

# NYU Division of Neonatology Hypothermia Protocol

## Hypothermia treatment with Olympic Cool-Cap System

### For full term infants with Hypoxic-Ischemic Encephalopathy

#### 1. Selecting Eligible patients:

**Must initiate hypothermia before six hours of age**

**Announce “Neonatal Rescue” when calling the ambulance co. to ensure swift arrival of the team.**

#### a. Inclusion Criteria:

The infant will be assessed sequentially by criteria **A**, **B** and **C** listed below:

##### **A. Infants $\geq 36$ weeks gestation admitted to the NICU with ONE of the following:**

- Apgar score of  $<5$  at 10 minutes after birth
- Continued need for resuscitation, including endotracheal or mask ventilation, at 10 minutes after birth
- Acidosis defined as either umbilical cord pH or any arterial pH within 60 minutes of birth  $<7.00$
- Base Deficit  $\geq 16$  mmol/L in umbilical cord blood sample **or** any blood sample within 60 minutes of birth (arterial or venous blood)

If the infant meets criteria **A** then assess for neurological abnormality:

##### **B. Moderate to severe encephalopathy (Sarnat 2 or 3)** consisting of an altered state of consciousness (as shown by lethargy, stupor, or coma) **and** at least **one or more** of the following:

- Hypotonia
- Abnormal reflexes including oculomotor or pupillary abnormalities
- Absent or weak suck
- Clinical seizures

*Recorded by neonatologist/fellow on early neurologic evaluation form.*

If the infant meets criteria **A & B** then assess by aEEG (read by a neonatologist):

##### **C. At least 20 minutes duration of amplitude integrated EEG recording that shows :**

- Abnormal background aEEG activity or seizures.
- The aEEG may be performed from one hour of age. If subsequently an abnormal aEEG is recorded before 6.0 hours of age, the infant will then become eligible for selective head cooling.
- Keep in mind that time must be allowed to place the cooling cap on the infant's head by 6.0

hours of age. The aEEG should not be performed within 30 min of anticonvulsant therapy as this may cause suppression of EEG activity.

**b. Exclusion Criteria:**

- Infants expected to be > 6 hours of age at the time of cooling cap placement.
- Major congenital abnormalities, such as diaphragmatic hernia requiring ventilation, or congenital abnormalities suggestive of chromosomal anomaly (trisomy 13, 18) or other syndromes that include brain dysgenesis.
- Imperforate anus (since this would prevent rectal temperature recordings).
- Evidence of neurologically significant head trauma or skull fracture causing major intracranial hemorrhage. Subgaleal bleeding is a relative contraindication; the infant should be fully stabilized before cooling is initiated.
- Coagulopathy with active bleeding
- Severe PPHN/possible need for ECMO
- Infants < 1,800 g birth weight
- Infants “in extremis” (those infants for whom no other additional intensive management will be offered). Record in detail reason for exclusion.

*At the discretion of Hypothermia Team and neonatology attending.*

**c. Special considerations:**

- Patients who clearly exhibit signs of severe HIE on early neurologic evaluation (Sarnat 3), but normal tracings on aEEG should be offered hypothermia treatment (check for artifact on the EEG).
- Patients who have moderate HIE on neurologic exam with normal aEEG (again check for artifact-usually due to movement), can be monitored with continuous aEEG recording up to 6 hours of life and treated with hypothermia if aEEG becomes abnormal (score 2-3 with or without seizure activity). *See HIE scoring system, see attached document.*
- If these inclusion/exclusion criteria are met and infants are found eligible for cooling, the hypothermia treatment can be initiated.
- No informed consent is necessary (FDA approved device), however parents should be given written information about the treatment (flyer for the parents).

**2. Neurologic evaluation**

- Initial neurologic evaluation to determine eligibility should be performed by neonatology fellow/attending for inborn infants or by neonatal transport physician and referring attending in phone consultation with neonatology attending for outborn infants.
- “Early Neurologic Evaluation” and “Fellow Transport” forms should be completed prior to treatment by fellow and confirmed by the attending (see attached document).
- Further daily neurologic evaluations should be done daily and after discontinuation of cooling in consultation with pediatric neurologist Dr. John Wells.

**3. Cerebral Function Monitor and MRI**

- Continuous aEEG/CFM monitoring for 72 hours during hypothermia treatment and for 4 hours while re-warming (needle electrodes in parietal area).

Note: For inborn infants (TISCH/Bellevue) if full EEG can be available, arrangements can be made to do initial assessment with CFM or full EEG. DO NOT DELAY TREATMENT.

