



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



EDMOND G. BROWN JR  
Governor

DATE: November 17, 2016

Numbered Letter: 06-1116  
Index: Program Administration

TO: CALIFORNIA CHILDREN'S SERVICES (CCS) PROGRAM COUNTY  
ADMINISTRATORS, MEDICAL CONSULTANTS, AND STATE SYSTEMS  
OF CARE DIVISION OFFICE STAFF

SUBJECT: PROGRAM REQUIREMENTS FOR PROVIDING NEONATAL  
THERAPEUTIC HYPOTHERMIA

## I. PURPOSE

This Numbered Letter (N.L.) describes minimum requirements for CCS Program-approved Neonatal Intensive Care Units (NICUs) to provide therapeutic hypothermia services to neonates.

## II. BACKGROUND

Neonatal encephalopathy is a condition that often results in adverse outcomes including death, cerebral palsy, developmental delay, and seizure disorder. Therapeutic hypothermia (TH) has become the standard in treatment of neonatal encephalopathy because it has been demonstrated to have the capability to prevent death and major disability during the neonatal period.

## III. POLICY

### A. Program

1. Neonatal Intensive Care Units providing therapeutic hypothermia (TH) shall be CCS Program-licensed and meet the American Academy of Pediatrics criteria for Level III care.
2. TH shall be conducted using a servo-regulated device.
3. Hospital birth rate and/or catchment area birth data shall support, on average, at least 6 treated patients per year.

4. Centers that provide TH to <12 patients/year shall have a formalized relationship with a regional center of expertise to ensure maintenance of education and competencies.
5. Each TH program shall be overseen by a neonatologist working in conjunction with a pediatric neurologist and clinical nurse specialist to:
  - a. Develop clinical guidelines for TH patient selection and management, as well as for neuroimaging, and neuromonitoring procedures;
  - b. Review adverse events, perform quality assurance, and conduct quality improvement initiatives as warranted by local data;
  - c. Oversee training of all providers who participate in providing TH.

## B. Medical/Diagnostic

### 1. Physician coverage

- a. A board-eligible/board-certified neonatologist shall oversee patient care for infants undergoing TH and provide 24-hour coverage in accordance with CCS Program standards.
- b. A child neurologist shall be accessible at all times for consultation, at minimum via telephone or telemedicine.
  - (1) Every infant undergoing TH shall have a consultation with a pediatric neurologist within the first 12 hours of life, at minimum via phone. Initial clinical assessment would ideally be performed in the first 24 hours of life.
  - (2) During the cooling process, the neurologist's role will encompass, at minimum, clinical assessment and regular review of neuromonitoring and neuroimaging studies.

### 2. Neuromonitoring

- a. All infants undergoing TH shall be monitored continuously during hypothermia and rewarming using conventional video EEG (cEEG) or amplitude-integrated EEG (aEEG)
- b. cEEG shall be available on-site, at minimum, daily during regular work hours.

- c. cEEG shall be reviewed by a neurophysiologist or child neurologist with experience in neonatal EEG and interpreted within 24 hours.
  - d. aEEG monitoring shall be reviewed on an ongoing basis at the bedside, with interpretation documented in the medical record by a provider with experience in neonatal aEEG.
  - e. Competency in aEEG interpretation may be obtained through:
    - (1) training from a device representative and supplemented with an online course;
    - (2) attendance at neuromonitoring conferences and workshops;
    - (3) experience obtained through neonatology fellowship training.
3. Neuroimaging
- a. Centers that perform TH shall have the equipment and staffing available on-site to perform magnetic resonance imaging (MRI) with diffusion weighted imaging in a neonate with and without sedation.
  - b. MRI shall be performed prior to hospital discharge on all infants undergoing TH.
  - c. MRI shall be interpreted by a neuroradiologist with experience in neonatal brain imaging.
  - d. Centers without a neuroradiologist on staff may partner through telemedicine support to ensure that adequate imaging sequences are obtained, and for interpretation purposes.
4. Transfer to higher level of care(LOC)
- a. TH programs that do not have the capacity to administer high frequency ventilation, inhaled nitric oxide, and/or extracorporeal membrane oxygenation shall develop guidelines for transfer to a higher LOC in conjunction with a regional center that can provide these treatments, including inhaled nitric oxide and TH during transport.
  - b. In addition to services outlined above, transfer to a higher LOC shall occur for the following circumstances:
    - (1) To facilitate enhanced neurological care;

- (2) Need for ancillary testing or specialty input not available at the local center;
- (3) Ethics consultation: If an ethics consultation has been requested and an on-site neurologist is not available, recommend transfer to higher LOC for complete evaluation;
- (4) At the discretion of the clinical care team, including neonatology and pediatric neurology.

