

Referral to St Mary's Hospital for Total Body Hypothermia

Following the recent completion of recruitment in the TOBY study, clinicians within the Greater Manchester Network may wish to refer babies with Hypoxic Ischaemic Encephalopathy for total body hypothermia. It is likely that the results of the TOBY study will not be available until 2009, however the combined data from other published studies of hypothermia look encouraging with improvements in survival and developmental outcome, particularly for infants with moderate HIE.

There does not currently appear to be an increased risk of death or disability associated with hypothermia, however the greatest benefit seems to follow treatment starting within 6 hours of birth. In view of this a decision will need to be taken at a very early stage if transfer for hypothermia is being considered. At present it is not possible to use a cooling mattress during transfer thus only infants within the Greater Manchester network will be eligible.

In this situation some clinicians may no longer feel in equipoise and may wish to refer infants for treatment. The TOBY study group has not recommended any course of action pending the results but has recognised that some clinicians may wish to treat infants with hypothermia. It has developed a register, analogous to the UK ECMO register, in order to maintain a body of information about infants treated since the study was closed to recruitment.

The Neonatal Medical Unit at St Mary's Hospital did join the TOBY study and has successfully treated several patients with hypothermia over recent months. It is proposed to offer this service for suitable infants born within or close to the Greater Manchester Network, where it is feasible for them to be transferred to St Mary's and commence the treatment within 6 hours of birth. It will remain within the discretion of the local neonatal consultant if they wish to refer infants for this treatment, however the guidelines below may assist clinicians in this decision.

In some instances clinicians may still wish to request a transfer to a level 3 or tertiary unit for intensive care management rather than specifically for hypothermia. These referrals will still be possible for infants that do not meet the eligibility criteria or after one hour of age but the normal referral processes will apply through the cot bureau and the infant will then be placed at the nearest appropriate neonatal unit.

Indications for referral

These indications for referral for hypothermia are largely based on the original TOBY study methodology. They have been simplified and adapted to take account of the need for very early decision making to facilitate transfer within 6 hours. In addition, there is now a consensus that if there are strong clinical features of moderate-severe HIE, an aEEG recording is not essential before commencing cooling. In cases where the clinical criteria are not definitive it may be possible for the transport service to undertake an aEEG at the referring hospital to clarify eligibility. An aEEG will not be routinely performed prior to transfer as this is likely to delay the transfer.

- Infants should be at least 36 weeks gestation and **60 mins age or less at referral**
- A neonatal cot and cooling mattress must be available at St Mary's Hospital
- The transport service must be able to undertake the transfer immediately
- There must be evidence of significant compromise at birth and evidence of moderate – severe hypoxic ischaemic encephalopathy (see below)

Evidence of significant Perinatal Asphyxia is defined as at least two of the following features:

- Cord pH or early blood gas (within first hour) showing metabolic acidosis with pH <7.0
- Significant ongoing resuscitation for at least 10 minutes at birth
- Ongoing ventilation is required at 10 minutes of age or on admission to the neonatal unit

Evidence of significant Hypoxic Ischaemic Encephalopathy is defined as one of the following:

- Clinical evidence of moderate to severe encephalopathy within first hour of life (Reduced conscious level or activity, hypotonia, seizures, apnoeas, baseline bradycardia)
- An abnormal amplitude integrated EEG recording*

* The aEEG machine may be brought by the transport team to the referring hospital and recordings undertaken where the clinical features of HIE are definitive but the patient is otherwise eligible. This will depend on the availability of staff to interpret the recordings and sufficient time to enable a transfer within 6 hours.

Exclusions

- There should be no major malformations which might threaten survival or cause longterm neurological problems
- There should be no immediate need for a surgical procedure
- The infant should not be moribund (e.g requiring ongoing full resuscitation) or appear too unstable for transfer within the 6 hour time frame.
- Infant is born at a hospital estimated at more than 1 hours travelling time from St Mary's.

Management

Referrals should be made in the usual way by telephoning the cot bureau on 0161 276 8847 within 60 minutes of birth. The checklist attached will be completed by the cot bureau and transport team when a referral is made for cooling. The final decision to transfer will be made by the accepting consultant Neonatologist at St Mary's Hospital.

Once a decision has been made that the infant is eligible for total body hypothermia and a cot has been confirmed at St Mary's Hospital, it may be

helpful to begin reducing the body temperature slightly by turning off the incubator and certainly to avoid overheating.

The transport team will also transport the infant with the heater turned off but will only commence formal cooling with the tecotherm cooling mattress on arrival at St Marys. The cooling mattress will then be used in conjunction with the rectal temperature probe, aiming for a core temperature of 33 – 34 centigrade.

Otherwise normal general intensive care management will be employed with the aim of maintaining normal blood gases, glucose levels and blood pressure. Maintenance fluid therapy will be commenced at 40-60 mls/kg/day. Overt clinical seizures may require anticonvulsant therapy if prolonged or frequent in nature. More details of the management of the infant are available within the clinicians handbook.

Infants who are cooled will be entered into the TOBY register – the parents will be approached for consent to provide this data following transfer to St Marys. A parent information sheet is also available and this should be used by the referring clinicians, however assent rather than formal written consent will be required for the transfer and use of hypothermia itself.

Hypothermia Referral Checklist

Section 1

Infants Name

Date of birth

Time of birth

Date of referral

Time of referral

Referring Hospital

Section 2 - Referral

Age <60 minutes, Gestation 36 weeks+

Greater Manchester Unit / journey within 1 hour

Neonatal Cot and cooling mattress available

Transport team available

**If all of above are true proceed to Section 3
Otherwise baby is not eligible for cooling**

Section 3 – Evidence of Perinatal Asphyxia

Cord gas **or** Blood gas within 60 mins showing metabolic acidosis with pH <7.0

Requiring resuscitation at 10 mins age

Ventilated at 10 mins or on admission

If two of the above are true, proceed to Section 4

Otherwise baby is not eligible for cooling

Section 4 – Evidence of seizures or encephalopathy

Clinical evidence of encephalopathy:

Seizure activity

Reduced conscious level or coma

Absent or reduced spontaneous movements

Hypotonia

Apnoeas

Baseline bradycardia

If one or more of the above are true, infant is eligible for cooling. If clinical features are indeterminate with strong evidence of Perinatal asphyxia consider aEEG recording at local unit.