June 2015

Winnipeg Regional Health Authority / Office régional de la santé de Winnipeg Caring for Health / À l'écoute de notre santé **NEONATAL CLINICAL PRACTICE GUIDELINE**	**Title:** **Hypothermia for Newborns with Hypoxic Ischemic Encephalopathy**	
	Approval Date: June 2015	**Pages:** *1 of 10*
	Approved by: Neonatal Patient Care Teams, HSC & SBH Child Health Standards Committee	**Supercedes:** *HSC: #80.275.501* *SBH: #014*

1.0 PURPOSE AND INTENT:

1.1 To provide systemic whole body hypothermia for infants who experienced perinatal asphyxia and have moderate to severe hypoxic ischemic encephalopathy.

Note: All recommendations are approximate guidelines only and practitioners must take in to account individual patient characteristics and situation. Concerns regarding appropriate treatment must be discussed with the attending neonatologist.

2.0 PRACTICE OUTCOME

2.1 To minimize the damage to the neonatal brain and other organs resulting from hypoxia.

3.0 GUIDELINES:

3.1 Determine hypothermia eligibility criteria using the checklist in Appendix A.

3.2 Hypothermia Exclusion Criteria:

- 3.2.1 Presence of known chromosomal anomaly.
- 3.2.2 Presence of major Central Nervous System anomalies or other anomalies that would preclude cooling.
- 3.2.3 Infants in severe condition for which no additional intensive therapy will be offered after discussion with parents by attending Neonatologist (ie. Refractory hypotension, refractory acidosis, comatose with absent brain-stem reflexes etc.)
- 3.2.4 Congenital ano-rectal anomaly based on visual inspection.
- 3.2.5 Other known causes of neonatal encephalopathy
- 3.2.6 Persistent Pulmonary Hypertension of the Newborn (relative contraindication)
- 3.2.7 Active bleeding
  - 3.2.7.1 Untreated coagulopathy (relative contraindication)
- 3.2.8 Intracranial bleeding
  - 3.2.8.1 If significant head trauma is present at birth an emergency CT scan should be done as soon as possible (preferably before starting cooling) to assess for intracranial bleeding
- 3.2.9 Proven sepsis

3.3 Intiate hypothermia as early as possible within the first 6 hours of life. It may not be effective if initiated later.

3.4 Initiate passive cooling in the High Risk Newborn Resuscitation Room or on Neonatal Transport.

3.5 Maintain hypothermia for 72 hours from the initiation of cooling to the initiation of rewarming.

3.6 Monitor the infant's core temperature continuously using a rectal or esophageal probe.

3.7 Apply an Amplitude Integrated EEG monitor. Consider use of a Near Infrared Spectroscopy monitor in severely affected infants.

3.8 Monitor the infant's cerebral function with Near Infrared Spectroscopy if this equipment is available.

3.9 Notify the Neonatologist before initiating hypothermia.

3.10 Discontinue hypothermia before 72 hours on the determination of the attending Neonatologist if the infant remains persistently hypoxemic or persistently hypotensive in spite of intensive management.

4.0 PROCEDURE:

A. Achieving Hypothermia

4.1 Place infant on an open radiant warmer bed with the warmer turned off. Remove all clothes, blankets and diapers.

4.2 Use the cooling equipment following the procedure outlined in Appendix C. Set the patient esophageal target temperature at 33.5 degrees C.

4.3 If there is no cooling equipment available, initiate hypothermia as described in the following steps:

4.3.1 Insert rectal probe 5 cm and mark with tape at that length. Each time temperature is recorded the probe position must be verified to ensure it has not become malpositioned.

4.3.2 Begin with passive cooling to allow the infant to cool slowly in order to reach the target core temperature of 34 degrees C within one hour.

4.3.3 Utilize active cooling only if the infant's temperature remains greater than 35.5 degrees C after one hour. If a specifically designed cooling device is available, follow the manufacturer's instructions. If one is not available, begin with refrigerated saline bags. Use the size of bag appropriate for the infant. It should not extend beyond the infant's torso. The 250 mL or 500 mL sizes are usually appropriate. Cover the cool bags with one layer of linen and place them beside the infant's abdomen. Start with one bag on either side of the infant's abdomen.

4.3.4 Place additional cool bags around the infant until the infant's temperature reaches 34 degrees C. Add one bag every 15 minutes.

4.3.5 Observe closely as the temperature approaches the target range to avoid over-cooling. Record the core temperature every 15 minutes until it reaches 33.5 degrees C and is stable at that temperature for 2 hours. Avoid overcooling which may lead to increased adverse effects. Then record hourly for the duration of cooling. If the temperature drops below 33.5 degrees C the warmer may need to be turned on and set to a skin temperature of 34.0 degrees C.

