1.0 Background

Moderate/severe Hypoxic–Ischaemic encephalopathy following perinatal asphyxia contributes significantly to neonatal mortality and morbidity including long-term neuro-developmental sequelae in 25%-60% of survivors.

Evidence from high quality studies including the TOBY trial\(^1,2,5,6,7\) indicates that moderate induced hypothermia of neonates at or greater than 36 weeks gestation with suspected moderate to severe HIE begun within 6 hours of birth and continued in a NICU setting is safe and reduces the risk of severe disability at 18 to 22 months of age.

Therefore cooling, initiated shortly after birth, is the first intervention which has been proven in rigorously conducted scientific studies to be beneficial in term & near term neonates with HIE. Therapeutic Hypothermia, in this group of infants, was recently advocated by NICE\(^4\).

NICE also suggested that units undertaking cooling do so in conjunction with the TOBY Register which has published guidance on the eligibility of babies, the practicalities of cooling and follow-up data collection. This Network guideline has been developed using TOBY Register\(^3\) guidance.

2.0 Therapeutic Cooling within SWMNN

Birmingham Heartlands has been designated as the SWMNN Cooling Centre and will accept appropriate referrals from other units around Network. Birmingham Women’s will cool their own babies, but not normally take external referrals.

To make a referral to Heartlands, contact the Neonatal Registrar to discuss the case.

- Call ‘Heart of England Switchboard’ on 0121 424 2000 and ask them to bleep ‘The Neonatal Registrar for Heartlands’
- Contacting the Neonatal Unit on 0121 424 3520 and ask to speak to the Registrar

If there is no space within Heartlands, referring units are advised to contact the cooling centres in the Northern Network. Both New Cross, Wolverhampton and University Hospital North Staffordshire, Stoke would be happy to accept babies following a Consultant to Consultant referral.

- New Cross Hospital, Wolverhampton Switchboard - 01902 307 999
- University Hospital North Staffordshire, Stoke Switchboard - 01782 715 444
If none of these units have space, then try Birmingham Women's (switchboard 0121 472 1377)
3.0 Early management Principles

Infants born following an asphyxial insult are sometimes very unwell. Effective initial resuscitation and stabilisation should be undertaken in accordance with Newborn Life Support Algorithms. However special consideration of thermal care should be made.

- Avoid Overheating. If it is clear that the infant fulfils Cooling Criteria A during the resuscitation, then allow passive hypothermia to occur.
  - Turn the overhead heater off
  - Leave the baby uncovered
  - Turn off the heater in the transport incubator (if used)
  - Do not re-warm the infant once on the Neonatal unit

- Request cord gases

- Ask the Midwives to send Placental swabs to Microbiology and the Placenta for Histological examination.

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

4.0 Eligibility for Cooling

To be considered eligible for cooling, infants must be at least 36+0 weeks gestation AND less than 6 hours old. They should have no major congenital abnormalities suggesting lethal chromosomal defect or other syndromes that include brain dysgenesis. They must then meet BOTH criteria A & B

**COOLING CRITERIA A**

**Baby Show signs of Hypoxia-Ischaemia** - by meeting one of the following four markers....

- **Low Apgar scores**
  5 or less at 10 minutes after birth

- **Prolonged resuscitation at birth**
  endotracheal or mask ventilation/chest compressions at 10 minutes

- **Severe Acidosis** - pH < 7.0
  from umbilical cord, arterial or capillary blood gas within 60 minutes of birth

- **Abnormal base Deficit ≥16 mmol/L**
  in umbilical cord or any blood sample from baby within 60 minutes of birth

**COOLING CRITERIA B**

**Have Seizures OR Moderate to severe encephalopathy** - consisting of ...

- **Altered state of consciousness**
  reduced or absent response to stimulation

- **Abnormal tone**
  focal or general hypotonia, or flaccid

- **Abnormal primitive reflexes**
  weak or absent suck or Moro reflex

OR

- **Abnormal aEEG background** (if available)
Note: Children with less severe anomalies who would normally receive full intensive care (like Down syndrome, cardiac or surgical anomalies) should be considered for Cooling if asphyxiated and fulfilling the criteria, as long as cooling is not seen to contradict the other interventions needed.

If an infant meets these criteria, but cooling is NOT offered, the reasons for this should be clearly documented in the medical notes. It is possible that this decision may need to be justified in the future, should

5.0 Referral for Cooling Algorithm

![Referral of a baby for cooling treatment (≥ 36 completed weeks gestation)](image)

**Actions for referring hospitals**

**Step 1**
- Birth to 1 hour of age
- Resuscitation: Standard NLS Procedures
  - Recovery
    - No encephalopathy
    - Continue normothermia
  - Encephalopathy present
    - Start passive cooling

**Step 2**
- 1-6 hours of age
- Passive cooling with continuous rectal or axillary temperature monitoring. Record temperature every 15 minutes
- Assess baby for treatment criteria A and B
  - NO
    - Cooling not appropriate. Stop passive cooling
  - YES
    - Telephone nearest cooling centre

**While awaiting transport team:**
- Keep parents informed about baby's condition; give them the "UK TOBY Cooling Register Parent Information Leaflet"
- Complete first page of "UK TOBY Register data collection form and
- Monitor vital signs, rectal/axillary temperature and manage baby's clinical condition as detailed in the guideline
- Complete the referring hospital check list (see page 16) and prepare all documentation to accompany baby on transfer.
6.0 Ongoing Management

- Ensure the airway is secured and the baby’s breathing and circulation are maintained. Babies requiring transfer to a cooling centre will almost all need intubation and ventilation. Ensure adequate sedation (Morphine/Diamorphine infusion).

