-by-case basis, including referrals, transfers, and follow-up care as appropriate; (2) to enhance institutional performance improvement activities, including protocol development; and (3) to facilitate the adaptation of children’s surgical center programs, including performance improvement and patient safety and prevention, to other institutions. It falls to the regional referral center (typically Level I and II) to facilitate this access.
Children’s surgical centers also should promote the quality and continuity of care in cases of referral or transfers out, by good communication with referring and receiving providers and establishment of guidelines applicable to referrals and repatriation transfers.
CHAPTER 11 Consultation/Verification Program

The American College of Surgeons has a long history of activities directed toward the improvement of surgical care. This new program defines the resources believed necessary to achieve optimal patient outcomes for children’s surgical care at verified centers. The verification program is administered by the American College of Surgeons (ACS) Committee on Children’s Surgery. This document, *Optimal Resources for Children’s Surgical Care* is to be used as a guide for the development and verification of centers throughout the United States. It is the basis upon which centers will be reviewed by ACS approved site surveyors. The ACS does not designate centers; rather, it verifies the presence of the resources detailed in *Optimal Resources for Children’s Surgical Care*.

The ACS Consultation/Verification Program is designed to assist institutions in the evaluation and improvement of children’s surgical care and provide objective, external review of institutional capability and performance. These functions are accomplished by an on-site review of the hospital by a peer review team composed of individuals experienced in the field of children’s surgical and anesthetic care. The team assesses commitment, readiness, resources, policies, patient care, performance improvement, and other relevant features of the program as outlined in *Optimal Resources for Children’s Surgical Care*. 
Consultation

The ACS-Committee on Children’s Surgery will provide a consultation visit, at the request of a hospital, community, or other relevant institution to assess children’s surgical care or to prepare for a verification review. The core two-surgeon team or a multidisciplinary team may be requested. A consultation visit will follow the same format as a verification review. It will provide recommendations and aid the facility in attaining verification.

Verification

Center verification is the process by which the ACS confirms that the hospital is performing as a children’s surgical center and meets the criteria delineated in Optimal Resources for Children’s Surgical Care. A verification review process results in a report outlining the findings and, if successful, a certificate of verification. This certificate is valid for 3 years, after which a reverification site visit may be requested.

If, during a verification review, a hospital is found to have criterion deficiencies, it must demonstrate that they have been corrected before a certificate is issued. If the deficiencies are significant, at the discretion of the ACS Committee on Children’s Surgery, an on-site focused review may be necessary, in which a team returns to the facility. Generally, one member of the original team will be involved in this review process. The focused review will be accomplished in no less than 6 months and not more than 1 year from the time of the notification of the results of the initial review.
When the correction of deficiencies can be demonstrated by submitting data to the ACS Committee on Children’s Surgery, the focused review can be completed without an on-site review. The information submitted must be signed by the medical director of children’s surgery (MDCS) and the hospital chief executive officer. If the deficiencies are remedied and their correction can be demonstrated in writing, a certificate will be issued.

If a hospital has previously been verified and criterion deficiencies are identified at the time of a reverification visit, the verification status may be extended for up to 6 months. During this time, the hospital must document the correction of all identified deficiencies. If all deficiencies are not corrected, further extensions will not be considered.

**Multidisciplinary Review**

The on-site review is led by two surgeons (core team) from the ACS; there may be a requirement or desire that center capability be evaluated by a multidisciplinary team. The ACS can assist in this process. Other members may include a representative of any discipline identified by the requesting institution or hospital.
The Consultation/Verification Process

Following the receipt of a request (application for site visit) and the completion of the prereview questionnaire, a review team is selected. A mutually acceptable date for the review will be established. All reviewers will be from out-of-state or province unless there is a special request for in-state or province reviewer. Surgeon reviewers are selected from specialty qualified children’s surgeons. The hospital is required to provide medical records needed at the time of the visit. A description of the medical records needed to conduct a site visit will be provided to allow the hospital 2 to 3 weeks or more to identify the charts and obtain or access the records.

Consistency of the review process is facilitated by the following:

1. A Pre Review Questionnaire (PRQ) allows site visitors to have a better understanding of the existing care capabilities and the performance of the hospital and medical staff before beginning the review. This questionnaire may be completed online by the hospital.

2. Guidelines for site visitors: A document describing the guidelines for a review is provided to all site visitors. This document is designed to ensure that reviews are conducted consistently. It defines the process of the review and elements of appropriate conduct by a reviewer.

3. An organized agenda is prepared for the review so that all reviews are performed in an efficient manner.
4. Every site visit team is led by a senior reviewer approved by the ACS.

5. The report is written in a standardized format.

6. A final review of all reports is done by the ACS Committee on Children’s Surgery.

**Prereview Meetings**

A prereview meeting facilitates an efficient on-site review process. The review team will meet with the medical director of children’s surgery, surgery program manager, and a hospital administrator selected by the applicant organization. Other individuals may be invited who are needed to clarify the prereview questionnaire and describe existing center activities. The meeting is intended to include discussion of the overall children’s surgery program, clarification of the prereview questionnaire, specific concerns, unique features of the institution, regional context, and clarification of the review process.

The on-site review will require approximately 6 to 8 hours. All children’s surgical care areas of the hospital may be visited. Emphasis is placed on evaluating medical records of selected surgical infants and children and correlating patient care with the performance improvement program. The visit concludes with an exit interview to discuss the reviewers’ findings and conclusions. The reviewers will prepare a report that reflects the statements made at the exit interview. This report is forwarded to the ACS Committee on Children’s Surgery which will review this report and determine the presence or absence of deficiencies and whether a hospital
can be verified. The ACS Committee on Children’s Surgery has the authority to issue final approval. This process ensures accurate interpretation of the findings, well-documented conclusions, and consistency and professionalism in the final report. This final process may modify the conclusions of the individual site reviewers’ report to ensure consistent interpretation of the resources documented. Confidentiality of the entire review process ensures an institution that the program is designed to be a constructive process in which a hospital can place its trust. If verified, a hospital will be included on an ACS list of currently verified children’s surgical centers which will be available publicly. This list will be updated every 3 months.

**Appeal Process**

If the applicant organization or hospital does not agree with the review process, the reviewers’ findings, or the final report, it may appeal in writing to the ACS Committee on Children’s Surgery. The ACS Committee on Children’s Surgery may require additional documentation, a new review team may be sent for another review, or the issue may be referred to the ACS.