B. Monitoring and Care During Hypothermia

4.7 Monitor arterial blood pressure continuously or if this is not possible use non-invasive monitoring at least hourly and more frequently as the infant's condition dictates.

4.7.1 Use of an invasive arterial line is strongly recommended for all patients undergoing therapeutic hypothermia because of the potential for major changes in blood pressure associated both with the underlying condition and therapy

4.8 Obtain required baseline blood work: CBC, INR, PTT, fibrinogen and D-Dimer, blood gas, lactate, blood culture, ionized Calcium, serum Magnesium and electrolytes.

4.9 Measure blood gases (including serum lactate and ionized calcium), serum electrolytes and Magnesium every 6-8 hours during hypothermia and rewarming

4.9.1 Repeat INR, PTT and fibrinogen daily if abnormal on initial screen or more often as indicated during hypothermia

4.9.2 Hypokalemia is common during hypothermia due to intracellular shifts and hypothermia induced diuresis. Do not over-correct hypokalemia during hypothermia as this may lead to hyperkalemia during rewarming

4.9.3 Keep $PaCO_2$ at 40-50 torr in ventilated patients. Keep PaO_2 50-70 torr. Avoid hyperventilation or excessive oxygen use.

4.9.4 When analyzing blood gases do not to temperature correction.

4.10 When no hypothermia blanket is available and passive hypothermia is used, monitor the infant's temperature continuously with a rectal probe attached to the cardio-respiratory monitor for the duration of hypothermia. When stool is present or rectal probe reads low without making any changes, check axilla temperature as the presence of stool can cause the rectal probe to give a false low reading.

4.11 Monitor the infant's oxygen saturation continuously with a Masimo® saturation monitor set to maximum sensitivity.
4.11.1 Normal saturation goals apply (88-92%).

4.12 Monitor central blood sugar from an arterial line (not infusing glucose) at least every hour for the first 4 hours and then every 4 hours for the duration of hypothermia and rewarming and more often if intervention is required. Blood glucose goal: 3.5-6.0 mmol/L. Send a true blood sugar to the lab if blood glucose less than 2.6 or greater than 8 mmol/L.
4.12.1 Because of poor capillary flow, capillary blood sugars are not accurate.
4.12.2 Hypoglycemia greatly exacerbates asphyxia induced brain injury and must be avoided.
4.12.3 Hypothermia reduces metabolic rate and if excessive may result in severe hyperglycemia.

4.13 Continue to provide routine care and monitoring based on the infant's clinical condition.
4.13.1 Bradycardia is expected during hypothermia. HR greater than 70 is acceptable unless accompanied by signs of cardiovascular compromise.
4.13.2 Decreased peripheral perfusion is expected during hypothermia. Adequacy of perfusion is monitored by serum lactate with the goal to have lactate less than 2.5 mmol/L.
4.13.3 Hypertension and hypotension can occur during cooling because of increased peripheral vascular resistance (hypertension), hypothermia induced diuresis (hypotension), myocardial injury and or depression (hypotension).
4.13.4 Hypotension can occur in previously normotensive patients during rewarming due to peripheral vasodilatation.

4.14 Metabolism of many drugs is prolonged by hypothermia leading to potential toxicity. A complete listing of drugs and potential effects are found in Appendix B.
4.14.1 Therapeutic drug monitoring should be used wherever available to guide dose.
4.14.2 Titrate doses from lowest possible dose to clinical effect (see caveat about efficacy of opiates during hypothermia).
4.14.3 Avoid scheduled doses and continuous infusions of drugs known to accumulate with hypothermia (See Appendix B). Drug metabolism may increase significantly during rewarming and increased dosing may be needed for desired effect..

4.15 Metabolism of drugs may rapidly increase during or following rewarming, monitor infant's response to medications closely.

4.16 Make decisions regarding enteral feeding taking the standard considerations into account. Minimal enteral feeding at 10 mL/kg/day should be used unless there are other contraindications as hypothermia is associated with ileus.

4.17 Check stools for occult blood if other abdominal symptoms are evident. It may be positive due to intestinal ischemia rather than the effect of the rectal probe.

4.18 Provide sedation and analgesia as appropriate, with effectiveness monitored by the pain and agitation scores.
4.18.1 Opiates are less effective as sedatives during hypothermia and should be used only for pain relief.
4.18.2 If an opiod is desired, morphine is the first choice at a reduced dose. Avoid using

fentanyl during hypothermia as it has been associated with lack of protection in animal studies. See Appendix B for more details.

