

**PROCEDURE/
PROTOCOL FOR:** Hypothermia Therapy for Infants \geq 36 Weeks Gestation with Moderate to Severe Hypoxic Ischemic Encephalopathy (HIE)

- POLICY:**
1. The decision to use hypothermia therapy must be approved by the attending physician.
 2. Esophageal probes will be placed by MDs or APs.

SUPPORTIVE DATA: A lack of oxygen before or during birth can destroy cells in a newborn baby's brain and this damage continues for some time afterwards. One way to try and stop this damage is to induce hypothermia - cooling the baby or just the baby's head for some hours to days. Induced body cooling may reduce the amount of damage to brain cells by decreasing secondary asphyxial injury.

EQUIPMENT: Cincinnati Sub Zero Unit
Cooling blankets - sizes 25x33 and 25x64 inches
Privacy screen
Clips
Sterile water
Philips Skin Surface Temperature Probe
Esophageal Temperature Probe

DOCUMENTATION: Neonatal Neurological Assessment / Seizure Assessment Flowsheet

PROCEDURE FOR: Determining Eligibility for Hypothermia Therapy

ACTION

POINTS OF EMPHASIS

1. Assess Eligibility Criteria:
 - a. Gestational age (\geq 36 weeks gestation and $>$ 1800 grams) admitted to the NICU with presumed birth asphyxia and for whom hypothermia can be initiated within 6 hours of birth.
 - b. Evaluate for the following clinical and biochemical criteria
 - 1) IF BLOOD GAS IS AVAILABLE:
 - Any blood gas (cord or postnatal) done within 60 minutes of birth with a pH \leq 7.0
 - OR
 - Any blood gas (cord or postnatal) done within 60 minutes of birth with a base deficit \geq 16 mEq/L
 - 2) IF BLOOD GAS NOT AVAILABLE or if pH 7.01 to 7.15, or Base Deficit 10 to 15.9 mEq/L:

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- Acute perinatal event AND EITHER:
 - Acute perinatal events may include as: abruption of the placenta, cord prolapse, and uterine rupture. These usually result in severe FHR abnormalities.
- Apgar Score \leq 5 at 10 minutes
 - OR
 - Demonstrated need for artificial ventilation initiated at birth and continued for at least 10 minutes. Ongoing need for ventilator support beyond 10 minutes.

c. A neurologic examination will be performed by a trained examiner on all potentially eligible infants to identify the presence of moderate to severe HIE.

c. A trained examiner is either a Neonatal Attending or Neonatal Fellow experienced in performing the neurological assessment.

1) The presence of moderate to severe encephalopathy is defined as seizures OR the presence of one or more signs in three (3) of the following six categories:

	CATEGORY	MODERATE HIE	SEVERE HIE
a)	Level of consciousness	Lethargic	Stupor/Coma
b)	Spontaneous activity	Decreased	No activity
c)	Posture	Distal Flexion, full extension	Decerebrate
d)	Tone	Hypotonia(focal, general)	Flaccid
e)	Primitive Reflexes		
	Suck	Weak	Absent
	Moro	Incomplete	Absent
f)	Automatic System		
	Pupils	Constricted	Skew deviation/ dilated/non-reactive
	Heart Rate	Bradycardia	Variable HR
	Respirations	Periodic breathing	Apnea

d. If the infant meets the eligibility criteria and has at least three (3) neurologic findings consistent with moderate to severe HIE and has not been deemed ineligible, the physician/LIP (licensed independent practitioner) must enter the following orders:

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- 1) "Begin induced hypothermia at a body temperature of 33.5 degrees C. Maintain body temperature of 33.5 ± 0.5 degree C for 72 hours using the Cincinnati Sub Zero Unit and then slowly rewarm by increasing the set point of the Cincinnati Sub Zero Unit by 0.5 degree C every hour for 6 hours."

