

Document Control

Title Passive Cooling Guidelines for Neonatal Encephalopathy			
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Version	Date Issued	Status	Comment / Changes / Approval
0.1	May 2015	Draft	Initial version for consultation
0.2	Oct 2015	Draft	To stakeholders for consultation, revised with comments
1.0	Jan 2016	Final	Approved by Paediatric Specialty Team 26/2/16
1.1	Sept 2019	Draft	Sent out to stakeholders for consultation, revised with comments
2.0	Nov 2019	Final	Updated to fit with practice. Approved at Clinical Audit and Guidelines Group 12 th November 2019.
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Superseded Documents None			
Issue Date Nov 2019	Review Date Nov 2022	Review Cycle Three years	
Consulted with the following stakeholders: (list all) <ul style="list-style-type: none"> • Paediatricians • SCU clinical staff 			
Approval and Review Process <ul style="list-style-type: none"> • Paediatric Specialty Team 			
Local Archive Reference G:\paediatricresources/neonatal/guidelines/passive cooling guidelines for neonatal encephalopathy Filename Passive Cooling Guidelines for Neonatal Encephalopathy			
Policy categories for Trust's internal website (Bob) Neonatal		Tags for Trust's internal website (Bob) Cooling, HIE, temperature, rectal, neurological, cerebral, CFM, seizures, hypoxic, ischaemic	

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1. Introduction

“Perinatal asphyxia severe enough to cause neonatal hypoxic ischaemic encephalopathy (HIE) occurs in approximately 3/1000 births in the UK. The risk of death or severe handicap in survivors of moderate or severe HIE is approximately 25 and 75% respectively, and children without motor impairments have lower cognitive scores on long term follow-up, poorer scholastic attainment in independent National Attainment Tests, and often need educational support. Perinatal asphyxia thus creates a major burden for the individual, the family and for society. Until recently no specific treatment for HIE was available. However the results of three randomised controlled trials, including the UK total body cooling trial (TOBY), confirm that 72 hours of cooling to a core temperature of 33-34^oC started within six hours of birth reduces death and disability at 18 months of age and improves a range of neurodevelopmental outcomes in survivors. A meta-analysis of these data and an economic evaluation shows that the treatment is cost effective in the context of the National Health Service” (BAPM 2010)

Therapeutic hypothermia for HIE is now undertaken as standard treatment.

This occurs in some level 2 and level 3 units across the Southwest Neonatal Network.

The sooner cooling occurs the better the outcome. Thus if a baby is born in a level one unit with suspected HIE then it is recommended that passive cooling is commenced prior to retrieval of the infant to a Neonatal Intensive Care Unit.

2. Definitions

2.1. Active Cooling

Therapeutic hypothermia maintained by using appropriately certified cooling equipment to keep the rectal temperature within the target range 33-34c for 72hours.

2.2. Passive Cooling

Therapeutic hypothermia commenced by discontinuing active warming of the baby, i.e. turning off the incubator, removing blankets etc.

3. Purpose

The purpose of this guideline is to provide recommendations for the initiation of passive cooling for infants who reach recommended criteria.

4. Scope

The guideline applies to:-

- All clinicians and nursing staff involved in the care of the neonate
- Southwest Neonatal Transfer Services who co-ordinate network transfers and cot space
- Southwest Neonatal Network – whose capacity of cots may be affected
- Parents and the neonate

5. Consent

Clinicians should always discuss the option of cooling treatment with parents and seek parental consent as soon as practically possible.

Details of all discussions with parents about their baby's treatment with cooling should be documented in the baby's notes according to Trust policies.

6. Inclusion Criteria for Cooling, (see appendix 1)

Initiation of cooling may begin prior to cerebral function monitoring.

Use of cerebral function monitoring can confirm suitability of infant for cooling or if a normal amplitude integrated EEG (aEEG) recording is found then the decision may be made to rewarm.

There should be consultant-to-consultant discussion of all infants who fall into the criteria for cooling with the tertiary unit. This should also include all those who fall just outside the criteria in whom there is a potential benefit of treatment.

The neonatal encephalopathy assessment should be documented and the details added to the HIE data form on Badger data base.

Document all conversations and rationale for decision-making.

7. Babies who fall just outside the criteria for cooling

Where babies fall just outside of the criteria for cooling a neonatal encephalopathy assessment should be documented on a daily basis for 5 days, (Appendix 2). The results of this should also be added to the HIE data form on Badger data base.

