CALIFORNIA DEPARTMENT OF HEALTH CARE SERVICES
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March 4, 2024

CALIFORNIA CHILDREN'S SERVICES PROGRAM
CHAPTER 3.34 – Neonatal Surgery Standards

In addition to the specialty and subspecialty requirements outlined in this standard, all California Children's Services (CCS) Neonatal Intensive Care Units (NICU) are required to comply with CCS Chapter 3.37 CCS Provider Core Standards.

A. Neonatal Surgery – Definitions

1. Neonatal surgery is defined as:

   Surgery performed on infants who receive care in a NICU, irrespective of age/weight.

2. A stable neonate is a neonate who does not have concurrent medical problems including, but not limited to:

   Acid/base disorder, dehydration, congenital heart disease, chronic lung disease, severe failure to thrive and/or liver dysfunction, or severe central nervous system or musculoskeletal impairment.

B. General

1. Regional NICUs shall be required to meet the neonatal surgery standards specified in section D of this document, and have CCS approval for neonatal surgery.

2. Community NICUs may gain CCS approval to provide neonatal surgery if they meet the standards specified in section D of this document.

3. Community NICUs may perform, without CCS approval for neonatal surgery, the following procedures on stable neonates:

   a. Hernia-hydrocele repair.

   b. Orchiopexy.

   c. Vascular access lines for monitoring long-term intravenous therapy or long-term parenteral nutrition.

d. Pyloromyotomy.

e. Superficial biopsies or simple plastic procedures such as repair of delivery-related lacerations.

f. Laser treatment for threshold retinopathy of prematurity when performed by a CCS-paneled ophthalmologist, with patient sedation under the close supervision of a CCS-paneled neonatologist and when no general anesthesia is used.

g. Patent Ductus Arteriosus (PDA) ligation for premature infants, as specified in Section E of this Chapter.

4. Cardiac surgery, other than PDA ligation for premature infants, shall be performed only in CCS-approved cardiac centers (See Section 3.13, CCS Manual of Procedures).

C. Procedure for Approval

1. Community NICUs that wish to perform neonatal surgery shall submit an application to the CCS Facility Review Team at CCSFacilityReview@dhcs.ca.gov.

2. Approval shall be based on compliance with applicable CCS standards, a review of procedures, and outcome data, and if needed a site visit conducted to address unresolved questions.

3. CCS approval shall be effective for a period of one year from the date of approval. The CCS program may, at its discretion, conduct site visits when appropriate to determine an applicant's continued compliance with CCS standards.

4. Within 30 days of occurrence, CCS providers shall report to the CCS program any changes in professional staff whose credentials are necessary to comply with CCS standards. CCS providers shall also send a list of personnel directly involved in the care specified in this document to the CCS program on at least a yearly basis.

D. Neonatal Surgery Standards

1. Organization

a. While in the NICU, the medical care of the patient shall be under the direction of a CCS-paneled neonatologist as outlined in CCS standards for NICUs.[1] However, direction of medical care for patients undergoing cardiac surgery and postoperatively, other than PDA ligation for premature infants, will reflect

the local standards of the particular CCS-approved cardiac center and CCS cardiac center standards.

b. The surgical care of the patient shall be under the direction of a CCS-paneled surgeon. The surgeon must maintain the minimum number of pediatric continuing medical education hours required by the American College of Surgeons.[2]

c. A log shall be kept in the NICU recording each operative procedure performed. Approximately 25 neonatal surgical cases, not including those in section B.3, shall be performed each year.[3]

   1) For NICUs already approved, annual neonatal surgery case volume is estimated from a running average over a 3-year period. NICUs performing exceedingly complex cases, e.g., congenital diaphragmatic hernia repair, warrant little or no variation from the minimum value. NICUs not performing exceedingly complex cases warrant accepting somewhat more variation from the minimum value.

   2) Regardless of case mix, any facility with an annual neonatal surgical case volume of 16 or fewer provides insufficient experience to care providers.

   3) For a NICU applying for initial approval to perform neonatal surgery, determination of insufficient case volume will reflect the complexity of cases and comprehensiveness of pertinent institutional policies and procedures.

d. Each NICU shall conduct monthly pediatric surgery section meetings to review morbidity, mortality, and the management of problem cases identified by explicit criteria for learning from past experience. These meetings shall be documented by minutes, and shall be submitted to CCS as part of the annual review and reapproval process.

   Each NICU shall have a procedure to review unresolved, problem cases and questions pertaining to patient care quality or conduct.

e. There shall be an annual review of the neonatal surgical data at a combined meeting of the NICU and surgical staff.

2. Staffing

   a. Pediatric Surgery

      1) Each pediatric surgeon shall be a CCS-paneled physician who is certified or is a candidate for certification by the American Board of Surgery with a certificate of special competence in pediatric surgery.