4.18.4 Phenobarbital is preferred for sedation

4.18 Treat seizures aggressively according to the best available evidence and pediatric neurologist consulted. A low threshold for suspicion of seizures should be maintained at all times. **Phenytoin should not be used as it is associated with life-threatening side effects during hypothermia.**

4.19 Consider using antibiotics for duration of hypothermia. (hypothermia blunts immune responses and may mask infection). Sepsis is the most common complication of hypothermia in adults.

4.20 Consider using Clonidine (1 ug/kg/dose) to treat excessive shivering.

4.21 Weigh infant at least daily. More often may be required.

4.22 Encourage parent's presence at the bedside and allow them to touch their baby and hold their hands. Avoid extensive skin to skin contact to prevent wide fluctuations in temperature.

4.23 Position the infant supine or side lying to avoid the baby's face being in direct contact with the cooling surface. Reposition the baby every 3-4 hours.

C. Rewarming and Monitoring Following Hypothermia

4.24 Rewarm the infant gradually at a rate no greater than 0.5 degrees C every 2 hours until the axilla temperature reaches approximately 36.5 degrees C and the rectal temperature approaches 37 degrees C This should take approximately 8-10 hours. Rapid rewarming may lead to morbidity including seizures, hypotension and bleeding. Follow these steps to achieve slow rewarming:

4.23.1 Remove cooling bags one at a time, at 15 minutes intervals.

4.23.2 Once all active cooling has been stopped, turn on the infant warmer, ensure the skin probe is in place and set the skin servo temperature at the current skin probe reading.

4.23.3 Increase the servo set temperature by 0.1 degrees C every 15 minutes.

4.23.4 Monitor and record the rectal and skin temperature every 15 minutes until the infant's temperature has reached 36.0 degrees C and then every 30 minutes for 2 hours, then every 3 hours as required.

4.25 Remove the rectal probe after the infant's temperature has reached 37 degrees C. The temperature can be managed and monitored in the routine way at this point.

4.26 Assess the infant's skin and soft tissues for evidence of subcutaneous fat necrosis (SFN) which may occur from 2 weeks to 6 months as a result of the hypoxic injury and/or hypothermia. It is first evident by firm subcutaneous nodules that are reddish or bluish in color and are painful to palpation. They may progress to full necrosis of overlying tissue. Serum calcium should be monitored periodically during this period.

5.0 DOCUMENTATION

5.1 While achieving hypothermia and during rewarming, document frequent temperature readings on Form# NS00826 Neonatal Intensive Care Special Monitoring Sheet.

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Appendix A

Example of charting form – obtain official form for documentation in the clinical record.

ASSESSMENT FOR THERAPEUTIC HYPOTHERMIA

Birth: Date ______________ Time __________

Physician assessments for hypothermia qualification are done: post resuscitation, 1 hour, 3 hours and 5 hours of age.

Qualification for Hypothermia Treatment:

☐ Infant greater than or equal to 35 weeks Gestational Age ________ (by best estimate).

AND any 2 of the following:

☐ Apgar score of 5 or less at 10 minutes.
☐ Cord pH or postnatal blood gas pH less than 7 within one hour of age.
☐ Base deficit of greater than 16 mEq/L on umbilical cord or arterial blood gas within one hour of age.
☐ Infant required at least 10 minutes of positive pressure ventilation during neonatal resuscitation at birth.

AND

☐ Clinical seizures OR
☐ Presence of at least one sign in at least 3 of the 6 categories in the table below.

