Policy Directive

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Whole Body Cooling - Neonates Suspected Moderate or Severe Hypoxic Ischaemic Encephalopathy (HIE)

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Functional Sub group Clinical/ Patient Services - Baby and child
Clinical/ Patient Services - Maternity
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Summary This policy has been developed to provide direction to clinicians regarding therapeutic hypothermia (whole body cooling) for neonates at or greater than 35 weeks of gestation born in a non-tertiary hospital with suspected moderate or severe hypoxic encephalopathy (HIE)

Replaces Doc. No. Whole Body Cooling - Neonates - Suspected Moderate or Severe Hypoxic Ischaemic Encephalopathy (HIE) [PD2009_049]

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Affiliated Health Organisations - Declared, Public Hospitals

Audience Neonatal, nursing/midwives, medical paediatric and obstetric professionals

Distributed to Public Health System, Divisions of General Practice, NSW Ambulance Service, Ministry of Health, Private Hospitals and Day Procedure Centres

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Policy Manual Patient Matters

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Director-General

WHOLE BODY COOLING FOR NEONATES ≥ 35 WEEKS GESTATION WITH MODERATE OR SEVERE HYPOXIC ISCHAEMIC ENCEPHALOPATHY (HIE)

PURPOSE

This policy statement and attached protocol has been developed to provide direction to clinicians regarding therapeutic hypothermia (whole body cooling) for neonates greater than 35 weeks of gestation who may be at risk of hypoxic ischaemic encephalopathy (HIE). The policy statement is applicable to the management of babies born in a hospital without a Neonatal Intensive Care Unit (NICU) who meet the criteria set out in the attached protocol.

Generally, therapeutic hypothermia should usually not be undertaken if the birthing hospital does not have a designated area for the care of newborn babies, e.g, a special care nursery (SCN). However, if the hospital does not have a SCN, then it may be reasonable to commence passive cooling prior to transfer after specialist consultation with a neonatologist.

MANDATORY REQUIREMENTS

If a baby appears to meet the criteria for cooling as set out in the attached procedure for Special Care Nurseries in Non-tertiary Centres under the heading 'Primary Principles', urgent discussion is required with the duty consultant at NETS 1300 36 2500, who will consult with a tertiary neonatologist.

The Primary Principles for Special Care Nurseries in Non-tertiary Centres regarding methodology for baby selection, body cooling, temperature monitoring, and communication with NETS/neonatologist as set out in the attached protocol must be followed.

IMPLEMENTATION

Directors of Clinical Governance are required to inform relevant clinical staff in special care nurseries and maternity services of the policy.

Area Health Services are required to engage relevant clinicians and ensure that consistent local protocols or operating procedures are developed and distributed to relevant clinical areas.

REVISION HISTORY

Version	Approved by	Amendment notes
July 2009 (PD2009_049)	Deputy Director-General Strategic Development	New policy
Jan 2010 (PD2010_006)	Deputy Director-General Strategic Development	Rescinds PD2009_049. Amended to remove the difference in target temperature ranges for rectal and axillary temperature measurement.

ASSOCIATED DOCUMENTS

1. Whole Body Cooling for Neuroprotection in Neonates ≥ 35 Weeks Gestation born in a non-tertiary hospital with suspected Moderate or Severe Hypoxic Ischaemic Encephalopathy (HIE) Protocol

Whole Body Cooling for Neonates ≥ 35 Weeks Gestation With Moderate or Severe Hypoxic Ischaemic Encephalopathy (HIE)

NSW HEALTH
PROTOCOL

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Changes from previous version:

1. The difference in target temperature range between rectal and axillary measurements has been removed. For both, the target range is now 33°C to 34°C

1 BACKGROUND

Moderate/severe HIE following perinatal asphyxia contributes significantly to neonatal mortality and morbidity including long-term neurodevelopmental sequelae in 25%-60% of survivors.

Evidence from high quality studies[1] indicates that "Active Cooling" of neonates ≥ 35 weeks gestation with **moderate** to **severe** HIE begun within 6 hours of birth and continued in a NICU setting is safe and reduces the risk of death or disability at 18 to 22 months of age. There is no evidence to support cooling of infants with mild HIE or those born before 35 weeks.

This guideline is designed for use with babies who are born in a hospital without a NICU and who meet the criteria listed below. Therapeutic hypothermia should usually not be undertaken if the birthing hospital does not have a designated area for the care of newborn babies, e.g, a special care baby nursery (SCN). However if the hospital does not have a SCN, then it may be reasonable to commence passive cooling prior to transfer after specialist consultation as described below.

