Clinical Guideline for: The Management of Commercial Umbilical Cord Blood Collection Following Birth

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By:	All staff
For:	Pregnant Women
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5	30/07/2020	Placental collection and third part agreement added	Charles Bircher, Carmel Sayer

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Document Summary

This document outlines guidance concerning requests from prospective parents for the collection of umbilical cord blood for commercial storage to enable possible future stem cell retrieval.

These guidelines do **not** apply to:

- The collection of cord blood for immediate therapeutic activity e.g. blood gas checks during or immediately following delivery; or
- The non-directed or altruistic cord blood banking service undertaken within the National Blood Service; or
- The collection of cord blood where procurement has been requested for medical purposes by a tertiary hospital/unit. In such a circumstance collection may be permitted under that unit's Human Tissue Authority (HTA) licence but these cases are rare and advice should be sought from the Trust's Legal Services Department.

Background

A number of commercial organisations offer parents the opportunity to store haemopoietic stem cells (HSC) from their baby's umbilical cord blood. The purpose of this storage is that the stem cells might be available for use if the child or his/her siblings ever develop a metabolic, immunological or haematological disease that might be treated by autologous or related cord blood stem cell transplantation. The therapeutic use of stem cells of this kind is still speculative and directed stem cell storage is not recommended by professional guidance[1]. Even so, some parents may wish to avail themselves of the commercial services that are now widely advertised.

Under the Human Tissue Act 2004, directions have been issued known as the Human Tissue (Quality and Safety for Human Application) Regulations 2007. These Regulations require that the procurement of cells and tissues for human treatment (including umbilical cord blood stem cells), must take place only on premises licensed by the HTA or under what is known as a Third Party Agreement (TPA) with a licence-holder.

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This Trust does not hold a HTA license for the collection of cord blood and there is no plan to apply for one. Furthermore the Trust (following professional guidance) does not intend to contract under a TPA for its staff to take cord blood for commercial storage.

Collection of cord blood for commercial storage can therefore only take place in the Trust if the procedures set out at Section 4 below are followed. Commercial umbilical cord blood collection outside those procedures must not be carried out by Trust staff. In the past some staff have obtained cord blood for parents who have requested this. **This is unlawful and a disciplinary offence and may lead to enforcement action by the Human Tissue Authority. This does extend to patients and relatives.**

Placental collection

There may be times when the Trust is unable to support commercial companies visiting the unit to undertake collection of blood for stem cell. This would be at times of restricted visits such as the Covid -19 pandemic when NHSBT and Anthony Nolan Trust stopped visiting units. In situations such as these the commercial companies are able to extract the stem cells from the placenta and this must be undertaken outside of the hospital. The parents are responsible for transporting the placenta off site to the company, the midwifery staff are able to assist with placing the placenta into a sealed bag (see appendix 1). In this instance it is necessary to have a TPA (third party agreement) with the Trust for this. This agreement is also in the appendix 2.

Aims and Objectives

Midwives and medical staff may be approached by parents who request that their baby's cord blood be collected at the time of delivery and stored commercially for later stem cell retrieval. The aim of this document is to enable staff to provide appropriate information in response to such requests, in particular:

- To explain to parents why (in line with national guidance) the Trust does not support commercial stem cell retrieval;
- To inform parents that without a licence from the HTA the Trust is prohibited from performing this procedure;
- To advise that the Trust will not hinder parents who make their own private arrangements with an appropriate third party collection agency, so long as those arrangements comply with the requirements of the HTA and professional guidance (as per section 4 below).

Umbilical Cord Blood Procurement for Stem Cell Guidance for Staff

Women who want to make arrangements for the collection of cord blood may only do this on the Trust's premises if they comply with the necessary regulatory obligations. They must:

- Provide the Trust with written confirmation in advance, to the Delivery Suite or Midwife Lead Birth Unit Matron (depending on planned place of delivery), that the commercial company with whom they have made a private arrangement holds a valid HTA licence; and

- Confirm they have made arrangements for a phlebotomist or trained technician from the commercial company to obtain the sample or confirm that the person to take the blood has a TPA with the commercial company. The application to the head of midwifery and subsequent correspondence should be copied to the Trust's le.g.al services, where a register is kept.

