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DIRECTOR

State of California—Health and Human Services Agency
Department of Health Care Services



EDMUND G. BROWN JR.
GOVERNOR

DATE: March 12, 2018

N.L.: 02-0318
Index: Benefits

TO: ALL COUNTY CALIFORNIA CHILDREN'S SERVICES (CCS)
ADMINISTRATORS, MEDICAL CONSULTANTS, STATE INTEGRATED
SYSTEMS OF CARE DIVISION STAFF, AND MEDI-CAL MANAGED
CARE PLANS

SUBJECT: CCS STANDARD 3.35: STANDARDS FOR EXTRACORPOREAL LIFE
SUPPORT (ECLS) CENTERS

The purpose of this Numbered Letter (N.L.) is to inform CCS Program facilities and providers about the updated CCS Program standards for the delivery of extracorporeal life support (ECLS) in CCS Program pediatric intensive care units (PICUs), by adding Chapter 3.35: Standards for ECLS Centers, available at:

<http://www.dhcs.ca.gov/services/ccs/Pages/ProviderStandards.aspx>

Effective March 12, 2018, when appropriate, CCS Program facilities are required to follow CCS Program Standard 3.35: Standards for ECLS Centers, for the delivery of ECLS services for their CCS Program eligible patients.

ECLS, formerly known as extracorporeal membrane oxygenation (ECMO), is the use of mechanical devices to temporarily support cardiac and/or pulmonary functions during cardiopulmonary failure, leading to organ recovery or transplantation. This N.L. updates CCS Program guidelines for the delivery of ECLS services. It also updates where CCS Program ECLS centers shall be located.

If you have any questions regarding this Numbered Letter, please e-mail them to the CCS Program Facility Mailbox at: CCSFacilityReview@dhcs.ca.gov.

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Sincerely,

ORIGINAL SIGNED BY

Sarah Eberhardt-Rios, Division Chief
Integrated Systems of Care Division

Attachment: CCS Program Standard 3.35: Standards for Extracorporeal life support
(ECLS) Centers

CALIFORNIA CHILDREN'S SERVICES MANUAL OF PROCEDURES

CHAPTER 3.35 – STANDARDS FOR EXTRACORPOREAL LIFE SUPPORT (ECLS) CENTERS

3.35.1 Definitions

Extracorporeal life support [ECLS; formerly known as extracorporeal membrane oxygenation (ECMO)] is the use of mechanical devices to temporarily support cardiac and/or pulmonary function during cardiopulmonary failure, leading to organ recovery or transplantation.

3.35.2 General

- A. ECLS centers shall be located in CCS-approved regional neonatal or pediatric intensive care units (ICUs). In addition, ECLS centers may be located in a pediatric cardiothoracic unit if the hospital also has a CCS-approved regional Neonatal Intensive Care Unit (NICU) or Pediatric Intensive Care Unit (PICU).
- B. They shall be located in geographic areas that can support a minimum of six patients on ECLS per center per year.

3.35.3 Procedure for Approval

- A. Regional ICUs that wish to perform ECLS shall apply for approval to the CCS Facility Review mailbox: CCSFacilityReview@dhcs.ca.gov

Department of Health Care Services
Integrated Systems of Care Division
California Children's Services
P.O. Box 997437, MS 4502
Sacramento, CA 95899-7437
- B. Approval will depend on the center documenting competence in the technique based on a review of ten or more of the most recent patients.
- C. Approval will depend on review by a State CCS team.
- D. Approval shall be based on compliance with CCS standards and on-site review of procedures and patient records.
- E. Continued approval shall be based on periodic review of outcome data and reappraisal by state staff, with follow-up team visits when indicated.
- F. Changes in professional staff whose qualifications are incorporated into any portion of these standards shall be reported to CCS whenever they occur; also yearly updates of these key personnel to the CCS PICU or NICU Directories shall be submitted to State CCS Program.