- Video/full EEG can be performed for 20 minutes during the time when the Cool Cap comes off for scalp inspection if indicated.
- Continuous video/full EEG will be initiated after the hypothermia treatment completed for about 48 hours.
- If clinical seizures noted after the treatment with Cool Cap initiated and there is no seizure activity detected on aEEG, **if available** confirm with full EEG before starting anticonvulsant therapy (CFM is not as sensitive for detection of focal seizures) otherwise treat clinical seizures aggressively.
- MRI with diffusion-weighted sequence and Kertosis will be done after treatment preferably at 5-7 days of life.

#### 4. Management in the Delivery Room (for inborn infants):

- If acute perinatal hypoxic-ischemic event was present and infant depressed at birth with need for resuscitation the overhead heater should be turn off as soon as adequate ventilation and heart rate obtained.
- Resuscitation of asphyxiated infants should be done according to NRP guidelines. Do not resuscitate with room air, 100% FIO2 is preferred.
- Avoid NaHCO3 boluses.
- Active heating is also turned in the transport incubator.
- Rectal probe is inserted to 6 cm to monitor core temperature within 20 minutes after birth.
- Maintain rectal temperature at 35 – 36 C° range; if necessary use radiant warmer to prevent overcooling of the infant.
- Inform Hypothermia Team as soon as possible and set up Olympic Cool Cap and CFM.

#### 5. General Care during treatment:

- *Placement of the infants:*
  - *Every NICU bedspot is hardwired for video EEG. The data outlets are labeled VEEG and are located in the middle of each wall. The wiring can reach any of the 3 beds along the wall. The baby needs to have 2 spots to accommodate all equipment. Area must be maintained as a quiet environment during cooling. **Do Not** conduct rounds at the bedside, limit personnel at the bedside and voices must be kept low.*
- Have the sending hospital **clean the head and get a head circumference** prior to arrival of the transport team to facilitate placement of the leads and the correct size Cool Cap

- After cool cap is initiated: if clinically possible, have a 20 minute “time out” “hands-off” period: no activity around the baby for aEEG recording with minimal artifact.
- Minimize interventions during the first 24 hours particularly if interventions are associated with electrographic seizures.
- Swaddle the infant as soon as possible.
- Treatment and prevention of hypoglycemia, (draw blood glucose prior to departure and again mid-transport), hypoxia, hypotension immediately before any diagnostic tests or procedures done.
- Avoid fluid overload (see treatment during cooling protocol)
- Pain management: Morphine 50-100mcg/kg q 3hrs during the first 24 hours of cooling, space it out to q 4hrs for the remaining time of hypothermia treatment.
- Order and have pharmacy make up drips: Dopamine, Dobutamine, to have on stand-by to prevent delays with initiation.
- Treatment of seizures:
  - Load with Phenobarbital 20mg/kg/dose and if seizure persists administer another 20 mg/kg/dose
  - Load with Phosphenytoin 20mg/kg/d if seizure activity continued
  - If seizure persist obtain Phenobarbital level and if < 40 give another 10mg/kg/dose
  - Consider other medications (continuous versed/midazolam) in consultation with neurologist if patient still not responding. The goal is to achieve a suppressed EEG pattern
- Maintain blood gases and O2 saturations WNL, avoid hypoventilation if on ventilator
- Keep NPO during cooling
- Initially start IVF with Dextrose and Ca Gluconate at TF 40cc/kg/day, add Magnesium to the fluids at 12 hours 1.5-2.0 mEq/ml. Consider doubling the concentration of the UV line fluids.
- TPN at 24 hours- add Zantac. The Cool Cap is removed every 12 hours for the inspection of the scalp
- Laboratory data:
  - ABG as soon as stable under cooling – the ABG has to be temperature corrected
  - **Bloods on admission and every 24 hrs. :**
    - Lactate: from the ABG sample or Grey top tube 1cc
    - Pyruvate: Lavender top tube 1cc (Keep on ice)

- Troponin and Ammonia: Green top tube (Fill half the tube, about 3cc and keep on ice. Do not draw from the line)
- Electrolytes at 12, 24, 48, 72 hours or more frequency as indicated- anticipate hyponatremia, hypomagnesemia, hypocalcemia
- CBC as soon as stable and then at 12, 24, 48, and 72 hours - watch for polycythemia and thrombocytopenia (consider partial exchange at lower hematocrit values 60-65%)
- Blood culture as soon as stable if it is not done at the referring hospital
- PT, PTT initially and then at 24 hours
- Liver function studies at 24, and 72 hours

