Commercial umbilical cord blood collection at UHL

University Hospitals of Leicester NHS
NHS Trust

Trust ref: C38/2020

1. Introduction and Who Guideline applies to

This Guideline applies to all UHL staff involved in the process of supporting commercial umbilical cord blood collection in the maternity service. This guideline should be used, where appropriate, in conjunction with the Human Tissue Authority (HTA) website.

The subject of non-clinical (by private companies) stem cell collection is sometimes requested at University Hospitals of Leicester and has been debated at length within the Trust and in conjunction with the Royal College of Obstetricians and Royal College of Midwives. It is important to distinguish between medically indicated and commercial umbilical cord blood collection for stem cell harvesting, the latter being for profit. Cord blood may be collected and stored through private blood banks or through the NHS Cord Blood Bank (NHSBT Colindale). UHL is already one of the few trusts in the UK supporting the Anthony Nolan charity in harvesting stem cells for clinical and research use.

Private facilities enable donors to store their cord blood so that if a member of their family becomes sick with a stem cell treatable disease it may provide a perfectly matched unit for their use, or if their child develops such a condition it could be treated with their own cord blood. For this service they charge a collection fee and a yearly rate for on-going storage of the cord blood unit.

The NHS Cord Blood Bank collects cord blood free of charge from the donor and stores it indefinitely for possible transplant. The stored unit is available for any patient that needs this particular special tissue type. The original donor may use it providing it has not already been used for another patient.

Related UHL documents:

Intrapartum Care and Fetal Heart Rate Monitoring in Labour UHL Obstetric Guideline

Umbilical Cord Clamping UHL Neonatal Guideline

2. Regulation and types of cord blood donation

The Human Tissue Authority (HTA) regulates the procurement of cord blood in the UK under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). Since 5th July 2008, any person collecting cord blood must be acting under the authority of an HTA license, or, where appropriate, a Third Party Agreement (TPA) with an HTA-licensed establishment. In addition, those collecting cord blood must be appropriately trained to ensure the collection takes place safely and that the sample is not contaminated inadvertently and is safe to use.

Collections have been undertaken from umbilical cord blood by NHS facilities within the National Blood Service largely through research and development funding. Women donate cord bloods to the Cord Blood Banks altruistically for transplantation in a similar way to bone marrow donors.

2.1 Directed donation in at risk families

Some transplant centres currently recommend Cord Blood Collection and storage for siblings born into a family where there is a known genetic disease amenable for HSC transplantation. Such donations are normally initiated by the clinician caring for the sick potential recipient making appropriate arrangements for the Blood Service and Cord Blood Bank.

2.2 Commercial stem cell collection

Practice of commercial umbilical cord blood collection and stem cell harvesting is already popular in the United States, where many parents see it as insurance against any future health problems their children may develop or "storing a spare immune system" for their children.

2.3 Dealing with requests antenatally

Trust staff should not get involved in arranging cord blood procurement but should refer the parents to the HTA website **http://www.hta.gov.uk** where details of licensed establishments can be found, or to the NHS cord blood bank website **http://cord.blood.co.uk**.

Parents requesting cord blood procurement can be directed to find a licensed company to act for them in collecting their baby's cord blood and storing their baby's stem cells. The licensed establishment then requests in writing to the Trust to allow the licensed establishment to attend to procure cord blood for the woman and her partner. This request must occur at least 2 weeks in advance of the intended collection and be addressed to the head of midwifery. The company will be given the guideline for Cord Blood procurement which is then returned to the Trust with a copy of the woman's consent form agreed and signed with the company.

The Matron for the area in which the woman intends to birth will ensure that the documents are stored within the woman's maternity notes. Once the request for stem cell collection has been received the relevant Matron will check the HTA website that the establishment is licensed and to ensure the form is completed correctly.

Permission to procure cord blood will only be granted if the establishment is licensed, all fields in the application form are complete and a copy of the signed consent form has been received from the licensed establishment. The relevant Matron signs the application form to authorise the procedure and the completed form is filed in the mother's medical records. The mother's birth plan should include the plan for cord blood collection.

2.4 Process for collection of cord blood

Procurement may only be undertaken by staff from the licensed establishment or their nominated third party. University Hospitals of Leicester trust staff must not take part in the procurement.

The parents are responsible for informing the nominated phlebotomist when labour commences, and keeping her/him updated as to the progress of labour. The phlebotomist should aim to arrive - approximately 1-2 hours before delivery.

On arrival the phlebotomist should show their identification to the midwife in charge, they should then be shown to a suitable area for taking the cord blood where s/he will not impede clinical staff.

S/he will require a clean room with a clean, flat surface on which to work and hand washing facilities. Relevant PPE should be provided by the company. A sharps box and placenta disposal bag should be provided. S/he will carry out a risk assessment to confirm that the environment meets the above criteria.

The most senior midwife present checks the identity of the phlebotomist. She checks that the risk assessment has been undertaken.

Management of labour and delivery should take place as normal, taking care not to exsanguinate the cord. In a clinical emergency, resuscitation of the mother and baby take priority. This may also include the need to take cord gases.

The placenta is handed to the phlebotomist outside the delivery room.

The phlebotomist completes the Procurement Record Sheet (as supplied by the company) which is copied to the Matron for updating the database, and the original filed in the mothers medical record.

The phlebotomist gives the sample to the parents. It is their responsibility to phone the courier to collect the sample and to hand it over to the courier. The sample may be kept at room temperature whilst awaiting collection.

The parents should be aware that sample contamination, e.g. with Group B streptococcus, can occur despite the best practices of a phlebotomist.

3. Education and Training

None

4. Monitoring Compliance

None

5. Supporting References

None

6. Key Words

Cord blood blank, Stem cell

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) **Fiona Ford** – Maternity Matron	**Executive Lead** Chief Medical Officer
Details of Changes made during review: **March 2023** No changes	