3.35.4 Administration

A. The ECLS center shall have its own administrative structure.

1. There shall be a medical director with responsibility for the overall operation of the center.
2. There shall be a coordinator or manager whose responsibilities include:
 - a. Selection, training, supervision, evaluation, and scheduling of ECLS specialists with the respective nursing, respiratory therapy, and/or perfusion services.
 - b. Collection, storage, and evaluation of patient data.
 - c. Oversight of all equipment and supplies related to ECLS.
3. The ECLS program shall also be comprised of:
 - a. ECLS specialists – specialists may be nurses, respiratory therapists, or perfusionists.
 - b. Physicians trained in ECLS – CCS-paneled physicians may be neonatologists, pediatric critical care physicians, pediatric surgeons, or cardiothoracic surgeons.

B. A key responsibility of the ECLS administration shall be to ensure the competency of ECLS care providers.

1. ECLS specialists:

a. Initial training shall include:

(1) 24-36 hours of didactic material covering the following:

- (a) Introduction to ECLS
- (b) Physiology of the diseases treated with ECLS
- (c) Pre-ECLS procedures
- (d) Criteria and contraindications for ECLS
- (e) Physiology of coagulation
- (f) ECLS equipment
- (g) Physiology of veno-arterial and veno-venous ECLS
- (h) Daily patient and circuit management
- (i) Emergencies and complications during ECLS
- (j) Management of complex ECLS cases
- (k) Weaning from ECLS

- (l) Decannulation procedures
 - (m) Post-ECLS complications
 - (n) Short- and long-term developmental outcomes
 - (o) Ethical and social issues.
- (2) Simulation (low-fidelity/water-drills) to allow each individual to demonstrate a full understanding of all possible circuit emergencies and the appropriate intervention. They should be able to change less complicated components of the circuit (raceway, pigtails, bladder, and pump head) in a pre-established period of time.
 - (3) A closed-book examination covering the course material with a required 75% correct response rate.
 - (4) Bedside training with an experienced ECLS specialist as the preceptor for a minimum of 24 hours.
- b. Continuing education shall include:
- (1) Formal team meetings to do case reviews, updates on ECLS therapy and policies/procedures, quality assurance, and administrative information.
 - (2) Simulation (low-fidelity/water-drills) every six months.
 - (3) Annual written examination.
 - (4) Annual documentation of completion of these activities as well as at least 48 hours of ECLS patient care per year.
2. Physicians:
- a. ECLS physicians may be neonatologists, pediatric critical care physicians, pediatric surgeons, or cardiothoracic surgeons.
 - b. They shall complete ECLS-specific training covering the same areas as defined above for the ECLS specialists.
- C. Program Evaluation
- 1. Formal meeting of the ECLS administration shall be held at least six times per year covering review of cases, equipment needs, administrative and other pertinent issues. The minutes of these meetings should describe the critical review process and the basis upon adjudication was determined.

2. A prompt review of any major complication or death will be held both with ECLS team members and with the responsible morbidity and mortality committee. These reviews may be conducted simultaneously or separately.
3. In addition to the patient medical record, a separate patient record shall be maintained documenting the type of cannulation, duration of the run, any observed or suspected complications, and condition at discharge.
4. ECLS centers will maintain membership in the Extracorporeal Life Support Organization (ELSO).

3.35.5 Patient Care

- A. Patient Selection – CCS will cover ECLS for selected infants and children with severe, acute cardiac and/or respiratory failure who have failed to respond to conventional medical management. Eligibility shall be based not on a specific diagnosis, but on the patient's meeting the following entry criteria.
 1. Neonatal Respiratory
 - a. Age and size: < 30 days old, gestational age > 34 weeks, weight > 1.8 kg
 - b. Indication: Neonates with severe respiratory failure refractory to maximal medical management with a potentially reversible etiology.
 - c. Contraindications are nonreversible conditions, such as a lethal chromosomal disorder.
 2. Pediatric Respiratory
 - a. Age and size: > 30 days old and < 21 years old
 - b. Indication: ECLS should be considered in patients with marginal or inadequate gas exchange at risk for ventilator-induced lung injury with a potentially reversible etiology who are failing less invasive therapy.
 - c. Contraindications are nonreversible disease processes.
 3. Cardiac
 - a. Age and size: In general, any infant considered old and large enough to undergo a cardiac operation is an appropriate candidate for ECLS.

b. Indications:

- (1) Unable to transition off of cardiopulmonary bypass.
- (2) Severe cardiac failure as defined by pressor and inotropic requirement, metabolic acidosis, decreased urine output for six hours.
- (3) Cardiac arrest from any cause thought to be reversible and without sustained return of spontaneous circulation.
- (4) Myocardial failure unrelated to cardiac surgery, e.g., myocarditis, cardiomyopathy, toxic drug overdose.
- (5) Elective support through high-risk catheter procedures.

c. Contraindication:

- (1) Prolonged CPR without evidence of good perfusion and metabolic support.

