Purpose

To ensure neonates, 35 weeks gestation or greater, with perinatal asphyxia receive appropriate therapeutic hypothermia to reduce mortality and improve neurodevelopmental outcomes.

To monitor patients for potential adverse effects related to therapeutic hypothermia and hypoxic ischemic encephalopathy (HIE).

Principles

Late preterm and term infants (greater than or equal to 35 weeks gestation) admitted to the Neonatal Intensive Care Unit with perinatal asphyxia, who meet the criteria for therapeutic hypothermia and when cooling can be implemented within the first six hours of life, will be cooled to achieve a rectal temperature of 33-34°C.

Patient Eligibility (Refer to eligibility sheets below)

The infant must satisfy criteria for A and B within 6(six) hours of birth

Infants greater than or equal to 35 weeks gestation admitted to the Neonatal Nursery will be assessed sequentially using 2(two) criteria.

Criteria A – Any ONE of the following:
- Apgar score ≤ 5 at 10 minutes
- Continued need for resuscitation at 10 minutes of age (this includes PPV)
- Cord (arterial or venous) or any arterial pH within 60 minutes of birth <7.00
- Base deficit ≥ 16 mmol/L in a cord, venous, or arterial gas sample within 60 minutes of birth

IF infant meets criteria A then assess neurological status (Criteria B).

Criteria B – Moderate to severe encephalopathy (Sarnat 2 or 3) with at least one of the following:
- Altered state of consciousness with lethargy, stupor or coma
- Hypotonia/Hypertonia
- Abnormal reflexes including oculomotor or papillary abnormalities
- Absent or weak suck
- Clinical seizures

An aEEG may be done to provide further clinical information but is not required to determine eligibility for therapeutic hypothermia.

Before Initiation of Therapeutic Hypothermia a Neurological Assessment is to be completed by a Neonatologist/Designate. (Refer to neurological assessment below)
**Patient Exclusion**

- Infants expected to be greater than 6 hours of age before therapeutic hypothermia can be initiated
- Major congenital abnormalities with known poor prognosis
- Evidence of head trauma or intracranial hemorrhage
- Infants “in extremis”, babies whom the Neonatologist recommends withdrawal of support
- Infants less than 35 weeks gestation and/or less than 1800 grams

**Consent**

Therapeutic hypothermia using cool blankets is a standard of care and within the guidelines for eligibility set out in this policy, expressed written consent is not required. Regardless, parents should be informed by the Neonatologist/Designate about the advantages and potential side effects of induced hypothermia, and an information sheet is to be given to the parents. Discussion with the parents should be documented in the progress notes of the chart. An order for therapeutic hypothermia must be written in the patient care orders by the Neonatologist/Designate.

**Adverse Events**

Therapeutic hypothermia and HIE may be associated with adverse events. Adverse events must be documented.

**Adverse Events**

- Electrocardiographic evidence of cardiac arrhythmias, or myocardial ischemia. Hypotension lasting more than 30 minutes
- Coagulopathy (clinical bleeding with abnormal clotting studies)
- Abnormal renal function (urine output <0.5 ml/kg/hour for >24 hours after birth or elevated serum creatinine > 40 µmol/L *levels may be higher in the first 24 hours of life)
- Hyponatremia (<130 mmol/L)
- Hypokalemia (<3.5 mmol/L)
- Bone Marrow depression (platelet count <100,000**9/L)
- Elevated liver enzyme levels (AST > 200 IU or ALT > 100 IU)
- Metabolic acidosis after initiating cooling (arterial pH, blood gases)
- Respiratory distress requiring ventilatory support (mechanical ventilation or CPAP) or need for ECMO or inhaled nitric oxide
- Systemic infection (blood, CSF or urine cultures)
- Hemoconcentration (increase of hematocrit by 20% or more) not associated with transfusions
- Hypoglycemia (<2.6 mmol/L)
- Hypocalcemia (<2 mmol/L) adjusted for albumin levels, or < 1.0 mmol/L on ionized calcium measurement
- Evidence of skin breakdown due to pressure of cooling blanket and shearing injury
- Difficulties in temperature control, e.g. rectal temperatures < 32°C or >35°C
- Shivering

**Serious Adverse Events**

- Major cardiac arrhythmia – e.g. ventricular tachycardia, ventricular fibrillation or acquired conduction block
- Major venous thrombosis not related to an infusion line
- Severe hypotension despite full inotrope support and volume correction

**Hypothermia Treatment**

To maximize the benefits of therapeutic hypothermia, it should be started as soon as possible after birth. Every effort should be made to start hypothermia before three hours of age.
Temperature Monitoring
Temperatures are monitored via rectal temperatures.
- Place a disposable rectal temperature probe for continuous temperature monitoring.
- Target rectal temperature is 33-34 °C.
- Check correct placement of rectal probe every hour.
- If ventilated, ventilator humidifier temperature is not adjusted.
- Temperatures are recorded on the Therapeutic Hypothermia for Treatment of Neonatal Encephalopathy Temperature Record.(Refer to record below)

Blood Work
- Blood work is collected as per the Hypothermia Blood Work Schedule.(Refer to record below)

Patient Care Precautions
- Temperature is closely tied to the baby's metabolic rate so be aware of situations that change this. Anticonvulsants or sedation will lower the metabolic rate and may cause the baby's temperature to drop. Seizures or increased activity increases the metabolic rate and may cause the baby's temperature to rise.
- Babies should not have enteral feeds initiated but may receive oral immune therapy.
- Interrupt cooling as infrequently and for as little time as possible.