Physician Assessment	After Stabilization	Hour 1	Hour 3	Hour 5
Date				
Time				
Hours of Age				
1. Level of Consciousness	☐ Lethargic ☐ Stupor/Coma	☐ Lethargic ☐ Stupor/Coma	☐ Lethargic ☐ Stupor/Coma	☐ Lethargic ☐ Stupor/Coma
2. Spontaneous Activity	☐ Decreased activity ☐ No activity	☐ Decreased activity ☐ No activity	☐ Decreased activity ☐ No activity	☐ Decreased activity ☐ No activity
3. Posture	☐ Distal flexion, full extension ☐ Decerebrate (arms extended and internally rotated, legs extended with feet in forced plantar flexion)	☐ Distal flexion, full extension ☐ Decerebrate (arms extended and internally rotated, legs extended with feet in forced plantar flexion)	☐ Distal flexion, full extension ☐ Decerebrate (arms extended and internally rotated, legs extended with feet in forced plantar flexion)	☐ Distal flexion, full extension ☐ Decerebrate (arms extended and internally rotated, legs extended with feet in forced plantar flexion)
4. Tone	☐ Hypotonia (focal, general) ☐ Flaccid	☐ Hypotonia (focal, general) ☐ Flaccid	☐ Hypotonia (focal, general) ☐ Flaccid	☐ Hypotonia (focal, general) ☐ Flaccid
5. Primitive Reflexes:				
Suck	☐ Weak ☐ Absent	☐ Weak ☐ Absent	☐ Weak ☐ Absent	☐ Weak ☐ Absent
Moro	☐ Incomplete ☐ Absent	☐ Incomplete ☐ Absent	☐ Incomplete ☐ Absent	☐ Incomplete ☐ Absent
6. Autonomic System:				
Pupils	☐ Constricted ☐ Skew deviation/ dilated/non-reactive to light	☐ Constricted ☐ Skew deviation/ dilated/non-reactive to light	☐ Constricted ☐ Skew deviation/ dilated/non-reactive to light	☐ Constricted ☐ Skew deviation/ dilated/non-reactive to light
Heart Rate/ Respirations	☐ Apnea/Bradycardia ☐ Variable heart rate ☐ Periodic breathing	☐ Apnea/Bradycardia ☐ Variable heart rate ☐ Periodic breathing	☐ Apnea/Bradycardia ☐ Variable heart rate ☐ Periodic breathing	☐ Apnea/Bradycardia ☐ Variable heart rate ☐ Periodic breathing
Eligible for Hypothermia	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Seizures	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Physician Signature				
Physician Printed Name				

Appendix B
Drugs known to be affected by Hypothermia

Drug	Effect	Comments
Morphine	Decreased metabolism	Decreased sedative effect with hypothermia
Fentanyl	Markedly decreased metabolism	Increased neuronal damage associated with fentanyl. Hypothermia not neuroprotective when used with fentanyl
Phenobarbital	Decreased metabolism	Improved neuroprotection in animal model
Midazolam	Decreased or variable metabolism	Potential for extremely high concentrations. Increased risk for hypotension
Phenytoin	Decreased metabolism	Increased potential for severe cardiac effects
Topirimate	Decreased metabolism	
Rocuronium	Increased duration of action	
Vecuronium	Increased duration of action	
Pancuronium	Decreased metabolism and increased sensitivity	
Phenytoin	Decreased metabolism	Potential for life-threatening complications
Aminoglycosides	Increased volume of distribution and decreased excretion	Increased potential for renal toxicity
Atropine	Decreased metabolism	Results in prolonged tachycardia. Avoid for RSI during hypothermia.

Drugs potentially affected by Hypothermia

Drug	Predicted Effect	Comments
Codeine	Decreased metabolism	
Meperidine	Decreased metabolism	
Lidocaine	Decreased metabolism	
Lorazepam	Decreased metabolism	
Epinephrine	Paradoxical effect of increased Calcium on contractility	Avoid hypercalcemia There may be potential benefit to keeping ionized calcium low-normal. (not enough information)
Fosphenytoin	Prolongation of QT and increased risk for arrhythmias	Theoretical risk (Hypothermia prolongs QT interval)
Chloral Hydrate	Prolongation of QT and increased risk for arrhythmias	Theoretical risk (Hypothermia prolongs QT interval)

APPENDIX C
Procedure for Use of Blanketrol® III Hypothermia System

1.0 Equipment:
- Blanketrol III cooling unit.
- Maxi-Therm Hyper-hypothermia blanket. Select the appropriate sized blanket (12" x 18" or 22" x 30")
- One set of two connecting hoses (kept with unit) if using disposable blanket. Re-usable blanket has hoses attached.
- Disposable esophageal temp probe.
- Blue cable for temp probe- (kept with unit)
- Distilled water.

2.0 Cooling set-up.

2.1 Check water level in the water fill opening (found under "Operating Instructions"). Water level should be up to the strainer. Add water as needed to reach the strainer. Wipe the unit and hoses with approved hospital disinfectant before each use.

2.2 Connect the black hoses to the unit, and to the cooling blanket

2.2.1 The metal couplings attach to the metal outlets on the side of the blanketrol. You may use any of the three circuits. Big to small, small to big. (To attach, push the metal ring in and hold it while attaching the "male" end, then release the ring to clip it in place).

2.2.2 If using a disposable blanket, the black and white plastic couplings attach to the black and white tubes on the cooling blanket. It does not matter black to white or white to white.

2.3 Plug in power cord and turn on power switch (Rocker switch in front)

2.4 If time allows, pre-cool the blanket by operating in the manual control mode.

2.4.1 Press the TEMP SET (Middle of panel)

2.4.2 Press the up arrow or down arrows to change the patient set point display to 33.5°C.

2.4.3 Press the MANUAL CONTROL button.

Make sure water is circulating into the blanket. Check wheel on side of unit. If it is spinning the unit is circulating water.