8. Exclusion Criteria for Cooling

Infants:-

- that are likely to require surgery in the first 3 days of life
- that have other abnormalities indicative of poor long term outcome

Cooling may not be appropriate if the infant has persisting extremely severe encephalopathy such that further treatment is likely to be futile.

Cooling may produce adverse respiratory or cardiovascular effects and should be used with caution in infants with an unstable respiratory or cardiovascular condition.

Cooling may not be beneficial for infants if started more than 6-8 hours after birth.

There is limited evidence to support treatment with cooling in infants less than 36 weeks gestational age or with other conditions such as postnatal collapse or cerebral infarction. Compassionate use of treatment with cooling outside the published protocols requires special arrangements for consent and explanation to the parents about the lack of evidence for safety and efficacy in these situations.

9. Equipment for Passive Cooling and Cerebral Function Monitoring (CFM)

(see CFM starter kits in CFM device basket, or cooling cupboard in the admission nursery)

- Sterile Philips rectal temperature probe
- Paper tape measure
- Lubricating gel agent
- Temperature monitor
- Cerebral function monitor, probes, hat, electrode glue

10. Procedure for Passive Cooling

Steps	Procedure for Passive Cooling
1	Perform neurological assessment once physiological stability is achieved
2	Check baby meets criteria A and B (see appendix 1) and document in clinical record sheet (appendix 2)
3	Check there are no contraindications for cooling
4	There should be consultant review and referral to level 3 unit and a management plan agreed.
5	Clinicians will discuss the treatment options with parents and consent is gained for cooling to be commenced and continued in a NICU.
6	Commence cooling as soon as possible after resuscitation and within 6 hours of birth prior to and including during transfer to a NICU (see appendix 3)
7	Discontinue all active-heat sources i.e. switch off overhead heaters, incubators, hot cots etc. Remove all covers. Nurse in open cot if possible, e.g. Giraffe incubator (open), Draeger baby Therm, Caleo incubator with lid removed, and ports open. If necessary a fan can be used, (use only with caution)
8	Discuss with Transport Service to arrange transfer.
9	The baby's age (in min/hours) at the time heating is turned off is documented as the time passive cooling started.

10	Use full monitoring, (including continuous monitoring of O ₂ sats, heart rate, BP, skin/rectal temp)
11	Pass lubricated rectal probe using measure to approx 5-6 cms and secure to thigh using a small piece of tape
12	Perform amplitude integrated EEG (aEEG) assessment using Cerebral Function Monitor (CFM). This should be commenced as soon as possible and ideally before any anti-convulsant therapy, (see manufacturer's instructions for use, using EEG glue to secure the needles). Record markers on the CFM when the baby receives any interventions
13	Reassess and document clinical observations every 30 mins:- <ul style="list-style-type: none"> ○ Check probe that it has not become dislodged ○ Record temperature readings every 15 mins, aim for rectal temp of 33-34⁰c by 6 hours of age ○ Document the age of the baby when it reaches the correct rectal temperature
14	Aim to keep (blood pressure) BP to > 45 mmHg, avoid hypotension.
15	Heart rate (HR) may slow by 14 bpm per degree of reduced temperature. Baseline heart rate may be 80bpm.
16	Ventilation - almost all infants who are cooled will require ventilation. Gases should be warmed and humidified as normal.
17	Monitor blood gases to guide ventilation requirements – Maintain normal pH. Always ensure the baby's rectal temperature is recorded on the blood gas analyser when using the analyser. Permissive hypercarbia is acceptable up to PaCO ₂ of 8
18	Insert central access (double lumen UVC and UAC) or other secure access if difficult/impossible
19	Treat seizures. In general, symptomatic seizures or frequent (>3/hr) subclinical (EEG) seizures will be treated with anticonvulsants. <i>Cooling may affect the metabolism of several drugs, including anticonvulsants and sedatives, and toxic drug levels may occur even with normal doses.</i>
20	Fluid management - as a guide start at 40 ml/kg/day. Infants may have renal impairment following severe asphyxia.
21	Sepsis - antibiotic therapy may be given if clinically indicated
22	Avoid stress (noise, light, excessive handling, pain etc)
23	Morphine for stress and sedation in ventilated babies. Chloral hydrate for stress in non-ventilated babies. Avoid muscle relaxants
24	Prepare for retrieval by transport team
25	If immediate retrieval to a cooling treatment centre is not possible e.g. due to lack of cots, passive cooling will be continued with guidance from the tertiary centre.
26	Complete datix form for unexpected admission of a term infant to SCU

11. If Cooling is Withdrawn

If cooling is not indicated or withdrawn then aim to rewarm at 0.5⁰c per hour over a period of at least 6 hours.