PROCEDURE FOR: Setting Up the Cincinnati Sub Zero Machine

ACTION

POINTS OF EMPHASIS

1. Obtain the Cincinnati Sub Zero Unit along with the hyper/hypothermia blankets (there are two blankets: one is 25 by 33 inches and the other is 25 by 64 inches), esophageal thermometer and skin temperature probe.
 2. Cincinnati Sub Zero Set-Up
 - a. Fill the reservoir with approximately 7 liters of sterile water, so that about an inch of water is visible in the strainer.
 - b. Suspend the 25x64 inch blanket behind the radiant warmer by attaching to privacy screens using the 4 clips found in the drawer of the Cincinnati Sub Zero machine.
 - c. Lay the 25x33 inch blanket on a flat surface - not under the infant at this time.
 - d. Connect the two sets of hoses to the 2 Maxi Therm-Life blankets (Black to Black and White to White).
 - e. Unclamp the hoses to allow the blankets to fill with water.
 - f. Plug the system into the red outlets.
 3. Pre-cool the blankets
 - a. Turn the power switch on
- b. Make sure the blanket and the hoses are not kinked. Recheck that the clamps are open.
- d. Blankets should be flat and hoses should not be twisted.
- f. Be sure the power is OFF before connecting the system to the electrical outlet.

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- b. Check to see that there are no leaks in the system. Double check the connections to the blanket.
 - c. Recheck the water level in the machine after the blankets have filled. If necessary, carefully add more water to the reservoir until it is visible in the strainer.
 - d. Set the Celsius/Fahrenheit switch so that Celsius is displayed.
 - e. Set the Cincinnati Sub Zero Unit to 5°C by pressing Temperature Set and using the UP or DOWN arrows until it reads 5°C.
 - f. Depress the Control switch.
- e. 5 DEGREES CELSIUS IS THE DESIRED WATER TEMPERATURE TO PRECOOL THE BLANKETS.

PROCEDURE FOR: Placing the YSI Series Esophageal Temperature Probe

ACTION

POINTS OF EMPHASIS

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| <ul style="list-style-type: none">1. The esophageal probe should be in place at least one minute before pressing the control switch. Measure from the infant's nares to the top of the ear and then to the lower sternum. Subtract 2 cm from that distance.2. Place a piece of ¼ inch cloth tape around the probe at the measured distance.3. Soften the temperature probe prior to placement by placing it in warm water for a few minutes and/or use a small amount of lubricant to ease insertion and placement.<ul style="list-style-type: none">a. If the probe cannot be passed through the nares, insert the esophageal probe orally.4. Tape the temperature probe securely; keep the tape marker at the opening of the nares or mouth.5. Confirm probe position with a chest x-ray. | <ul style="list-style-type: none">1. This measurement should position the tip of the probe in the lower third of the esophagus.<ul style="list-style-type: none">a. Use Surgilube to coat probe surface.5. The film does not need to be done immediately after placing the probe, but placement should be confirmed at the next scheduled chest film. |
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PROCEDURE FOR: Cooling the Infant

<u>ACTION</u>	<u>POINTS OF EMPHASIS</u>
1. Place the 25x33 inch blanket under the infant.	
2. Turn the radiant warmer or any other source of exogenous heat off.	
3. Insert the YSI 400 Series esophageal probe into the patient probe jack.	
4. Switch the Cincinnati Sub Zero Unit from Manual to 10 degree variable mode.	4. The 10 degree variable mode prevents "overshoot".
5. Set the desired patient temperature to 33.5°C by pressing the Temperature Set switch and then using the Up and Down arrows to change the set point display.	5. There must be an order placed in the medical record stating the desired infant's temperature.
6. Expose as much of the infant's body surface as possible to the cooling blanket. Use the smallest sized diaper possible.	6. <u>NO PINS NEAR OR ON THE BLUE COOLING BLANKET.</u>
7. Record on the flow sheet and SCP that cooling is initiated.	