**Verification Quality Assurance Process**

In keeping with the concept of self-evaluation for the purpose of improvement, the ACS Committee on Children’s Surgery will institute a process to ensure that the needs of applicant hospitals/organizations are being met in a satisfactory manner. At the time the final report is sent, an extensive questionnaire will be sent to the medical director of children’s surgery and surgery program manager. This survey will cover the entire process, from the purpose of the
prereview meeting to the quality of the final report. Comments will be solicited about the
conduct of the reviewers and obtain an assessment of the total program. The chair of the ACS
Committee on Children’s Surgery, as well as other selected members of the Committee, will
carefully review these comments.

Changes will be made in certain areas identified and, if appropriate, reviewers will be counseled.
For similar reviews in other programs, the biggest concern occurs when the institution is told one
thing at the exit interview and additional deficiencies appear in the final report. A concentrated
effort will be made at the time of the review to inform the organization or hospital that the ACS
Committee on Children’s Surgery makes the final decision.

Application Forms and Site Visit Information

Requests for verification or consultation information should be addressed to:
American College of Surgeons
Children’s Surgical Care
Verification Review Program

633 N. St. Clair St.
Chicago, IL 60611-3211
312/202-5456

These forms also are available from the American College of Surgeons web site at
www.facs.org/??/application.doc.
Levels of Neonatal Care
COMMITTEE ON FETUS AND NEWBORN

The online version of this article, along with updated information and services, is located on the World Wide Web at:

http://pediatrics.aappublications.org/content/130/3/587.full.html
Policy Statement

Levels of Neonatal Care

Committee on Fetus and Newborn

Key Words
neonatal intensive care, high-risk infant, regionalization, maternal and child health, health policy, very low birth weight infant, hospital newborn care services, nurseries

Abbreviations
AAP—American Academy of Pediatrics
aOR—adjusted odds ratio
CI—confidence interval
CON—certificate of need
ELBW—extremely low birth weight
TIOP—“Toward Improving the Outcome of Pregnancy”
VLBW—very low birth weight

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Abstract

Provision of risk-appropriate care for newborn infants and mothers was first proposed in 1976. This updated policy statement provides a review of data supporting evidence for a tiered provision of care and reaffirms the need for uniform, nationally applicable definitions and consistent standards of service for public health to improve neonatal outcomes. Facilities that provide hospital care for newborn infants should be classified on the basis of functional capabilities, and these facilities should be organized within a regionalized system of perinatal care. Pediatrics 2012;130:587–597

Objective

This revised policy statement reviews the current status of the designation of levels of newborn care definitions in the United States, which were delineated in a 2004 policy statement by the American Academy of Pediatrics (AAP). Since publication of the 2004 policy statement, new data, both nationally and internationally, have reinforced the importance of well-defined regionalized systems of perinatal care, population-based assessment of outcomes, and appropriate epidemiologic methods to adjust for risk. This revised statement updates the designations to provide (1) a basis for comparison of health outcomes, resource use, and health care costs, (2) standardized nomenclature for public health, (3) uniform definitions for pediatricians and other health care professionals providing neonatal care, and (4) a foundation for consistent standards of service by institutions; state health departments; and state, regional, and national organizations focused on the improvement of perinatal care.

Background

The availability of neonatal intensive care has improved the outcomes of high-risk infants born either preterm or with serious medical or surgical conditions. Many of these improvements can be attributed to the concept and implementation of regionalized systems of perinatal care, broadly articulated in the 1976 March of Dimes report “Toward Improving the Outcome of Pregnancy” (TIOP I). The TIOP I report included criteria that stratified maternal and neonatal care into 3 levels of complexity and recommended referral of high-risk patients to higher-level centers with the appropriate resources and personnel to address the required increased complexity of care. However, since the initial TIOP I report was published more than 3 decades ago, there have been signs of deregionalization, including (1)
an increase in the number of NICUs and neonatologists, without a consistent relationship to the percentage of high-risk infants, (2) a proliferation of small NICUs in the same regions as large NICUs, and (3) failure of states to reach the Healthy People 2010 goal that 90% of deliveries of very low birth weight (VLBW; <1500 g) infants occur at level III facilities.

In the environment of deregionalization, preterm birth rates have increased 13% overall from 1990 to 2010 (10.6%–12.0%) as a result of a variety of factors, including increases in elective early cesarean deliveries, multiple births, advanced maternal age, and complications of pregnancy. The majority of the increase in the preterm birth rate (≥70%) is attributable to late preterm births. Infants born late preterm can experience significant morbidity that may result in the need for specialized care and advanced neonatal services. An increase in the supply of specialty staff and availability of new neonatal therapies (eg, bubble continuous positive airway pressure), have expanded the scope of care in level II facilities. Some have expressed concern that level II hospitals have expanded their scope of care without sufficient evidence of favorable outcome. Because most infant deaths in the United States occur among the most immature infants in the first few days after birth, improvements in regionalized systems may reduce mortality among the most preterm newborn infants.

**REVIEW OF THE LITERATURE ON NEONATAL LEVELS OF CARE SINCE THE 2004 AAP POLICY STATEMENT**

In 2004, the AAP defined neonatal levels of care, including 3 distinct levels with subdivisions in 2 of the levels. Level I centers provided basic care; level II centers provided specialty care, with further subdivisions of IIA and IIB centers; and level III centers provided subspecialty care for critically ill newborn infants with subdivisions of level IIIA, IIIB, and IIIC facilities. Data published since the 2004 statement have informed the development of the levels of care in this new policy statement.

A meta-analysis of the published literature from 1978 to 2010 clearly demonstrates improved outcomes for VLBW infants and infants <32 weeks’ gestational age born in level III centers. Lasswell et al reviewed 41 English-language US and international studies, which included >113,000 VLBW infants and found that VLBW infants born at non–level III hospitals had a 62% increase in odds of neonatal or predischarge mortality compared with those born at level III hospitals (adjusted odds ratio [aOR], 1.62; 95% confidence interval [CI], 1.44–1.83). Subset comparisons of studies identifying infants <32 weeks’ gestation and extremely low birth weight (ELBW) infants (<1000 g) demonstrated similar effects (aOR, 1.55; 95% CI, 1.21–1.98; aOR, 1.64; 95% CI, 1.14–2.36, respectively). When only higher-quality studies were included, the findings were consistent (VLBW aOR, 1.60; 95% CI, 1.33–1.92; <32 weeks’ gestation aOR, 1.42; 95% CI, 1.06–1.88; ELBW aOR, 1.80; 95% CI, 1.31–2.36). The effect of level of care on VLBW mortality did not vary by decade of publication; hence, the risk of death for VLBW infants born in level I or II facilities remained higher than those born within a level III facility. Figures 1, 2, and 3 summarize the findings of these studies.