12. Long Term Outcome

Infants should be followed up regularly after discharge and a formal neurological examination and psychomotor assessment should be carried out at approximately 2 years of age.

13. Associated Documentation

[Admission of a baby to SCU guideline](#)

[Transfer of Neonates SOP](#)

[Seizures in Neonates guidelines](#)

[Neonatal Ventilation guidelines](#)

14. Standards / Key Performance Indicators

Key Performance indicators on which to base care in the Special Care Unit are:

- BAPM Position Statement on Therapeutic Cooling for Neonatal Encephalopathy
- Nice Neonatal Quality Standards
- NICE Therapeutic hypothermia with intracorporeal temperature monitoring for hypoxic perinatal brain injury
- NHS Toolkit for High Quality Neonatal Services
- National Neonatal Audit Programme
- NHS Standard Contract for Neonatal Critical Care

15. Monitoring Compliance with and the Effectiveness of the Guideline

- Staff are informed of revised documentation. There is an expectation that staff are responsible to keep updated on any improvements to practice and deliver care accordingly.
- Data on the number of infants with HIE and that require cooling is collected by use of Badger data base and can be used to generate output for clinical and operational benchmarking.

- All babies with significant HIE including those cooled will be subject to incident review both by the Trust and through the South West Neonatal Network governance group. Incidents and trends will be analysed and plans made to improve future practice and minimize further risk.
- Exception reporting occurs via the South West Neonatal Network.
- Non-adherence to guidance is reviewed and action plans made if required. Discussion and reviews occur at Directorate meetings, Governance meetings and Ward meetings. Learning and action plans are cascaded at these meetings and improvements implemented. Key findings and learning points will be disseminated to relevant staff.

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Appendix 1 – Inclusion Criteria for Cooling

Infants must meet criteria A and B to be eligible for cooling

A – Infants \geq36 weeks gestation admitted to the neonatal unit with at least one of the following:-
<ul style="list-style-type: none"> • apgar \leq 5 at 10 minutes after birth • continued need for resuscitation, including endotracheal tube or mask ventilation 10 minutes after birth • acidosis within 60 minutes of birth (defined as any pH $<$7.0 in umbilical cord or infant blood - arterial or capillary) • base deficit \geq 16mmol/L in umbilical cord or any sample (arterial, venous for capillary) within 60 minutes of birth <p>Infants that meet criteria A should be assessed for whether they meet the neurological abnormality entry criteria (B)</p>
B – Seizures or moderate to severe encephalopathy, consisting of:-
<ul style="list-style-type: none"> • Altered state of consciousness (reduced response to stimulation or absent response to stimulation) and • Abnormal tone (focal or general hypotonia, or flaccid) and • Abnormal primitive reflexes (weak or absent suck or Moro response)

Infants who meet criteria A and B may be considered for treatment with cooling. The consultant on-call must be informed about all eligible infants as soon as possible.