B. Staffing

1. There shall be an ECLS physician assigned to the center at all times to provide 24-hour coverage for the ECLS patient.
2. There shall be an ECLS specialist to provide 1:1 care throughout the course of ECLS.
3. There shall be an ICU nurse to provide 1:1 care throughout the course of ECLS.

C. Physical Facilities and Equipment

1. Adequate space shall be provided for each patient on ECLS.
2. If the space allocated for ECLS is outside the ICU, it shall be located in close proximity to and have appropriate communication with the ICU to assure additional staff support for any emergency that may arise.
3. Each of the following shall be available at the patient's bedside for use during the ECLS procedure:
 - a. ECLS circuit, including, pump, tubing, oxygenator, heater, and safety monitoring equipment
 - b. Appropriate tubing clamps
 - c. Sterile scissor packs

- d. Oxygen regulators and gas source
- e. At least one unit of packed red blood cells
- f. Adequate lighting to support emergency surgical procedures
- g. Battery backup and hand crank

4. Also available to the patient's bedside as backup shall be:

- a. ECLS circuit
- b. All supplies to re-prime a circuit (e.g., 25 percent albumin, heparin, calcium, buffer)
- c. Spare connectors, stopcocks, tubing, etc.
- d. A surgical instrument set to manage such mishaps as emergency decannulation
- e. Other blood products, such as fresh frozen plasma, platelets, and cryoprecipitate

D. Patient Follow Up

- 1. Graduates of ECLS who are discharged from an ICU with a CCS-eligible condition shall receive the necessary medical follow-up through the general CCS program, as recommended by the center director or authorized panel physician. Suggested follow up for children under six years of age includes:
 - a. 4 – 6 Months of Age
 - (1) Medical history, physical and neurological exam, repeat BAER, if abnormal
 - (2) Neurodevelopmental screening (Denver II, Bayley, or Gesell)
 - (3) Occupational therapy (OT)/physical therapy (PT) evaluation and treatment if motor delay
 - b. 1 Year of Age
 - (1) Medical history, physical and neurological exam, behavioral screening evaluation
 - (2) Neurodevelopmental exam (Bayley or Gesell)
 - (3) OT/PT evaluation and treatment if motor delay
 - c. 2 Years of Age
 - (1) Medical history, physical and neurological exam
 - (2) Behavioral audiometry if not done at 1 year
 - (3) Neurodevelopmental exam (Bayley, Gesell or Binet)
 - (4) Language screening (e.g., PPVT-R, Language Development Survey)
 - (5) Nutrition counseling and low cholesterol diet for family

d. 3 Years of Age

- (1) Medical history, physical and neurological exam
- (2) Neurodevelopmental exam: formal assessment with Stanford-Binet, Gesell or McCarthy
- (3) Language screening (e.g., PPVT-R, Language Development Survey)
- (4) Social/Adaptive functioning (e.g., Vineland Adaptive Behavior Scales, Child Behavior Checklist)

e. 5 Years of Age

- (1) Medical history, physical and neurological exam
- (2) Neuropsychological exam:
 - (a) General intellectual functioning: WPPSI-R, McCarthy or Stanford-Binet
 - (b) Language screening: PPVT-R, verbal memory (e.g., verbal tests from the McCarthy or the Wide Range Assessment of Memory and Learning)
 - (c) Visual-motor integration: e.g., Developmental Test of Visual-Motor Integration
 - (d) Behavior screening: e.g., Child Behavior Checklist or Conner's Behavior
 - (e) Questionnaires, parent and teacher reports

2. Graduate of ECLS who are under four years of age and are discharged from an ICU as "normal" (i.e., no evidence of a CCS-eligible condition) are eligible for the High Risk Infant Follow-Up Program.

3. Infants/children greater than four years of age should have a medical and neuropsychological assessment every six months after discharge for one year.