As Lasswell and colleagues found, part of the difficulty in collecting evidence to provide accurate assessments of VLBW outcomes has been in obtaining appropriate standardized measures. Heterogeneity among studies on neonatal levels of care suggests the need for a quality standard for comparison which includes the following elements: (1) population-based studies within well-defined geographic regions, (2) clear definitions of the “intervention” or hospital level of care, and (3) appropriate adjustment for confounding factors to include maternal social and demographic risk factors, pregnancy and perinatal risks, and severity of illness at delivery.

**Current Controversies in Levels of Care Designation**

Although little debate exists on the need for advanced neonatal services for the most immature and surgically complex neonates, ongoing controversies exist regarding which facilities are qualified to provide these services and what is the most appropriate measure for such qualification. These issues are, in general, based on the need for comparison of facility experience (measured by patient volume or census), location (inborn/outborn deliveries, regional perinatal center, or children’s hospital), or case mix (including stillbirths, delivery room deaths, and complex congenital anomalies).

Several studies have explored the topic of center experience as measured by volume or census of VLBW infants. Phibbs et al conducted a population-based retrospective cohort study of 48,237 California VLBW infants to examine differences in neonatal mortality among NICUs with various levels of care and patient volumes. When compared with high-volume, high-level centers, the odds ratio of death was 1.19 (range, 1.04–1.37) for level IIIB, IIIC, or IIIC centers with <100 annual admissions, 1.78 (range, 1.35–2.34) for level IIIC centers with 26 to 50 annual admissions, and 2.72 (range, 2.37–3.12) for level I centers with <10 annual admissions. The authors also found that the percentage of VLBW infants delivered in level IIIB, IIIC, or IIIC centers decreased from 36% in 1991 to 22% in
2000 and estimated that shifting VLBW births in urban areas (92% of VLBW births) to level IIIC or IIID centers with >100 annual admissions would have prevented 21% of VLBW deaths in 2000.30

In a secondary data analysis, Chung et al found that deregionalization of California perinatal services resulted in 20% of VLBW deliveries occurring in level I and level II hospitals, with lower-volume hospitals having the highest odds of mortality.31

A population-based study of 4379 VLBW infants who were born between 1991 and 1999 in Lower Saxony, Germany, evaluated neonatal mortality in relation to both the annual volume of births and NICU volume.32 There was an increased odds of mortality in centers with annual NICU admissions of fewer than 36 VLBW infants; the largest...
effect on mortality was for infants born at less than 29 weeks' gestation.

Other studies assessing NICU volume suggest caution in using this measure as an effective indicator of quality of care. Rogowski and colleagues assessed the potential usefulness of NICU volume as a quality indicator among 94,110 VLBW infants entered into the Vermont Oxford Network database between 1995 and 2000 and compared NICU volume with other indicators based on hospital characteristics and patient outcomes. They found that although annual volume explained 9% of the variation in hospital mortality rates, other hospital characteristics explained another 7%. They suggested that direct measures based on patient outcomes are more useful quality indicators than volume for the purpose of selective referral.

Several studies have compared the short-term outcome of VLBW infants born in centers with level III units (inborn) compared with those born at lower level centers and soon transferred to a higher level (level III or children's hospital; outborn). Many of these studies are retroactive and may be subject to selection bias because infants who were transferred most likely had the highest chance of survival and thus gave the impression of lower mortality. In a secondary analysis of a randomized placebo-controlled study of preemptive morphine analgesia on neonatal outcomes, Palmer et al compared neonatal mortality as related to place of birth for 894 infants who were born at 23 to 32 weeks' gestation. Outborn babies were more likely to have severe intraventricular hemorrhage (P = .0005), and this increased risk persisted after controlling for severity of illness. However, when adjusted for antenatal steroids, the effect of birth center was no longer significant.

Evaluating and controlling for confounding variables and "case-mix" presents another set of challenges because these factors vary by population. For example, race and insurance status may have more of an effect on birth outcomes in the United States than in countries with a more homogenous population and universal national health care. There are also potential confounding factors for which measurement is frequently lacking, such as parental wishes regarding aggressive resuscitation of an infant. Arad et al noted that parental wishes varied by religious affiliation in their 2-hospital study. Because religious affiliation was unequally distributed between the 2 hospitals, fewer attempts at resuscitation may have been made at the level III hospital, with a result of improved survival at the level II facility. More comprehensive studies controlling for confounding factors are needed.

Measured outcomes other than VLBW mortality (notably, fetal mortality, postdischarge mortality, and long-term physical and neurodevelopmental outcomes) may offer important information in assessing the evidence for newborn levels of care and perinatal regionalization. Studies measuring the effect of hospital level of birth on fetal
and neonatal outcomes stratified by gestational age, as well as by birth weight, are also helpful, because gestational age is a better gauge of fetal maturity.\textsuperscript{41-44} Although some studies include stillbirths and intrapartum fetal deaths, measurement and surveillance of fetal death varies widely.\textsuperscript{5} Congenital anomalies are often excluded from studies of perinatal regionalization but should be considered in the provision of risk appropriate care.\textsuperscript{45} Additional studies are also needed to assess the effectiveness and potential cost savings of centralizing expensive technologies and provider expertise for relatively rare conditions at a few locations and to assess the effectiveness, including costs, of antenatal transport.

**IMPORTANT OF NEONATAL LEVELS OF CARE**

**Provision of Standardized Nomenclature for Public Health**

Since 2004, efforts have been made to improve the comparison of health outcomes by hospital facility through the use of standardized nomenclature on the US birth certificate. The National Center for Health Statistics at the Centers for Disease Control and Prevention has worked with states to use the newly revised US Standard Certificate of Birth.\textsuperscript{66} This 2003 revised certificate defines a NICU as a “hospital facility or unit staffed and equipped to provide continuous mechanical ventilatory support for a newborn infant.” It also includes information on the use of antenatal therapies and postpartum surfactant, which may be useful in monitoring population-based utilization of technologies at birth.\textsuperscript{57} In an analysis of 16 states using the revised certificate of birth, Barfield et al found that overall, 77.3% of VLBW infants were admitted to NICUs; this estimate varied by state and ranged from 63.7% in California to 93.4% in North Dakota. Among VLBW infants of Hispanic mothers, 71.8% were admitted to NICUs, compared with 79.5% of VLBW infants of non-Hispanic black mothers and 80.5% of VLBW infants of non-Hispanic white mothers. In multivariable analysis, preterm delivery, multiple gestation, and cesarean delivery were associated with higher prevalence of NICU admission among VLBW infants.\textsuperscript{13} State variations in the receipt of intensive care for VLBW infants may explain, in part, variation in VLBW outcomes across the country.

**Use of Uniform Definitions of Levels of Care for Pediatricians and Other Health Care Professionals**

Variation in definition, criteria, and state enforcement still occurs despite the TIOP I guidelines. Blackmon et al conducted an extensive review of all 50 states and the District of Columbia governmental Web sites to assess state definitions and levels terminology, functional and utilization criteria, regulatory compliance and funding measures, and citation of AAP documents on levels of neonatal care. The authors found that state definitions, criteria, compliance, and regulatory mechanisms for the specific type of care neonatal centers provide varied considerably, and they suggested a consistent national approach.\textsuperscript{48} Lorch et al assessed all 50 states and the District of Columbia to identify state certificate of need (CON) legislation, a mechanism that regulates the expansion of NICU facilities and NICU beds. Thirty states regulated the construction of NICUs through CON programs, and non-Congress program states were associated with more NICU facilities and NICU beds. Thirty states regulated the construction of NICUs through CON programs, and non-Congress program states were associated with more NICU facilities and NICU beds (relative risk, 2.06; 95% CI, 1.74–2.45; and relative risk, 1.96; 95% CI, 1.89–2.03, respectively). In large metropolitan areas, non-Congress states had higher infant mortality for all birth weight groups.\textsuperscript{49} The Maternal and Child Health Bureau of the Health Resources and Services Administration has worked with state Title V agencies to document the percentage of VLBW infants delivered in level III hospitals or subspecialty perinatal clinics. In 2009, only 5 states met the goal of at least 90% of VLBW infants delivered at high-risk facilities.\textsuperscript{12} Yet, the interpretation and reporting of these facilities may be inconsistent as some states had unclear facility definitions or included level II facilities in their reporting. Recently, several states, in partnership with national organizations, have taken more definitive action in defining and regulating organization of perinatal care.\textsuperscript{50}

**Development of Consistent Standards of Service**

Efforts by quality-improvement collaboratives, health services researchers, and public health officials will continue to improve the standards by which to measure quality of care.\textsuperscript{51,52} Quality-improvement activities have begun to flourish at all levels to improve maternal and perinatal health and ideally prevent preterm births; this includes provider-level quality-improvement activities, hospital-level performance measures, and regional, state, and national performance measures.\textsuperscript{53} Organizations such as the March of Dimes have promoted standard definitions of levels of care since the introduction of perinatal regionalization in the 1970s, reaffirmed its importance in 1993 (TIOP II),\textsuperscript{54} and included the concept of quality care for the prevention of preterm birth with a new TIOP (TIOP III) in 2010.\textsuperscript{55}

**DEFINITIONS OF LEVELS OF NEONATAL CARE**

The updated classification consists of basic care (level I), specialty care (level II), and subspecialty intensive care (level III, level IV, Table 1). These definitions reflect the overall evidence for risk-appropriate care through the availability of appropriate personnel, physical space, equipment, technology, and
Each level reflects the minimal capabilities, functional criteria, and provider type required. Currently, there are 148 specialty care units and 809 subspecialty care units self-identified in the 2009 AAP perinatal section directory.

### Level I

Level I facilities (well newborn nurseries) provide a basic level of care to neonates who are low risk. They have the capability to perform neonatal resuscitation at every delivery and to evaluate and provide postnatal care to stable term newborn infants. In addition, they can care for preterm infants at 35 to 37 weeks’ gestation who are physiologically stable and can stabilize newborn infants who are less than 35 weeks of gestation or who are ill until they can be transferred to a facility at which specialty neonatal care is provided. Because late preterm infants (34–36 weeks’ gestation) are at risk for increased neonatal morbidity and mortality, more evidence is needed to determine their outcomes by level of care.

### Level II

Care in a specialty-level facility (level II) should be reserved for stable or...
moderately ill newborn infants who are born at $\geq 32$ weeks’ gestation or who weigh $\geq 1500$ g at birth with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty-level services on an urgent basis. These situations usually occur as a result of relatively uncomplicated preterm labor or preterm rupture of membranes. There is limited evidence to support the specific subdivision of level II care, in part because of the lack of studies with well-defined subdivisions. Level II facilities should take into consideration geographic constraints and population size when assessing the staffing resources needed to care appropriately for moderately ill newborn infants.

Level II nurseries may provide assisted ventilation on an interim basis until the infant’s condition either soon improves or the infant can be transferred to a higher-level facility. Delivery of continuous positive airway pressure should be readily available by experienced personnel, and mechanical ventilation can be provided for a brief duration (less than 24 hours). Level II nurseries must have equipment (eg, portable x-ray machine, blood gas analyzer) and personnel (eg, physicians, specialized nurses, respiratory therapists, radiology technicians, laboratory technicians) continuously available to provide ongoing care as well as to address emergencies. Referral to a higher level of care should occur for all infants when needed for pediatric surgical or medical subspecialty intervention.

Level III

Evidence suggests that infants who are born at $< 32$ weeks’ gestation, weigh $< 1500$ g at birth, or have medical or surgical conditions, regardless of gestational age, should be cared for at a level III facility. Designation of level III care should be based on clinical experience, as demonstrated by large patient volume, increasing complexity of care, and availability of pediatric medical subspecialists and pediatric surgical specialists. Subspecialty care services should include expertise in neonatology and also ideally maternal-fetal medicine, if mothers are referred for the management of potential preterm birth. Level III NICUs are defined by having continuously available personnel (neonatologists, neonatal nurses, respiratory therapists) and equipment to provide life support for as long as necessary. Facilities should have advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care.

Level III facilities should be able to provide ongoing assisted ventilation for 24 hours or more, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide. Level III facility capabilities should also be based on a region’s consideration of geographic constraints, population size, and personnel resources. If geographic constraints for land transportation exist, the level III facility should ensure availability of rotor and fixed-wing transport services to quickly and safely transfer infants requiring subspecialty intervention. Potential transfer to higher-level facilities or children’s hospitals, as well as back-transport of recovering infants to lower-level facilities, should be considered as clinically indicated. A broad range of pediatric medical subspecialists and pediatric surgical specialists should be readily accessible on site or by prearranged consultative agreements. Prearranged consultative agreements can be performed by using telemedicine technology and/or telephone consultation, for example, from a distant location. Pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity should be readily available in level III facilities. Level III units should have the capability to perform major surgery on site or at a closely related institution, ideally in close geographic proximity. Because the outcomes of less complex surgical procedures in children, such as appendectomy or pyloromyotomy, are better when performed by pediatric surgeons compared with general surgeons, it is recommended that pediatric surgical specialists (including anesthesiologists with pediatric expertise) perform all procedures in newborn infants.