2) Each NICU must have at least two pediatric surgeons on the medical staff with 1 available to respond to the bedside within 60 minutes of request 24 hours a day, 7 days a week. A published on-call schedule for these surgeons must be available to NICU staff.

b. Anesthesiology

1) All anesthesia for neonatal surgical cases shall be administered by CCS-paneled anesthesiologists with special expertise in neonatal anesthesia, meeting at least one of the following criteria:

a) Board certified or board eligible pediatric anesthesiologists; board eligible anesthesiologists must complete final certification within three years of board eligibility, or

b) Anesthesiologists similarly qualified by alternative pathway specified by the American College of Surgeons,[4] or

c) Anesthesiologists already in clinical practice who meet CCS standards up to the date of issue of the neonatal surgery standards in this document may continue to provide their services.

2) Each NICU must have at least two anesthesiologists who meet the above criteria, on-call and available to respond within 60 minutes. A published on-call schedule must be available to NICU staff.

c. Radiology

1) Neonatal imaging shall be interpreted by one or more CCS-paneled pediatric radiologists certified by the American Board of Radiology and with certification or eligibility in pediatric radiology.

2) Each NICU must have at least one radiologist on-call and available to respond within 60 minutes. A published on-call schedule must be available to NICU staff

3) Community NICUs can alternatively meet this staffing requirement by having a radiologist with pediatric expertise as currently defined by the American College of Surgeons.[5]

d. Surgical subspecialties

CCS-paneled specialists including but not limited to, cardiovascular-thoracic surgery, neurosurgery, ophthalmology, orthopedics, otolaryngology, and urology, qualify to provide neonatal surgery in an approved NICU if each such specialist performs approximately 25 major pediatric cases per year in their

respective specialty.

e. Nursing: if a surgical procedure is to be performed in the NICU, the following are required:

1) The operating room nursing staff shall bring all equipment necessary to perform the procedure and participate in the procedure just as though it were to be done in the operating room.

2) NICUs must maintain a nurse-to-patient ratio between 2:1 and 3:1 during the intraoperative and postoperative periods. The particular ratio is determined by the complexity of the surgical procedure and the patient status, with the exact nursing ratio determination left to the judgment of the provider.

3. Facilities

a. The operating room shall have the capability for monitoring and supporting the vital functions of a critically ill neonate, including:

1) Temperature regulation, including overhead and mattress heating equipment.

2) Continuous monitoring of patient's temperature, heart rate, and blood pressure.

3) Air-oxygen blending equipment and provision of warm humidified gases during the administration of inhalation anesthesia.

4) Continuous monitoring of respiratory gases, and noninvasive continuous monitoring of oxygen and carbon dioxide. Blood gas analysis turnaround time shall be no greater than 10 minutes.

5) Equipment and instruments appropriate for neonatal surgery; including, artificial replacement materials for abdominal wall defects.

6) Equipment to provide intravenous infusions with small volume containers, low-rate pumps, and blood warmers.

b. If a surgical procedure is to be performed in the NICU, a minimum of 120 square feet of floor space shall be allocated for this purpose.

E. PDA Ligation Standards for Premature Infants

CCS will not approve new applications to perform this surgical procedure without full neonatal surgery approval. Facilities previously so approved to perform PDA ligation

may continue offering this service if they meet the following criteria and the following personnel are members of the active medical staff as defined by each hospital:

1. CCS-paneled pediatric cardiologist.

2. Anesthesiologists as outlined in D.2.b.

3. CCS-paneled cardiovascular or pediatric surgeon, with expertise in pediatric cardiovascular surgery and has performed a minimum of five pediatric cardiovascular surgical procedures in the past year. The CCS facility review team approval process includes requesting a list of such procedures from candidate surgeons.

4. The operating room nursing staff shall bring all equipment necessary to perform the procedure and participate in the procedure just as though it were done in the operating room.

5. Nurses at a nurse-to-patient ratio between 2:1 and 3:1 during the intraoperative and postoperative periods.

6. The neonatologist, pediatric anesthesiologist (D.2.b.), and qualified cardiovascular surgeon shall be present at the procedure.

F. Performance evaluation

All NICUs must maintain a neonatal surgical database listing counts of neonatal surgical cases by diagnosis and birth weight, with accompanying complications; including, sepsis, wound infection, dehiscence, anastomotic leak, re-operation, survival outcome, and PDA ligations for the premature infant. This list shall be made available to CCS upon request, and reported as specified by the American College of Surgeons.[6]

The NICU must also operate a Pediatric Surgery Performance Improvement and Patient Safety (PIPS) program, as specified by the American College of Surgeons.[7]

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[1] Chapter 3.25, CCS Manual of Procedures
[2] Optimal Resources for Children's Surgical Care
[3] Optimal Resources for Children's Surgical Care
[4] Optimal Resources for Children's Surgical Care
[5] Optimal Resources for Children's Surgical Care
[6] Optimal Resources for Children's Surgical Care
[7] Optimal Resources for Children's Surgical Care