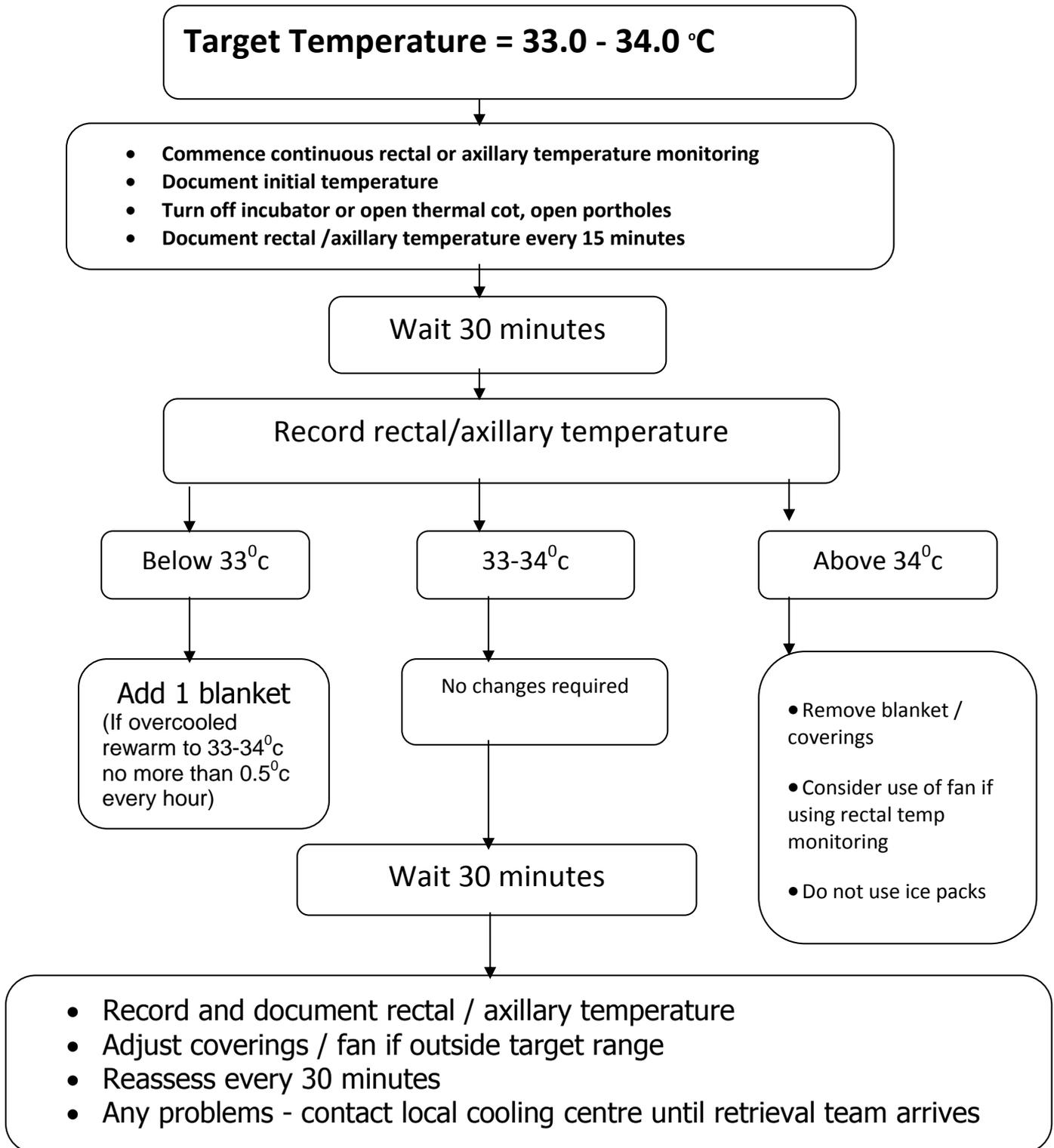
If an infant meets these criteria, but cooling is NOT offered, the reasons for this should be clearly documented in the medical notes. It is possible that this decision may need to be justified in the future, should litigation ensue for example

Appendix 2 – Clinical Record Sheet SCU Neurology Cooling Assessment .



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Appendix 3 – Passive Cooling Flowchart



Ice packs should not be used for cooling as these can result in severe hypothermia and skin damage.

Appendix 4 – Assessment and criteria for defining encephalopathy

The criteria for defining moderate and severe encephalopathy are listed in this table:

Parameter	Moderate Encephalopathy	Severe Encephalopathy
Level of consciousness	Reduced response to stimulation	Absent response to stimulation
Spontaneous Activity	Decreased Activity	No activity
Posture	Distal flexion, complete extension	Decerebrate
Tone	Hypotonia (focal or general)	Flaccid
Suck	Weak	Absent
Moro	Incomplete	Absent
Pupils	Constricted	Constricted
Heart rate	Bradycardia	Variable
Respiration	Periodic breathing	Apnoea

Encephalopathy score

The severity of encephalopathy should be assessed using the criteria in the table, but there is no specific score threshold that indicates treatment with cooling. This score should be recorded daily for the first five days after birth for all babies. All fields should be completed using the highest scoring option if a lower score cannot be elicited on examination (e.g. if ventilated and sedated).

Sign	0	1	2	3	Score
Tone	Normal	Hyper	Hypo	Flaccid	
LOC	Normal	Hyper alert, stare	Lethargic	Comatose	
Fits	None	Infrequent <3/day	Frequent >2/day		
Posture	Normal	Fisting, cycling	Strong distal flexion	Decerebrate	
Moro	Normal	Partial	Absent		
Grasp	Normal	Poor	Absent		
Suck	Normal	Poor	Absent / bites		
Respiration	Normal	Hyperventilation	Brief apnoea	Apnoeic	
Fontanelle	Normal	Full, not tense	Tense		