Level III facilities should have the capability to perform advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography. Level III facilities should collect data to assess outcomes within their facility and to compare with other levels.

Level IV

Level IV units include the capabilities of level III with additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants and should have pediatric medical and pediatric surgical specialty consultants continuously available 24 hours a day. Level IV facilities would also include the capability for surgical repair of complex conditions (eg, congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation). More evidence is needed to assess the risk of morbidity and mortality by level of care for newborn infants with complex congenital cardiac malformations. A recent study by Burstein et al was not able to note a difference in postoperative morbidity or mortality.
associated with dedicated pediatric cardiac ICUs versus NICUs and PICUs but did not separately assess the newborn and postneonatal periods. Although specific supporting data are not currently available, it is thought that concentrating the care of such infants at designated level IV centers will allow these centers to develop the expertise needed to achieve optimal outcomes.

Not all level IV hospitals need to act as regional centers; however, regional organization of perinatal health care services requires that there be coordination in the development of specialized services, professional continuing education to maintain competency, facilitation of opportunities for transport and back-transport, and collection of data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies. These functions usually are best achieved when responsibility is concentrated in a single regional center with both perinatal and neonatal subspecialty services. In some cases, regional coordination may be provided adequately by the collaboration of a children’s hospital with a subspecialty perinatal facility that is in close geographic proximity.

STANDARDS OF SERVICE FOR HOSPITALS PROVIDING NEONATAL CARE

Current evidence indicates that family and cultural considerations are important for care of sick neonates. These considerations include family- and patient-centered care, culturally effective care, family-based education, and opportunities for back-transport to level II facilities or transfer to the family’s local community facility when medically and socially indicated.

SUMMARY AND RECOMMENDATIONS

1. Regionalized systems of perinatal care are recommended to ensure that each newborn infant is delivered and cared for in a facility most appropriate for his or her health care needs, when possible, and to facilitate the achievement of optimal health outcomes.
   - Because VLBW and/or very preterm infants are at increased risk of predischarge mortality when born outside of a level III center, they should be delivered at a level III facility unless this is precluded by the mother’s medical condition or geographic constraints.
   - Level II: a hospital NICU organized with personnel and equipment to perform neonatal resuscitation, evaluate and provide postnatal care of healthy newborn infants, provide care for infants born at 35 to 37 weeks’ gestation who remain physiologically stable, and stabilize ill newborn infants or infants born at less than 35 weeks’ gestational age until transfer to a facility that can provide the appropriate level of neonatal care.
   - Level III: a hospital special care nursery organized with the personnel and equipment to provide care to infants born at 32 weeks’ gestation or more and weighing 1500 g or more at birth who have physiologic immaturity, such as apnea of prematurity, inability to maintain body temperature, or inability to take oral feedings; who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis; or who are convalescing from a higher level of intensive care. A level II center has the capability to provide continuous positive airway pressure and may provide mechanical ventilation for brief durations (less than 24 hours).
   - Level IV: a hospital NICU organized with personnel and equipment to provide continuous life support and comprehensive care for extremely high-risk newborn infants and those with critical illness. This includes infants born weighing <1500 g or at <32 weeks’ gestation. Level III units have the capability to provide critical medical and surgical care. Level III units routinely provide ongoing assisted ventilation; have ready access to a full range of pediatric medical subspecialists; have advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography; have access to pediatric ophthalmologic services with an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity; and have pediatric surgical specialists and pediatric anesthesiologists on site or at a closely related institution to perform major surgery. Level III units are not expected to resolve rapid deaths and may provide mechanical ventilation for brief durations (less than 24 hours).

2. The functional capabilities of facilities that provide inpatient care for newborn infants should be classified uniformly on the basis of geographic and population parameters in collaboration with state health departments, as follows:
   - Level I: a hospital nursery organized with the personnel and equipment to perform neonatal resuscitation, evaluate and provide postnatal care of healthy newborn infants, provide care for infants born at 35 to 37 weeks’ gestation who remain physiologically stable, and stabilize ill newborn infants or infants born at less than 35 weeks’ gestational age until transfer to a facility that can provide the appropriate level of neonatal care.
   - Level II: a hospital special care nursery organized with the personnel and equipment to provide care to infants born at 32 weeks’ gestation or more and weighing 1500 g or more at birth who have physiologic immaturity, such as apnea of prematurity, inability to maintain body temperature, or inability to take oral feedings; who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis; or who are convalescing from a higher level of intensive care. A level II center has the capability to provide continuous positive airway pressure and may provide mechanical ventilation for brief durations (less than 24 hours).
   - Level III: a hospital NICU organized with personnel and equipment to provide continuous life support and comprehensive care for extremely high-risk newborn infants and those with critical illness. This includes infants born weighing <1500 g or at <32 weeks’ gestation. Level III units have the capability to provide critical medical and surgical care. Level III units routinely provide ongoing assisted ventilation; have ready access to a full range of pediatric medical subspecialists; have advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography; have access to pediatric ophthalmologic services with an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity; and have pediatric surgical specialists and pediatric anesthesiologists on site or at a closely related institution to perform major surgery. Level III units are not expected to resolve rapid deaths and may provide mechanical ventilation for brief durations (less than 24 hours).
   - Level IV: a hospital NICU organized with personnel and equipment to provide continuous life support and comprehensive care for extremely high-risk newborn infants and those with critical illness. This includes infants born weighing <1500 g or at <32 weeks’ gestation. Level III units have the capability to provide critical medical and surgical care. Level III units routinely provide ongoing assisted ventilation; have ready access to a full range of pediatric medical subspecialists; have advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography; have access to pediatric ophthalmologic services with an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity; and have pediatric surgical specialists and pediatric anesthesiologists on site or at a closely related institution to perform major surgery. Level III units are not expected to resolve rapid deaths and may provide mechanical ventilation for brief durations (less than 24 hours).
are located within institutions that can provide on-site surgical repair of serious congenital or acquired malformations. Level IV units can facilitate transport systems and provide outreach education within their catchment area.