- All infants who meet the criteria for cooling should be discussed with the Network Cooling Team to arrange a bed and for instruction on passive cooling prior to transfer. If no bed is available in the local cooling centre contact alternative cooling providers.

- Contact the Newborn Transfer service to arrange urgent transfer, as soon as is possible. Then work on preparing the baby, the aim is to have the baby ready for transfer before they attend.

- Discuss the option of cooling treatment with the parents and seek parental assent as soon as practically possible. Details of all discussion with parents about their baby’s treatment with cooling should be documented in the baby’s notes. Give them the NICE parent information leaflet (appendix 2).

- Document both the admission and current temperature of the baby. This should be measured by whatever means is routine in the referring unit. Ideally, continuous rectal temperature monitoring should be commenced. If this is not available, axilla temperature should be measured every 15 minutes.

- The incubator heater should be turned off (and the portholes opened if in a closed incubator). The baby should be naked apart from a nappy.

- If possible pass a rectal temperature probe to about 6 cm and secure. Aim to achieve a rectal temperature of 34-35°C. This level is higher than target cooling temperature which is 33.5°C to avoid uncontrolled overcooling.

- Hypocarbia is undesirable as this reduces cerebral blood flow. Aim to maintain a PaCO2 6-8 kPa (cooling reduces PCO2 levels in itself).

- Watch for signs of persistent pulmonary hypertension – consider monitoring pre and post ductal saturations.

- Aim to site double-lumen umbilical venous line and an arterial line. Restrict IV fluids to 40ml/kg/day initially watch glucose closely, use concentrated glucose infusions if needed. Do not give Bicarbonate purely based on pH.

- Monitor blood pressure invasively if possible and aim to keep blood pressure >45 mmHg. Additional volume may be needed as the baby becomes colder. Also be aware that the baby’s heart rate will gradually become lower as the baby cools (down to baseline of approx. 80-90 bpm when hypothermic and sedated).

- Take blood for the following investigations – Culture, FBC, Gas, Lactate, U&E, Creatinine, Calcium, Magnesium, PT, APTT, Glucose, LFT’s. Collect the first urine passed by baby (cotton wool in nappy is OK) and transfer this to the cooling centre with the baby.

- If despite following the guidelines the baby does not passively cool to the target temperature follow the Passive cooling algorithm as outlined in section 7.0 or take further advice from the Cooling Team.

- Print out a copy of the TOBY patient observation paperwork and start recording patient data (appendix 3). This should be transferred along with the baby.

- Transfer should be made as soon as possible – make every effort to prepare the baby fully. Current advise is that all babies deemed fit for transfer should be cooled even if the chances of intact survival are very slight.
8.0 Audit

Audit of all babies born within the network with a diagnosis of HIE. This will provide us with information regarding clinical condition of babies at the outset of treatment. This audit will continue indefinitely and will be reviewed yearly, although numbers will be small. Data will be collected regarding cooling by the national TOBY cooling register which will look at short and long term outcomes.
9.0 References

1. Moderate hypothermia to treat perinatal asphyxia encephalopathy

2. Treatment of asphyxiated newborns with moderate hypothermia in routine clinical practice: how cooling is managed in the UK outside a clinical trial.

3. UK TOBY Cooling Register, Clinician’s Handbook Version 4 May 2010

4. NICE guidance for Cooling in babies following hypoxic brain damage

5. Cooling for newborns with hypoxic ischaemic encephalopathy – Cochrane Review


7. Whole-body hypothermia for neonates with hypoxic-ischemic encephalopathy.

8. California Hospital NICUs Providing "Whole Body Cooling" and Cool CAP for Hypoxic Ischemic Encephalopathy (HIE);(October 31, 2009)

9. Whole Body Cooling - Neonates Suspected Moderate or Severe Hypoxic Ischaemic Encephalopathy (HIE); Department of Health, NSW; jan 2010

10. Systemic cooling for neuroprotection in neonates >35 weeks gestational age with hypoxic ischaemic encephalopathy(HIE); Neonatology Clinical guidelines, King Edward Memorial Hospital, Perth


12. TOBY handbook, Whole body hypothermia for the treatment of perinatal asphyxia encephalopathy, Feb 2006


15. Does Head Cooling With Mild Systemic Hypothermia Affect Requirement for Blood Pressure Support?
Checklist for referring hospital