If a baby appears to meet the criteria for cooling as described below, urgent discussion is required with the duty consultant at NETS who will contact a tertiary neonatologist.

2 GUIDELINE FOR SPECIAL CARE NURSERIES IN NON-TERTIARY CARE CENTRES

Primary Principles

1. Of primary importance in a situation where whole body cooling is being considered is to ensure appropriate resuscitation of the neonate. Therefore, attention to airway, breathing and circulation takes priority over cooling. See NSW Health PD 2008_027.

2. **ALL** infants who meet the eligibility criteria should be considered for cooling. Refer to inclusion and exclusion criteria in next section.

3. There is nearly always time to discuss the possibility of cooling with the parent(s) before cooling is commenced.

4. Cooling must **NOT** be commenced without discussion through NETS with a tertiary centre neonatologist. Since a decision to cool must be made within the first 6 hours after birth, this discussion may be required before a destination bed is finalised.

5. The continuing management of a baby who requires cooling should occur in a neonatal intensive care unit (NICU). Therefore all babies for whom cooling is commenced should be transferred to a NICU by NETS.

6. Cooling is only for neonates born after 34 weeks gestation, in other words 35 weeks and above. Cooling should not be undertaken for preterm neonates born before 35 weeks.

7. Cooling is an adjunct therapy. The ability to commence cooling of neonates should NOT influence decisions to cease resuscitation attempts at birth.

8. The preferred method of temperature monitoring during hypothermia is by continuous monitoring with a rectal probe but intermittent axillary temperatures are acceptable if skills and/or equipment are not available for continuous rectal temperatures.

3 ELIGIBILITY CRITERIA FOR COOLING (ACTIVE OR PASSIVE)

All of the following four criteria must be met.

1. More than or equal to 35 weeks gestational age.
2. Less than 6 hours post birth.
3. Evidence of asphyxia as defined by the presence of at least two of the following:
   a) Apgar less than 6 at 10 min or continued need for resuscitation with positive pressure ventilation +/- chest compressions at 10 mins.
   b) Any acute perinatal event that may result in HIE (ie. abruptio placentae, cord prolapse, severe FHR abnormality etc).
   c) Cord pH less than 7.0 or base excess of -12 mmol/l or less.
   d) If cord pH is not available, arterial pH less than 7.0 or BE less than -12mmol/L within 60 mins of birth.
4. The presence of moderate/severe HIE; defined as seizures **OR** presence of signs in at least three of the six categories given below:

Category	Moderate encephalopathy	Severe encephalopathy
Level of consciousness	Lethargy	Stupor/coma
Spontaneous activity	Decreased activity	No activity
Posture	arms flexed, legs extended (decorticate)	arms and legs extended (decerebrate)
Tone	Hypotonia	Flaccid
Primitive reflexes	Weak suck, incomplete Moro	Absent suck, absent Moro
Autonomic system (any one of) Pupils Heart rate Respirations	 Constricted Bradycardia Periodic breathing	 Dilated/non - reactive Variable heart rate Apnoea

Exclusion Criteria

1. Oxygen requirement greater than 80%
2. Major congenital abnormalities
3. Uncontrolled severe clinical coagulopathy (low platelet count or clinical evidence of abnormal clotting and/or clotting studies which has not responded to appropriate therapy).
4. Baby unlikely to survive. This should be discussed with NETS and the receiving neonatologist.

Risks and complications.

In meta-analysis of the randomised trials, the following effects were reported with significantly higher frequency in the cooled arm of the trials; sinus bradycardia, hypotension requiring inotropes and thrombocytopaenia. These are unlikely to occur in the time prior to transfer to a NICU unless there is a significant delay. Sinus bradycardia may be seen in this early time and is not a concern as long as the blood pressure is adequate, the oxygenation is good and the temperature is not below the target range.