PROTOCOL FOR: Monitoring During Body Cooling

**CLINICAL
ASSESSMENT
AND CARE:**

- Using the intensive care patient flow sheet, record the esophageal actual and SETPOINT and skin temperatures at the beginning of the cooling and every hour for four hours as follows:
 - Skin temperature is measured using a Philips Skin Surface Probe. (The cable for invasive BP monitoring will need to be connected to a BP cassette.)
 - If after 4 hours the esophageal temperature fluctuates $> 2^{\circ}\text{C}$ around the SETPOINT, change to manual mode. Return to the 10o variable mode once the desired temperature is achieved.
- Obtain vital signs hourly. Monitor for changes in cardiac rate and rhythm. Bradycardia (90s - 110s) is seen with cooled term infants.
- Once the infant's esophageal temperature has reached the 33.5 degrees C (the set point), a single layer such as a thin receiving blanket may be placed between the cooling blanket and the infant to prevent soiling of the cooling blanket.

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4. Assess the condition of the infant's skin in contact with the blanket every 20 minutes.
 - a. Note changes in color, edema, inflammation, or any indication of pressure over bony prominences.
 - b. Prevent prolonged tissue pressure and shearing forces over bony prominences.
5. Reposition the infant hourly. Rolled cloth blankets and other positioning aids may be used but should be placed UNDER the cooling blankets.
6. Assess level of consciousness, strength of extremities, pupil size and reactivity every hour.
7. Note the esophageal temperature of the infant on blood gas requisition. Bring this to the attention of the therapist.

- SAFETY:**
1. DO NOT USE SAFETY PINS NEAR OR ON THE COOLING BLANKET.
 2. Turn the radiant warmer or any other source of exogenous heat off.
 3. If after 4 hours the esophageal temperature fluctuates $> 2^{\circ}\text{C}$ around the SETPOINT, change to manual mode.
 4. Confirm the placement of the esophageal probe with the next scheduled CXR.
 5. ANY TIME WATER IS FOUND LEAKING INTO OR AROUND THE UNIT, THE CONNECTING HOSE, AND/OR BLANKET, TURN THE UNIT OFF, DISCONNECT THE POWER CORD FROM ITS POWER SOURCE, AND CORRECT THE PROBLEM.
 6. Any time the unit sounds an alarm, immediately check the Status display and act accordingly, e.g. add water, remove from service, check the probe.

PROCEDURE FOR: Rewarming the Infant

ACTION

POINTS OF EMPHASIS

1. Upon completion of 72 hours of body cooling, core body temperature will be gradually increased using the following steps:
 - a. Each hour, increase the esophageal SETPOINT temperature on the cooling machine by 0.5 degrees C by pressing the temperature set indicator and using the UP arrow to change the SETPOINT display then PRESS THE AUTOMATIC CONTROL SWITCH.
1. The rewarming process requires at least 6 to 8 hours.

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- b. Continue this pattern hourly for 6 hours.
- c. Turn the power to the Cincinnati Sub Zero Unit off.
- d. Set the radiant warmer 0.5 degrees warmer than the skin temperature and raise the warmer set temperature every hour until infant is 36.5 degrees C.
- d. The infant's temperature can drift down 0.5 - 1 degree C after therapy has been discontinued.

PROCEDURE FOR: Discontinuation of Therapy

ACTION

POINTS OF EMPHASIS

- 1. When hypothermia therapy is concluded and the unit is turned off:
 - a. Permit the blankets and hose to remain connected to the unit for about 10 minutes. This allows some of the water to drain back into the unit.
 - b. Remove the probe from the patient and probe jack.
 - c. Disconnect the power cord from the power source, loosely coil it and attach it to the back panel using the nylon strap.
 - d. Disconnect the connecting hose from the unit.
 - e. Remove the blankets.
- 2. The cooling blanket the infant is lying on should be discarded after use.
- 3. The cooling blanket hanging at the head of the warmer should be taken down but saved.
- 4. The esophageal probe and temperature probes should be discarded.
- 5. Following each use, remove the attached drain hose and empty the water reservoir.
- 3. Put the clips that suspended the cooling blanket in the front drawer of the Cincinnati Sub Zero Unit.

APPROVAL: Nursing Standards Committee

EFFECTIVE DATE: 11/07

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REVISION DATES: