

BE A
MATCH
SAVE
A LIFE

Ethics and Consent Cord Blood Donation
BBTS 30th Annual Conference, Harrogate

ANTHONY
NOLAN
BE A MATCH, SAVE A LIFE

Ethics and Consent Umbilical Cord Blood Donation

Linda Moss – Midwife Supervisor Cord
Blood Programme UHL

Introduction

- Overview of cord blood
- Anthony Nolan Programme
- HTA Legislation
- Consent issues

What's so great about Cord Blood

- Approximately 100-200mls blood left in the placenta and cord once it's been clamped and cut following a baby's birth
- Rich in stem cells, which contribute to the body's ability to create new cells to repair and renew it's damaged blood or tissue
- Normally thrown away
- Recycling of the very best kind!



Overview– Cord Blood (CB)

25,000 Clinical
Transplants to date

Accounts for over
15% of all annual
unrelated donor stem
cell transplants

Allogeneic Use from
HLA matched donors

Used to treat a wide
variety of malignant
and non-malignant
conditions. Primarily
acute leukaemias



Global Network of
public banks with
inventory in region of
500,000 CB units

On-going research
into CB use for wide
variety of
degenerative
conditions

Cord Blood Advantages & Challenges as a Stem Cell Source

Advantages

- Ease of Access
- Immediate Use
- Long Storage potential
- Tested for IDM's and HLA
- Tolerance for HLA mismatch
- No ethical issues
- Donor Safety
- Long term cost benefit

Challenges

- Delayed engraftment
- Cell dose
- Conditioning Regime
- Initial cost
- Regulation
- Standardisation of Quality standards
- Confused perceptions of public v private banking

Anthony Nolan Cord Blood Bank – Model of Collection & Operation

- Five fixed collection sites at major UK maternity hospitals operating under collaborative TPA



Anthony Nolan Cord Blood Bank – Model of Collection & Operation

- Trained dedicated collecting staff and supervising midwife fully integrated into hospital maternity team
- Full informed consent obtained from expectant mothers in accordance with the Human Tissue Act 2004, the Human Tissue Regulations 2007 and the HTA's Code of Practice
- The collection of cord blood does not interfere with usual care provided in labour and birth and is performed ex utero in dedicated collection areas using aseptic technique

Human Tissue Authority Regulation

- **SAFETY:** HTA regulation ensures that the cord blood is collected in a way that minimises the risk to mother and child. This is why collection must be carried out by a properly trained professional and on appropriate premises.
- **QUALITY:** HTA regulation ensures that the best quality samples are taken. It also means that samples are traceable; so should there be a problem the cells can be traced to other batches.
- **CONSENT:** HTA regulation means consent must be given by the mother for cord blood to be taken. Risks, benefits and options must be explained to the parents so that informed consent can be given.
- **LAWFUL:** Activities involving the collection, testing, processing, storage, distribution or import / export of cord blood must take place under the authority of an HTA licence or where appropriate, a third party agreement with an HTA-licensed establishment.
- (Ref to the HTA website for further information)

Anthony Nolan Cord Blood Programme

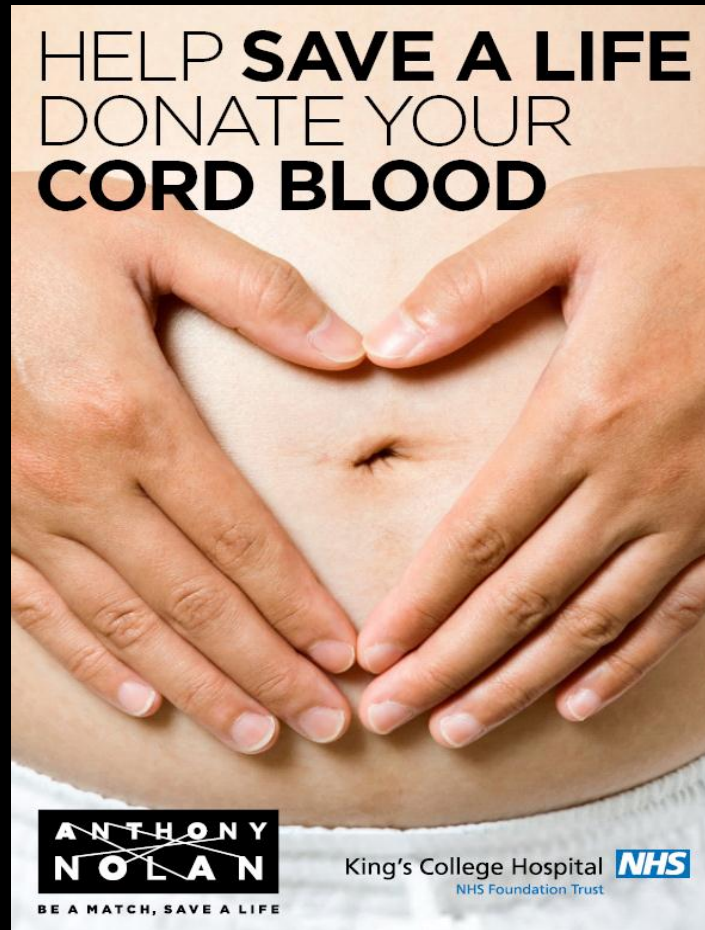


Consent

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Information Leaflet



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Sticker and pre-consent Form


ANTHONY NOLAN CORD BLOOD DONATION PROGRAMME

Did you know that following the safe birth of your baby, you could save a person's life just by donating its umbilical cord? The blood from your baby's placenta and cord is rich in stem cells. We can use these in stem cell transplants to help people with leukaemia and other serious blood disorders. For someone who needs a transplant, it's often their last chance at life.

The stem cells in cord blood have the potential to save countless lives. Anthony Nolan's cord blood programme is a pioneering initiative to collect and bank stem cells from donated umbilical cords.

Cathy received her life-saving cord blood donation through the work of Anthony Nolan.

Anthony Nolan finds matches for people with blood cancers such as leukaemia who need a lifesaving transplant. For someone with leukaemia, a bone marrow transplant can be their only hope of life. We use our register, cord blood bank and research to find remarkable people who can give them that hope by donating their stem cells. By doing this, we save lives. Every day.



HOW DO I TAKE PART?

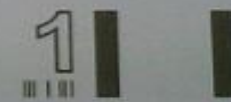
Please follow these simple steps:

- 1 Peel off the attached Pre-Consent sticker and stick this to the front of your medical notes. This helps us to identify you as a cord donor when you come on to the maternity ward.
- 2 Complete and return the attached form on this leaflet. Alternatively you can fill in our online form at www.anthonynolan.org/cordblood.
- 3 If you want to ask further questions before completing the form please call us on 0303 303 0303 or email UHL.Cord@anthonynolan.org. Further information can be found at www.anthonynolan.org/cordbloodfaq and at www.hta.gov.uk.

Once we receive your completed form we will contact you to discuss any questions you may have. We'll then arrange an appointment for your formal consent. The sticker on this leaflet gives you the option of 'pre-consent'. If you stick it on the front of your medical notes, it shows you intend to donate. Ideally we will arrange a meeting to take your formal consent before your labour starts. If this isn't possible, the sticker on your notes gives us permission to collect your baby's cord blood. We'll then complete the formal consent process with you following your baby's birth, before processing your donation.

PRE-CONSENT ANTHONY NOLAN CORD BLOOD DONATION PROGRAMME

Please peel off and stick to the front of your medical notes.



Freepost Plus RSJZ-CRER-LYKE
Anthony Nolan Cord Collection UHL
Maternity Unit
Leicester General Hospital
Gwendolen Road
LEICESTER
LE5 4PW

Formal Consent

- Verbal explanation following a HTA compliant script
- Consent form (triplicate)
- Screening form
- Family questionnaire
- Demographic form
- Stickers and written entry in maternity records
- Reaffirmation of consent

Collection



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Transport daily

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Consent Issues

- Eligibility
- Access to women limited pre labour
- Language
- Religion and cultural beliefs
- Research programme
- Maternal blood tests
- Capacity
- Paperwork
- Ownership



TIME FOR Questions