3. The functional capabilities of facilities that provide inpatient care for newborn infants should be classified uniformly and with clear definitions that include requirements for equipment, personnel, facilities, ancillary services, training, and the organization of services (including transport) for the capabilities of each level of care.

4. Population-based data on patient outcomes, including mortality, morbidity, and long-term outcomes, should be obtained to provide level-specific standards for patients requiring various categories of specialized care, including surgery.

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REFERENCES

22. Engle WA, Tomashek KM, Wallman C; Committee on Fetus and Newborn, American PEDIATRICS Volume 130, Number 3, September 2012

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APPENDIX 2

SAMPLE

PATIENT TRANSFER AGREEMENT

THIS AGREEMENT is made effective as of ______________ by and between
(Children’s Hospital) a nonprofit corporation, and
(Hospital), a corporation.

WHEREAS, operates a tertiary level acute care pediatric hospital to
provide access to patient care for the residents of its primary service area and to provide tertiary
level services on a regional and national basis to individuals requiring specialized pediatric care; and

WHEREAS, Hospital operates a general acute care hospital to provide access to
patient care for the residents of its primary service area; and

WHEREAS, and Hospital (the “Institutions”) have determined that it
would be in the best interest of patient care and it would promote the optimum use of facilities,
including addressing surge capacity, to enter into a transfer agreement for transfer of patients
between the respective Institutions;

NOW, THEREFORE, in consideration of the mutual covenants and agreements
contained in this Agreement, and for other valuable consideration, the receipt and sufficiency of
which is acknowledged, and Hospital agree as follows:

1. **Term.** This Agreement shall commence on the date written above and shall
continue for a period of one year. Thereafter it shall be renewed automatically for successive
periods of one year unless terminated earlier as provided in this Agreement.

2. **Purpose of Agreement.** Each Institution agrees to transfer to the other
Institution and to receive from the other Institution patients in need of the care which may not be
available in the other Institution and provided by their respective Institutions for the purpose of
providing continuity of patient care and treatment appropriate to the needs of each patient.

3. **Patient Transfer.** This Agreement shall apply to transfers between
hospital location and referring Hospital. The need for transfer of a patient from
one Institution to another shall be determined by the patient’s attending physician who will
contact the receiving hospital regarding the need for transfer. The receiving Institution shall
confirm its acceptance of the patient after confirming the following: a) the receiving Institution
has appropriate space, equipment and personnel to provide safe patient care; and b) the receiving
physician has been identified and has agreed to accept responsibility for the care of the patient.
Requests for transfer shall be made only after the patient has been evaluated and the referring
Institution has provided appropriate treatment, personnel and equipment to stabilize the patient
within the capabilities of the referring Institution in compliance with EMTALA. The receiving
Institution agrees to admit the patient as promptly as possible. However, the receiving Institution is not obligated to accept a patient if the receiving Institution determines, in its sole discretion, it does not then have the capacity to provide the services required for the patient, that the care required can be provided at the referring Institution (unless transfer is required by a third party payor) or that the transfer request is based solely on the patient’s lack of financial resources. The receiving Institution may deny requests for non-emergent transfers to a specific hospital program if the patient does not meet the specific admission criteria of the program to which transfer is proposed.

4. **Medical Staff Membership.** Once the receiving Institution has accepted the transfer, if the attending physician responsible for determining the medical need for transfer is not a member of the receiving Institution’s medical staff with admitting privileges, that physician shall arrange for transfer of responsibility for the care of the patient to a member of receiving Institution’s medical staff for the period of hospitalization, or the non-member physician must apply for and obtain appropriate clinical privileges to admit and attend the patient during hospitalization.

5. **Provision of Information to Each Institution.** The Institutions agree to provide to each other information about the type of resources offered at their respective facilities and the types of patients and health conditions that each Institution will accept and/or transfer. Each Institution shall provide the other Institution with the names or classifications of persons authorized to initiate, confirm and accept the transfer of patients on behalf of their respective Institution and shall update such information at least annually.

6. **Patient Record and Personal Effects.** Each Institution agrees to provide the following information to accompany the patient from one Institution to the other. The information shall include the following when available:

   a. Patient’s name, address, patient identification number, age and the name, address and telephone number of at least one of the following (in the order of priority): the patient’s legal guardian or other person authorized to make medical decisions for the patient;

   b. Pertinent administrative and social information;

   c. Patient’s third party billing data, if any, including information regarding whether the patient participates in a managed care plan and any prior authorizations for treatment, provided, with respect to emergency transfers, that this information can be obtained without delaying treatment;

   d. All medical records (or copies of such records) related to the patient’s condition that are available at the time of transfer, including available history, records relating to the patient’s emergency medical condition, observation of signs or symptoms, preliminary diagnosis, results of
diagnostic studies or telephone reports of the studies, treatment provided and results of any tests;

e. Written informed consent to transfer signed by the patient or the patient’s legally authorized representative or written certification by a physician that the medical benefits reasonably expected from the provision of appropriate treatment at the receiving Institution outweigh the risks to the patient (or unborn child) from being transferred;

f. Name, address and phone number of physician referring patient;

g. Name of physician in receiving Institution to whom patient is to be transferred, if different from the referring physician;

h. Name of physician at receiving Institution who has been contacted about patient; and

i. Name of any on-call physician at the referring Institution who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment.

Each Institution agrees to supplement the above information as necessary for the maintenance of the patient during transport and treatment upon arrival at the receiving Institution and to send other pertinent records not readily available at the time of transfer to the receiving Institution as soon as practicable after transfer. Each Institution shall provide the other with a receipt for any original medical records received from the other and the patient’s valuables and personal effects exchanged between the parties as a result of a transfer.

7. **Transfer Consent.** The referring Institution shall have the responsibility for obtaining the patient’s or guardian’s written informed consent to the transfer or that of the patient’s authorized representative prior to the transfer. If such consent is not possible, the Institution shall obtain certification of the need for the transfer from the attending physician or other qualified medical personnel in accord with the requirements of the Emergency Medical Treatment and Active Labor Act (“Act”). When the patient has an emergency medical condition that has not been stabilized within the meaning of the Act, the referring Institution shall comply with the requirements of the Act in securing the patient’s consent to transfer or certification of the need for transfer by a physician or other qualified medical personnel in accord with the Act’s requirements.