### **5. Monitoring during Hypothermia:**

- Nurse is responsible for monitoring the aEEG screen and consulting with Fellow or Attending for any suspicious or seizure like activity (whether clinical, subclinical or both)
- Nurse is responsible for q 4 hour neurochecks and documentation on the flowsheet
- Nurse
- Nurse is responsible for skin integument assessment every shift by removing cap and examining scalp for any excoriations or lesions
- Nurse is responsible for all labs in the order set and documentation on the flowsheet/computer
- Nurse is responsible for managing the cooling unit during interruptions in cooling for HUS/MRI/CT/full montage EEG should these be necessary
- Temperature – the goal is 34.5 °C- the temperature can fluctuate widely and at times unpredictably– anticonvulsant administration, drafts will cause the temperature to fall, correcting the temperature can take a long time, so preempt by raising the cap temperature when the temperature starts to fall (34.2 °C ). If temperature continues to fall despite increasing the water T, consider: a) screening off the area to minimize the draft, b) using saran wrap and c) a transwarmer pack.
- The heart rate will immediately fall upon cooling – as long as the blood pressure is stable and the oxygen saturation is stable and the oxygen saturation is good, no intervention is necessary.
- The infant will become edematous – particularly periorbital and around the scalp – the urine output will likely be initially low- in part a consequence of redistribution of cardiac output and in part as a consequence of the edematous state- may need a urine catheter.

### **6. Re-warming**

- After the 72 hour cooling period, to avoid seizures during this period, warm up gradually over 4 hours. At the 72 hour time point remove the cap and set the warmer at 35.3C ISC skin temperature which usually gives 25% power so that the rectal temperature does not increase greater than 0.5 degrees C per hour. Increase the ISC by 0.5 degrees C per hour.

### **7. Withdrawal of care:**

- Recommendations: Severely asphyxiated infants (with no cortical/brain stem activity) with flat tracings on aEEG on initial assessment should not be treated with hypothermia and supportive care should be provided unless parents decide to withdraw the care (see exclusion criteria in the protocol).
- Withdrawal of care can be provided for ventilator dependant patients who have poor long-term prognosis (group 3 or 3S plus severe HIE by Sarnat criteria). Parents must agree to withdrawal after consultation with neonatologist and neurologist. Completion of hypothermia treatment should be advised to the parents. Consideration may be given to provide CT/MRI assessment before withdrawal of care.

## **8. Early Identification of eligible infants:**

- Inform RPC and other hospitals in the area about initiation of Hypothermia Program at NYUMC and explain the importance of early diagnosis and identification of infants with hypoxic-ischemic insult.
- Education/training at the referral hospitals.

## **9. Transport policy/guidelines for outborn infants:**

- Consider as a neonatal emergency, consult with an attending physician before accepting the transfer, initiate transport ASAP. **Tell the ambulance: Neonatal Rescue** to expedite the crew arriving.
- Advise on placement of double lumen umbilical vein catheter and umbilical artery catheter prior to departure, if there is time.
- Avoid possible conditions that can complicate the outcome (hypoglycemia, hypotension, hypoxia, etc.). Get a blood glucose level prior to departure and mid-way through transport.
- Don't treat with phenobarbital (prophylactic treatment) unless evidence of clinical seizures
- At the referring hospital do quick assessment and initiate transport ASAP (do not wait for the XR's, paper work, blood gases).
- Maintain skin temperature at greater than 36°C and less than 37 °C at the referral center. Prior/during transport will decrease rectal temperature to 34-35 °C
- Provide parent with information flyer for hypothermia treatment.
- As soon as possible after arrival, contact the family for updates and then frequently for the duration of the treatment.
- Ask the mom if she wants to be transferred to NYUMC to be near her baby.

## **10. Clinical Data Base Development:**

- Demographics (basic clinical background information about the pregnancy and delivery), criteria for cooling, time of initiation of treatment, vital signs, hourly rectal temperature recording, abnormalities during aEEG or video EEG recording; results of MRI or other imaging, documentation of abnormal laboratory data, conditions requiring treatment such

as seizures, hypotention, coagulopathy, daily score of encephalopathy, short-term outcome information.

- See Database sheet.

#### **11. Developmental Follow-up:**

- Infants with moderate/severe HIE (regardless of treatment received) will be followed at NCCP by 3, 6, 12, 18 months and 3 years of age.
- Bayley Developmental scores at 18 months, followed by 3 years of age.
- MRI

#### **12. NYC Hypothermia Consortium:**

- Regular meetings to review progress, address issues and update protocols, reporting and sharing experience
- Continuous education for current staff an affiliate staff
- Participation in the meetings with Cool Cap NYC Consortium
- Further research related to hypothermia treatment collaborations to improve care
- Develop Registry