4 GENERAL MANAGEMENT BEFORE COOLING COMMENCES

1. Ensure adequate resuscitation (see NSW Health PD 2008_027) and support for the neonate including Airway, Breathing, Circulation, and Dextrose.
2. Assess eligibility criteria.
3. Call NETS to discuss suitability for cooling with NETS consultant and receiving neonatologist; either “Passive Cooling” or “Active Cooling”.
4. Discuss with parents the option of cooling. **But note that it is recommended that discussion with NETS should usually occur before talking with parents.**

5 PASSIVE COOLING

- **Should be commenced in a non-tertiary setting when there is agreement between NETS and the receiving neonatologist.**

- **No active processes (such as fans or wet cloths) for cooling the infant should be undertaken unless the two criteria described in the next section on ‘Active cooling’ are met.**

This is a process of allowing the infant to cool down of their own accord through the removal of the usual interventions undertaken to keep infants warm. The eventual goal is a **rectal or axillary** temperature between 33^{o}C and 34^{o}C. To achieve this, follow these steps:

1. Nurse the infant on a radiant warmer with warmer off. Do not nurse in incubator.
2. Do not nurse on a sheepskin.
3. Nurse infant naked: Do not; dress, or use a hat, or use any form of wrap (plastic or cloth)
4. Leave nappy unfastened.

5. Full cardiopulmonary monitoring.
6. If nursed in headbox oxygen, do not humidify or warm the air/oxygen gas mixture.
7. If ventilated, use normal humidifier settings.
8. Record time of commencement of passive cooling and record temperature every 15 minutes.
9. All other documentation/care/treatment should be the same as in any asphyxiated infant waiting for transport by NETS.
10. If **rectal** or **axillary** temp drops below 33.5° C, set radiant warmer on manual and gradually adjust heater output to maintain **rectal** or **axillary** temp in the range 33°C – 34°C.

6 ACTIVE COOLING

Only to be commenced if the following 2 points are met:

1. There is agreement between NETS and the receiving neonatologist.
2. Passive cooling has been underway for one hour and the rectal or axillary temperature is still **above 35.5°C.** (Infants are likely to be at least 90 minutes of age before this could begin.)

Protocol and algorithm for Active Cooling:

1. Use cold packs (Nexcare™ First Aid, 3M, Sydney) from the fridge, never use frozen.
2. Cold packs should be wrapped in cotton or equivalent. They should never be applied directly to the skin.
3. The cold packs can be placed under the shoulders/upper back, under the head and/or across the chest/body.
4. If using continuous rectal temperature monitoring, insert **rectal thermistor/probe** into anus at least 5cm: tape at the 10cm (first) mark to the upper inner thigh.
   a. It is very important that the probe is in at least this far to accurately measure the baby's core temperature – the probe is designed for this purpose and will not cause mucosal trauma.
   b. Leave the probe in until change over with NETS.
5. Connect rectal probe to cable, temperature module and monitor.
   a. Set temperature alarm limits at 33°C (low) and 34°C (high) during the cooling period.
   b. Record time of initiating *active cooling* and monitor rectal temperatures every 15 minutes.
6. **If using intermittent axillary temperature measurements then ensure that observations are taken at least every 15 minutes**

Temperature algorithm: Aim for 33 - 34°C

Temperature algorithm	Number of cool packs to be applied	Areas to apply
≥ 35.5°C	2*	Under shoulders, across chest
34.0 – 35.5°C	1	across chest
< 34.0°C	0	Nil

Having more than 2 packs prevents radiant loss of heat into the environment and makes it more difficult to cool the baby

7. If rectal or axillary temperature drops below 33.5°C, remove all cool packs and repeat temperature in 15 minutes. If the temperature continues to fall, set radiant warmer on manual and gradually adjust heater output to maintain rectal or axillary temp at 33.0°C – 34.0°C
8. Aim is to achieve target temperature range within 1 hour but more importantly continue to manage airway, breathing, circulation.
9. Advise/reassure parents about baby's appearance and that he/she will feel cool to touch.
10. The transport team will bring all the necessary equipment to continue the cooling process during transport.

References

1. Jacobs, S. Hunt, R. Tarnow-Mordi, W. Inder, T. Davis, P. Cooling for newborns with hypoxic ischaemic encephalopathy. Cochrane Database of Systematic Reviews. 3, 2008.
2. Therapeutic Hypothermia. RPA Neonatal Guidelines. www.cs.nsw.gov.au/rpa/neonatal

HYPOTHERMIA GUIDELINE REFERENCE GROUP

Dr Adam Buckmaster, Paediatrician, Gosford Hospital representing the NSW Perinatal Services Network Level 4 SCN Working Group.

A/Prof Nick Evans, Neonatologist, Royal Prince Alfred Hospital, Sydney.

Prof William Tarnow-Mordi, Neonatologist, Westmead Hospital, Sydney

Dr Sue Jacobs, Neonatologist, Royal Women's Hospital, Melbourne.

7 FLOW CHART FOR COMMENCING THERAPEUTIC HYPOTHERMIA IN A SPECIAL CARE NURSERY IN A NON-TERTIARY HOSPITAL