- Baby meets Group A and Group B criteria
- Contact cooling centre and transport team
- Discuss with the baby’s parents
- Give NICE parent information leaflet
- Initiate passive cooling as soon as possible Document the age at which cooling started
- Monitor (rectal) temperature continuously Document every 15 minutes
- Intubate and insert umbilical venous and arterial lines
- Restrict total fluids to 40 ml/kg/day
- Commence on morphine infusion
- Aim to keep blood pressure > 45 mm Hg
- Obtain sample of blood samples for asap Culture, FBC, Clotting Gas, Glucose, U&E, Creatinine, LFTs Calcium, Magnesium Lactate
- Speak regularly to cooling centre
Understanding NICE guidance
Information for people who use NHS services

Controlled cooling to treat newborn babies with brain injury caused by oxygen shortage during birth

This leaflet is about when and how controlled cooling can be used in the NHS to treat newborn babies with brain injury caused by a shortage of oxygen during birth. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which babies will benefit most from it. This leaflet is written to help parents or carers whose baby has been offered this procedure to decide whether to agree (consent) to it or not. It does not describe brain injury or the procedure in detail – a member of your baby’s healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your baby’s doctor to help you reach a decision. Some sources of further information and support are on the back page.

Information about NICE interventional procedure guidance 347
Issue date: May 2010
## UK TOBY Cooling Register

**Patient identification number (PIN)**
please call 01865 289735 during office hours if a PIN is required

<table>
<thead>
<tr>
<th>Cooling treatment provided at</th>
<th>Name of Hospital</th>
<th>Sex M</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month and year of treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gestational age at birth</td>
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</table>

### Clinical Details of Baby at Birth

<table>
<thead>
<tr>
<th>Birth weight (gm)</th>
<th>Head circumference (cm)</th>
<th>First Gasp at (min)</th>
<th>Resuscitated &gt; 10 minutes</th>
<th>Apgar Score (please write X if unknown)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 min</td>
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<tr>
<td></td>
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</tbody>
</table>

### Blood gas results (worst set of results within 60 minutes including cord blood)

<table>
<thead>
<tr>
<th>pH</th>
<th>pO₂</th>
<th>pCO₂</th>
<th>kPa</th>
<th>Base deficit</th>
<th>Seizures</th>
<th>Encephalopathy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</table>

### Hypoxic Ischaemic Encephalopathy Score prior to cooling

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<th>Sign</th>
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<th>2</th>
<th>3</th>
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<tbody>
<tr>
<td>Tone</td>
<td>Normal</td>
<td>Hyper</td>
<td>Hypo</td>
<td>Faccoid</td>
</tr>
<tr>
<td>LOC</td>
<td>Normal</td>
<td>Hyper-alert, stare</td>
<td>Lethargic</td>
<td>Comatose</td>
</tr>
<tr>
<td>Fits</td>
<td>None</td>
<td>Infrequent</td>
<td>Frequent</td>
<td></td>
</tr>
<tr>
<td>Posture</td>
<td>Normal</td>
<td>Fasting, cycling</td>
<td>Strong</td>
<td>distal</td>
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<tr>
<td>Moro</td>
<td>Normal</td>
<td>Partial</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>Grasp</td>
<td>Normal</td>
<td>Poor</td>
<td>Absent</td>
<td></td>
</tr>
<tr>
<td>Suck</td>
<td>Normal</td>
<td>Poor</td>
<td>Absent / bile</td>
<td></td>
</tr>
<tr>
<td>Respiration</td>
<td>Normal</td>
<td>Hyper-ventilation</td>
<td>Brief</td>
<td>apnoea</td>
</tr>
<tr>
<td>Fontanelle</td>
<td>Normal</td>
<td>Full, not tense</td>
<td>Tense</td>
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</table>

### Age when cooling commenced

<table>
<thead>
<tr>
<th>mins</th>
<th>hrs</th>
<th>mins</th>
</tr>
</thead>
</table>

### Pregnancy complications (please tick all those that apply):

- None
- Diabetes
- Ilicit drug use
- Maternal seizure
- Placenta praevia
- Pre-eclampsia
- Thyroid disorder
- Other sentinel event(s) during pregnancy

Other details: 

### Mode of Delivery (please tick one):

- Pre-labour CS
- in labour CS
- SVD cephalic
- SVD breech
- Instrumental delivery

### Delivery complications (please tick all those that apply):

- None
- Head entrapment
- Placental abruption
- Prolapsed cord
- Ruptured uterus
- Shoulder dystocia
- Other sentinel event(s) during delivery

Other details: 

### Congenital abnormalities apparent at birth

- Yes
- No

If yes, please describe: 

### Was an eEEG or EEG performed prior to cooling? (please tick)

- No
- eEEG
- EEG

### CFM findings:

<table>
<thead>
<tr>
<th>Background</th>
<th>Seizures</th>
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</thead>
<tbody>
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<td>Normal / Mildly abnormal</td>
<td>Yes</td>
</tr>
<tr>
<td>Moderately abnormal</td>
<td>No</td>
</tr>
<tr>
<td>Severe abnormal</td>
<td>No</td>
</tr>
</tbody>
</table>

* Definitions for all items on this form marked with an asterisk may be found in the Clinician’s Handbook and in the appendix to this form.