3.0 Insertion of Esophageal Temperature Probe

Oral placement is preferred. The probe should be placed in the lower third of the esophagus. Measure the distance from the mouth to the ear to the xyphoid process and subtract 2 cm. Secure the probe by taping as for an OG tube.

Probe position must be confirmed by x-ray. Body cooling may be initiated prior to x-ray confirmation.

Mark the temp probe at the mouth with an indelible pen after its position has been confirmed by x-ray. Use this mark to confirm the probe remains in proper position through out the cooling and rewarming process.

4.0 Cooling Phase:

4.1 Lay infant on blanket. If using a disposable blanket with a fabric-like covering, lay patient directly on it. If using a plastic or vinyl covered blanket, place a thin sheet between the patient and the blanket. Confirm esophageal probe is plugged into the black interconnect cable. Plug the black interconnect cable into side of the Blanketrol III.

4.2 Set the infant's goal temperature:

4.2.1 Press TEMP SET (Middle of panel)

4.2.2 Using the up and down arrows set the goal temperature for 33.5 degrees C

4.3 Set the GRADIENT VARIABLE at 20 degrees C

4.3.1 Press GRADIENT VARIABLE (Right side of panel)

4.3.2 Press and hold the up or down arrows to set 20 degrees C

4.3.3 Press the GRADIENT VARIABLE button again. Water will begin to flow into the blanket.

This initiates cooling.

Note: The cooling blanket will operate at a temperature no more than 20 degrees C less than the infant's esophageal temp. As the infant's temperature decreases, so will the temperature of the cooling blanket, until the patient's esophageal temp reaches 33.5, at which time therapy moves into the maintenance phase. If the infant's esophageal temperature does not reach 33.5 degrees C within one hour, notify NNP / Fellow / Neonatologist.

5.0 Maintenance Phase:

5.1 Press TEMP SET (stops the flow of water.)

5.2 Press GRADIENT 10C (restarts the flow of water.)

5.3 The maintenance phase lasts for 72 hours.

The cooling blanket will operate at a temperature no more than 10 degrees C more or less than the patient's esophageal temperature, to keep the infant's temperature at 33.5 C

6.0 Rewarming Phase

The goal for rewarming is for the infant's esophageal temperature to increase by 0.5 degrees C every 2 hours. Rewarming to 36.5 degrees C should take approximately 12 hours.

6.1 Start the rewarming phase 72 hours after the patient's esophageal temperature first reached 33.5 degrees C.

6.1.1 Press TEMP SET

6.1.2 Using the up and down arrows, increase the patient set point by 0.5 degrees C.

6.1.3 Press GRADIENT 10C to restart water

Repeat the above 3 steps hourly until patient's esophageal temperature reaches 36.3-36.4 degrees C.

6.2 When the patient's esophageal temperature reaches 36.3-36.4 degrees C,

6.2.1 Press MONITOR ONLY (lower right side of panel)

6.2.2 Place skin temperature probe.

6.2.3 Turn on radiant warmer bed.

6.2.4 Maintain normothermia using warmer in servo control mode.

6.2.5 Assess and record axillary *and* esophageal temps Q1hr.

6.2.6 When axillary temperatures have been 36.5-37.2 for 2 hours, the esophageal probe may be removed, and the Blanketrol may be turned off and removed from beside.

6.2.7 Continue to monitor axillary temps Q1hour x 2 more hours, or until stable and normothermic, per orders.

6.3 If the infant's temperature does not increase by 0.5 degrees C in an hour, or goes up by more than 0.5 degrees C in an hour, suspend rewarming process, and notify NNP, fellow or neonatologist.

6.4 If the infant's temperature exceeds 37.5 degrees C, notify NNP, fellow or neonatologist.

7.0 Cleaning after use.

7.1 When re-warming is complete, allow the blanket and hoses to remain connected to the unit for about 10 minutes. Water will drain back into the reservoir by gravity.

7.2 Discard the single-use esophageal probe. Wipe the cable with a hospital approved disinfectant (do not use alcohol) and store in the unit's front storage panel.

7.3 Disconnect the power cord before removing the hoses. Attach the cord to the back of the unit.

7.4 Clamp the blanket tubes. Disconnect the blanket from the hoses and discard. Loosely coil the hose and strap to the unit's back panel.

7.5 The unit and tubing are wiped down using only NON-ALCOHOL hospital approved disinfectant.

7.6 Water in the reservoir does not need to be drained after each use.