8. **Return of Patient.** In the event the transfer is only temporary and for a specific procedure or service with the intent that the patient is to be returned to the referring Institution, the referring Institution agrees to accept the patient for continued care upon completion of the procedure or service that necessitated the transfer, provided the patient is stabilized within the meaning of the Act.
9. **Payment For Services.** The patient is primarily responsible for payment for care received from each Institution. Except as otherwise agreed to in writing between transferring hospital and receiving hospital, each Institution shall be responsible for collecting its own payment for services rendered to the patient by it from the patient, insurer or Medicare/Medicaid programs, as appropriate. No clause of this Agreement shall be construed to authorize either party to look to the other to pay for services rendered as a result of a transfer pursuant to this Agreement, except to the extent that such liability for a particular transfer is set forth in a written agreement signed by both parties or is negotiated between the parties, or where such liability would exist separate and apart from this Agreement.

10. **Transfer Arrangements.** Transfer arrangements will be made by mutual consent of the referring and receiving physicians. It shall be the responsibility of the receiving physician to arrange the admission of the patient to the receiving Institution. The referring physician, in collaboration with the receiving physician (pursuant to ss 146.50, 2006 Interfacility Transport Guidelines, U.S. Department of Health and Human Services), shall determine the mode of transport and team configuration based on patient needs and the scope of practice of the transporting team.

Requests for children’s Transport Team and Medical Control support and patient transfer can be generated by telephone to:

11. **Transportation of Patient.** Unless contrary arrangements have been mutually agreed upon in advance, referring Institution shall have responsibility for arranging and paying for transportation of the patient to the other Institution, including selection of the appropriate mode of transportation and providing appropriate health care practitioner(s) to accompany the patient. The referring Institution retains the right to seek payment from the patient or other third party payor for the cost of transfer. Subject to Section 13 below, the receiving Institution’s responsibility for patient care shall begin when the patient is physically delivered into the hands of a health care professional authorized by the receiving Institution to accept transfers under this Agreement.

12. **Responsibility For Care or Treatment of Patients Transported by Transport Team.** The Transport Team provides care based on patient specific orders submitted by on-line Medical Control. The team assumes primary care responsibilities in collaboration with the referring Institution for transferring patients while the patient is within the referring Institution and after formal patient hand-off has been completed. The referring physician and patient care team should remain available to the Transport Team for mutual support as patient acuity dictates and to provide further information.

13. **Responsibility For Care or Treatment.** The receiving Institution shall not be responsible for any care or treatment provided by the referring Institution. The referring Institution is responsible for any care or treatment given any transferred patient or any untoward...
event concerning such patient unless and until the referring Institution fulfills its responsibility for all of the following: a) notifying the receiving Institution promptly and providing all information appropriate under the circumstances whenever it wants to transfer a patient to the receiving Institution; b) obtaining any necessary medical authorization by a physician or other qualified medical person and any necessary consent by or on behalf of the patient for the transfer; c) documenting the medical justification for the transfer in the patient’s medical records; d) making all transportation arrangements required to accomplish the transfer; and e) delivering the patient to the receiving Institution or the receiving Institution’s Transport Department, with his or her billing information (if, in the case of an emergency transfer, the referring Institution is able to obtain the same without causing delay in providing appropriate treatment or screening to patient), valuables, medical records and other information sufficient to allow knowledgeable treatment of the patient at the receiving Institution.

To the extent possible, stabilization and treatment will be initiated prior to transfer to ensure that the transfer will not, within reasonable medical probability, result in harm or jeopardize survival of the patient or transporting team.

14. Advertising and Public Relations. Neither Institution shall use the name of the other Institution in any promotional or advertising material unless review and approval of the intended advertisement is first obtained from the party whose name is to be used. Both Institutions shall deal with each other publicly and privately in an atmosphere of mutual respect and support.

15. Medicare/Medicaid Certification. Each Institution shall remain Medicare/Medicaid certified, shall accept and treat Medicare/Medicaid patients and shall remain eligible for payment from the Medicare/Medicaid programs.

16. Applicable Standards. Each Institution shall assure that all duties performed and services provided pursuant to this Agreement are in compliance with applicable standards, rulings and regulations of The Joint Commission, the United States Department of Health and Human Resources, the State Department of Health Services, and/or any other government agency, corporate entity or individual exercising authority with respect to the Institution.

17. Compliance With COBRA. Each Institution acknowledges that it is aware of and agrees to comply with the requirements of the Consolidated Omnibus Budget Reconciliation Action of 1985, as amended, as it relates to patient transfers.

18. Confidentiality. Each party agrees to maintain the confidentiality of patient information disclosed for the purposes of providing necessary medical care and not to disclose any such information except where permitted by law. Both parties acknowledge that in receiving or otherwise dealing with any records or information relating to patients receiving treatment for alcohol or other drug abuse, both Institutions are fully bound by the provisions of the federal regulations governing confidentiality of alcohol and drug abuse patient records (42 C.F.R. Part 2, as amended from time to time).
19. **Independent Contractor Status.** Both Institutions are independent contractors. Neither Institution is authorized or permitted to act as an agency or employee of the other. Nothing in this Agreement is intended nor shall be construed to create an employer/employee partnership, or joint venture relationship or to allow either party to exercise control or direction over the manner or method by which either party provides services to patients, provided that such services are performed in accordance with all applicable medical standards and the terms and conditions of this Agreement.

20. **Liability.** Each Institution shall be responsible for its own acts and omissions and agrees to indemnify and hold the other Institution harmless from any actual or threatened harm caused by or arising out of any claimed improper, negligent or wrongful act or omission of the indemnifying Institution, its trustees, officers, agents and employees. The term “harm” as set forth in the preceding sentence includes any and all: claims, suits or legal proceedings; damages or injuries; interest; costs, expenses or fees, including costs associated with investigating and defending claims, suits or legal proceedings and including reasonable attorneys’ fees attributable to such investigation or defense or attributable to enforcing the provisions of this Agreement; loss of profits; and all other loss or liability of whatever kind or nature.

21. **Insurance.** Each Institution shall secure and maintain, or cause to be secured and maintained during the term of this Agreement, comprehensive general and professional liability insurance and property damage insurance providing adequate limits of liability for their respective operations. Each party shall cause its insurance carrier to file a certificate of continuous coverage with the other party, and each party shall immediately notify the other of any notice received from its insurance carrier of intent to modify or cancel such insurance coverage.