5. High Risk Infant Follow Up (HRIF)

- a. All patients receiving TH shall be referred to a CCS Program-approved HRIF program at the time of discharge.
- b. Infants diagnosed with seizures, discharged on anti-seizure medication, or with brain injury on MRI shall be referred to a pediatric neurologist upon discharge.

C. Training/Competency

- 1. Prior to establishing a TH program, nurses, nurse practitioners, and physicians shall undergo at least 8 hours of training to gain adequate background knowledge in the care of TH patients in the following areas:
  - a. Pathophysiology of hypoxic-ischemic encephalopathy (HIE) and differential diagnosis of neonatal encephalopathy;
  - b. Mechanisms by which TH provides neuroprotection;
  - c. Early screening and identification of neonates eligible for TH;
  - d. Application and interpretation aEEG to detect seizures and background patterns (for sites where aEEG will be used);
  - e. Standardized neurologic examination to determine eligibility for TH;
  - f. How to initiate TH with a servo-regulated device and perform temperature monitoring during induction, maintenance, and rewarming phases of treatment;
  - g. Recognition of clinical seizures;

- h. Management of non-neurologic complications associated with global hypoxia-ischemia, including multi-organ failure, glucose homeostasis, and adverse events associated with TH.
6. A mechanism shall be in place to review staff competencies on an annual basis.

B. Ancillary support

- 1. In addition to the ancillary supports required for community and regional NICUs, the following ancillary supports are required:
  - b. Developmental care team: Occupational therapy, physical therapy, and developmental care plans should be routinely included in the care plan of infants receiving TH;
  - c. Lactation support: Each center must have equipment and resources to support pumping, breast milk storage, and specialist consultation for issues of milk supply, latch and swallow, and supply maintenance;
  - d. Palliative care: Each center shall have a neonatal-specific palliative care clinical guideline that includes:
    - (1) Training and continuing education for staff specific to palliative care, including attention to staff well-being through debriefings or other activities;
    - (2) Spiritual care/chaplain resources available for staff and families.

C. Outreach

- 1. Centers providing TH shall provide family-centered care by developing culturally sensitive handouts for parents to explain HIE and TH, and by encouraging parents to participate in the care of their infants.
- 2. Centers providing TH are responsible for offering outreach to community hospitals for the purpose of:
  - b. Providing education regarding the awareness and timely identification of infants at risk for encephalopathy;
  - c. Educating providers regarding the eligibility criteria for TH, including obstetric and general pediatric care providers;

- d. Conducting outreach for the purposes of morbidity and mortality review.
- D. Quality improvement/Quality assurance
1. Centers providing TH shall have a written protocol and system in place to monitor quality of care and pre-discharge outcomes and to guide quality improvement activities, including:
    - a. Mechanism to screen for infants at risk for HIE through blood gas and/or clinical criteria (see California Perinatal Quality Care Collaborative toolkit: “Neonatal Therapeutic Hypothermia”);
    - b. Assurance that cooled infants have met center’s eligibility criteria, receive recommended neuromonitoring and neuroimaging, and are referred for appropriate follow-up;
    - c. Temperature control, including time to target temperature and frequency of temperatures out of range once cooled;
    - d. Adverse events including but not limited to: bradycardic arrest associated with overcooling, and pressure ulcers acquired during cooling.
  2. Data shall be collected and reviewed, at minimum, on an annual basis.

For questions regarding this N.L., please contact Joseph Schulman, MD MS at 916- 327-2487 or via e-mail at [Joseph.Schulman@dhcs.ca.gov](mailto:Joseph.Schulman@dhcs.ca.gov). Thank you for your services to California’s children.

Sincerely,

**ORIGINAL SIGNED BY ROBERT DIMAND**

Robert Dimand, M.D.  
Chief Medical Officer  
Children’s Medical Services