Further in order to comply with guidance from the Royal College of Obstetricians and Gynaecologists (RCOG) and to maximise safety for mother, baby and staff:

- Intended collection of cord blood should not proceed where the attending clinician believes it to be contraindicated, such as nuchal cord or maternal haemorrhage
- Usual clinical practice should take precedence over elective cord blood collection e.g. there should be no pressure on clinical staff to avoid cutting the cord to allow delivery (e.g. where the cord is around the neck) and taking of umbilical blood samples for blood gas status should not be delayed
- Collection of cord blood should be made from the ex-utero separated placenta i.e. blood must not be taken while staff are attempting to deliver the placenta
- There should be no alteration or delay in the 'usual management' of the third stage e.g. controlled cord traction should not be withheld in the presence of post-partum haemorrhage in an attempt to maximise the volume collected with the placenta still in utero
- The person intending to take the blood must agree to abide by the Trust's health and safety policies and to take responsibility for the safe disposal of any needles/sharps.

Women should be advised of the position on stem cell retrieval, **if the issue is raised with Trust staff. Staff may print and give one of the web links** at the end of this guideline.

An example of good practice quoted by the RCOG is that used by the NHS Cord Blood Bank, where cord blood is collected aseptically after delivery of the placenta by trained NBS staff within the delivery unit but outside the delivery room. This ensures privacy for the mother and removes any conflict between collection of cord blood and care of the mother and baby.

Why doesn't the Trust apply for a licence from the HTA?

The Trust's position in relation to this procedure as set out in this Guidance is based on recommendations of the Royal College of Midwives (RCM), RCOG, and the National Health Service Litigation Authority (NHSLA). Guidance from the RCOG, RCM, and NHSLA does not support commercial collection of umbilical cord blood for the purpose of retrieving and storing stem cells when there is insufficient scientific evidence to support this practice

The rational behind the Trust's decision not to apply for a licence for cord blood procurement includes:

- This commercial collection is not supported by professional guidance as evidence based practice;
- The collection is made at a point when both mother and the new-born baby require close attention. Attempting collection could distract the attention of staff from their primary purpose of providing appropriate care for mother and baby;
- There is financial and bureaucratic cost associated with the licence that cannot be justified by the scientific evidence base or professional guidance.

Training and Dissemination

A copy of this Guideline will be widely distributed throughout the relevant clinical areas. It will also be available on the Trust Intranet. Relevant staff will be alerted to the Guideline's introduction through the O&G Department Risk Management Committee and regular O&G Risk Management Newsletter.

References

Cells4life https://cells4life.com/?gclid=EAIaIQobChMIoojqit2k6wIVBrDtCh3pewhVEAAYASAAE.g.Kc6_D_BwE

Human Tissue Authority - Cord blood procurement FAQ's: http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/tissueandcellsforpatienttreatment/cordbloodprocurementfaqs.cfm

Human Tissue Authority – Position Statement on Cord Blood Collection (March 2010); www.hta.gov.uk

Human Tissue Authority – Cord Blood Collection – FAQs for parents: http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/tissueandcellsforpatienttreatment/cordbloodcollectionfaqsforparents.cfm

RCOG (2006) *The Royal College of Obstetricians and Gynaecologists Scientific Advisory Committee*, Opinion paper 2: Umbilical Cord Blood Banking June 2006

RCOG Cord Blood Banking: information for parents http://www.rcog.org.uk/womens-health/clinical-guidance/cord-blood-banking-information-parents

RCM (2002) The Royal College of Midwives Position Statement No 1 2002
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Appendix 1

Appendix 2