22. **Termination.**

a. **Voluntary Termination.** This Agreement may be terminated by either party for any reason, by giving at least thirty (30) days’ written notice of its intention to withdraw from this Agreement, and by ensuring the continuity of care to patients who already are involved in the transfer process.

b. **Involuntary Termination.** This Agreement shall be terminated immediately upon the occurrence of any of the following:

1) Either Institution is destroyed to such an extent that the patient care provided by such Institution cannot be carried out adequately;

2) Either Institution loses or has its operating license or approval, its Joint Commission accreditation or its Medicare/Medicaid certification suspended or revoked;
3) Either Institution no longer is able to provide the services for which this Agreement was sought; or

4) Either Institution is in default under any of the terms of this Agreement.

23. **Nonwaiver.** No waiver of any term or condition of this Agreement by either party shall be deemed a continuing or further waiver of the same term or condition or a waiver of any other term or condition of this Agreement.

24. **Governing Law.** This Agreement is made and entered into in the State of __________ and shall be governed and construed in accordance with the laws of ________.

25. **Assignment.** This Agreement shall not be assigned in whole or in part by either party without the express written consent of the other party.

26. **Severability.** If any provision of this Agreement shall be held or declared to be invalid, illegal or unenforceable under any applicable law, such provision shall be deemed deleted from this Agreement and shall be replaced by a valid and enforceable provision which so far as possible achieves the same objectives as the severed provision was intended to achieve and the remaining provisions of this Agreement shall continue in full force and effect.

27. **Amendment.** This Agreement may be amended at any time by a written agreement signed by the parties, which amendment shall be attached to and become a part of this Agreement.

28. **Notices.** All notices regarding the transfer or care of patients shall be made via telephone to the parties designated in this Agreement, as amended from time to time. Any other notice required or allowed to be given under this Agreement shall be deemed to have been given upon facsimile transmission with confirmation of receipt, upon personal delivery, or upon deposit in the United States mail, registered or certified, with return receipt requested and addressed as follows, unless and until either of the parties notifies the other in accordance with this section of a change of address:

_________________________________
_________________________________
_________________________________
Attention: _______________________

29. **Entire Agreement.** This Agreement constitutes the entire agreement between the parties and contains all of the agreements between them with respect to the subject
matter hereof and supersedes any and all other agreements, either oral or in writing, between the parties with respect to the subject matter of this Agreement.

30. **Binding Agreement.** This Agreement shall be binding upon the successors or assigns of the parties.

31. **Confidentiality of Information.** Neither party shall disclose information relating to the operations of the other persons other than to authorized agents or employees of the other, state licensing boards, The Joint Commission or third-party reimbursement agencies and professional organizations, without the prior written consent of the other party.

32. **Headings.** The headings to the various sections of this Agreement have been inserted for convenience only and shall not modify, define, limit or expand express provisions of this Agreement.

**IN WITNESS WHEREOF,** CHW and Hospital have executed this Agreement effective the day and year first above written.
### Appendix 3 – Anesthesia related safety

The following events are to be monitored and reported in all patients ≤ 18 years who have undergone a surgical procedure requiring anesthesia services during the 12 months of the reporting period.

<table>
<thead>
<tr>
<th>Event</th>
<th>Description</th>
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<tbody>
<tr>
<td>Death within 48 hours of procedure (not including ASA 6)</td>
<td></td>
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<tr>
<td>Cardiac arrest within 48 hours of procedure (defined as need for cardiac compressions or defibrillation)</td>
<td></td>
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<tr>
<td>Anaphylaxis – severe intraoperative allergic response with sudden drop in blood pressure</td>
<td></td>
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<tr>
<td>Malignant hyperthermia – clinical or suspected and/or use of dantrolene</td>
<td></td>
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<tr>
<td>Transfusion reaction - intraoperative</td>
<td></td>
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<tr>
<td>Stroke, CVA or coma after anesthesia – within 48 hours</td>
<td></td>
</tr>
<tr>
<td>Visual loss – permanent impairment or total loss of sight</td>
<td></td>
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<tr>
<td>Operation on incorrect site – sentinel event</td>
<td></td>
</tr>
<tr>
<td>Operation on incorrect patient – sentinel event</td>
<td></td>
</tr>
<tr>
<td>Medication error – wrong medication or wrong dosing (intraoperative)</td>
<td></td>
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<tr>
<td>Unplanned ICU admission within 48 hours</td>
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<tr>
<td>Intraoperative awareness – explicit awareness during anesthesia Yes/No</td>
<td></td>
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<tr>
<td>Reintubation within 6 hours after extubation due to respiratory distress, hypoxia, hypercapnia or acidosis</td>
<td></td>
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<tr>
<td>Dental trauma – unanticipated loss of permanent tooth</td>
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<tr>
<td>Perioperative aspiration with consistent radiologic findings</td>
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<tr>
<td>Vascular access complication with vascular injury or pneumothorax</td>
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<tr>
<td>Infection following epidural or spinal anesthesia – abscess, meningitis or sepsis</td>
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<tr>
<td>Epidural hematoma following epidural or spinal anesthesia</td>
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<tr>
<td>Unintentional high spinal with bradycardia, respiratory insufficiency or intubation</td>
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<tr>
<td>Postdural puncture headache within 72 hours</td>
<td></td>
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<tr>
<td>Major systemic local anesthetic toxicity</td>
<td></td>
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<tr>
<td>Peripheral neurologic deficit following regional anesthesia – residual sensory, motor or autonomic block 72 hours after placement</td>
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<tr>
<td>Infection following peripheral nerve block</td>
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<tr>
<td>Unanticipated need for ECMO within 72 hours of a procedure</td>
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<tr>
<td>Unanticipated need for hemodynamic (vasopressor) support within 72 hours of a procedure</td>
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<tr>
<td>Unanticipated perioperative seizure</td>
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<tr>
<td>Post-operative hemorrhage requiring transfusion within 48 hours or reoperation for control</td>
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<tr>
<td>Surgical fire and/or patient burns</td>
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<tr>
<td>Pressure ulcers related to events in the OR or perioperative environment within 30 days</td>
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<tr>
<td>Unplanned return to the operating room within 72 hours of operation</td>
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<tr>
<td>Unscheduled admission to the hospital for inpatient care within 30 days</td>
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<tr>
<td>Unscheduled admission or transfer to the intensive care unit or a higher level of care within 72 hours of operation</td>
<td></td>
</tr>
<tr>
<td>Event Description</td>
<td>Definition</td>
</tr>
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<td>-------------------</td>
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</tr>
<tr>
<td>Transfer to another institution for higher level of care within 72 hours of operation</td>
<td></td>
</tr>
<tr>
<td>Venous thromboembolic event (VTE) within 30 days</td>
<td></td>
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</tbody>
</table>