Skin Care
- Check condition of skin in contact with the cooling wrap every hour –color, edema, inflammation or indications of pressure.
- Prevent excessive or prolonged tissue pressure and shearing forces.
- Change in positioning of baby should occur every 1 - 2 hours.

Equipment and Procedure for Therapeutic Hypothermia

Equipment
- CritiCool Unit
- Cooling wrap
- Criticool rectal temperature probe
- CritiCool skin temperature probe
- Connecting hoses with quick-disconnect fitting
- Therapeutic Hypothermia Documentation Forms

Procedure

<table>
<thead>
<tr>
<th>ACTION</th>
<th>RATIONALE</th>
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</thead>
<tbody>
<tr>
<td>1. Verify that an order has been written to start therapeutic hypothermia and using two patient identifiers verify the correct patient to receive treatment.</td>
<td>Serious adverse events can be associated with therapeutic hypothermia.</td>
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<tr>
<td>2. Perform hand hygiene and glove prior to handling infant.</td>
<td>Standard precautions.</td>
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<tr>
<td>3. Turn the heat off of the radiant warmer. Set up the CritiCool Unit (Refer to Criticool Unit Reference Guide).</td>
<td>Removes ambient heat source.</td>
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<tr>
<td>4. Remove all clothing from baby except for a diaper and place baby on the cooling wrap.</td>
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</table>
5. Insert a disposable rectal temperature probe 5 cm into the infant's rectum and secure with tape. Attach skin surface probe to an area on the infant’s skin that is not in contact with the cooling wrap. Connect the rectal probe and skin surface probe to appropriate cables of the CritiCool Unit.

6. Patient rectal temperature is checked on initiation of treatment and then recorded every 15 minutes for the first four hours then every hour until 72 hours of completed therapeutic hypothermia treatment, on the Therapeutic Hypothermia for Treatment of Neonatal Encephalopathy Temperature Record. Temperatures are closely monitored and recorded on specific records for data collection.

7. Heart rate, respirations and blood pressure are recorded hourly throughout cooling and rewarming.

8. Ensure the Criticool Unit is in the cooling mode and water is flowing through the cure wrap before securing the cure wrap loosely around the baby. When the cure wrap is filled with water it expands and becomes more constrictive around the baby. This also ensures even distribution of the water.

9. The condition of the skin in contact with the cooling wrap is checked hourly for color, edema, inflammation or indications of pressure. Avoid excessive or prolonged tissue pressure and shearing forces. Prolonged contact with a cold surface could impair skin circulation to a degree that there is an increased risk for tissue injury.

10. Obtain hour zero blood samples as directed by the open square on the protocol sheet. Refer to “Hypothermia Blood Work Schedule”.

11. Record and report any adverse effects of cooling.

12. Commence aEEG.

13. Baby shall remain NPO throughout therapeutic hypothermia but may receive oral immune therapy. Perinatal asphyxia compromises blood flow distribution to the baby’s gut.

14. Parents/caregivers are encouraged to sit at baby's bedside and offer support through touch and soft talking. They will not be able to hold their baby during the cooling and re-warming phases of treatment. To maximize time receiving treatment.

15. If an x-ray is needed change Criticool Unit to standby mode, loosen the cooling wrap and position x-ray plate between baby and the cooling wrap. Interrupt the cooling or rewarming phase as briefly as possible. The cooling wrap shows shadows on x-ray.
16. Notify Neonatologist/Designate for equipment failure that does not respond to troubleshooting, resulting in interruption to the cooling process.

### Procedure For Re-warming

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<tr>
<td>1. Re-warming is commenced after 72 hours of therapeutic hypothermia at a rate of 0.5°C every hour over a 6 hour period.</td>
<td>Re-warming can be stressful and should not be done too quickly.</td>
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<tr>
<td>2. Rectal temperatures are recorded every 30 minutes for the duration of re-warming.</td>
<td>Prevention of hyperthermia after re-warming is very important.</td>
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<tr>
<td>3. When the rectal temperature reaches 36.5°C remove baby from cooling wrap then remove rectal and skin surface probes. Reactivate radiant warmer and attach temperature probe from overhead warmer to baby to maintain an axillary temperature of normal range.</td>
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<tr>
<td>4. Confirm with Neonatologist/Designate before discontinuing aEEG.</td>
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<tr>
<td>5. Ongoing monitoring of the axillary temperature should continue for 24 hours. Record the temperature every 30 minutes until temperature is stable for 2 hours, then hourly for 2 hours, then every 4 hours.</td>
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<tr>
<td>6. Upload stored data from the Clinilogger to Computer as per instructions in the Criticool Unit Reference Guide.</td>
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<tr>
<td>7. Nursing staff to clean Criticool Unit as per instructions in the Criticool Unit Reference Guide.</td>
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Related Documents
Adapted with permission from Stollery Children’s Policy and Procedure Manual:

Therapeutic Hypothermia Forms and Documentation located on the Policy and Procedure page
- Inclusion Criteria
- Exclusion Criteria
- Hypothermic Blood Work Schedule
- Therapeutic Hypothermia for Treatment of Neonatal Encephalopathy Temperature Record
- Therapeutic Hypothermia Physical Assessment Tool (THAT)
- Guidance tool for THAT
- Neonatal Encephalopathy Assessment Tool for Therapeutic Hypothermia (NEAT)
- Guidance tool for NEAT
- Parent Handout
- Criticool Unit Reference Guide

Revisions
June 2011
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March 2017

RELATED POLICIES AND PROCEDURES
Assessment of the Newborn
Neurobehavioral Assessment Guidelines

References


Therapeutic Hypothermia

Date Approved
April 2017

Policy Group
Neurological

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Signing

Original Signed

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