

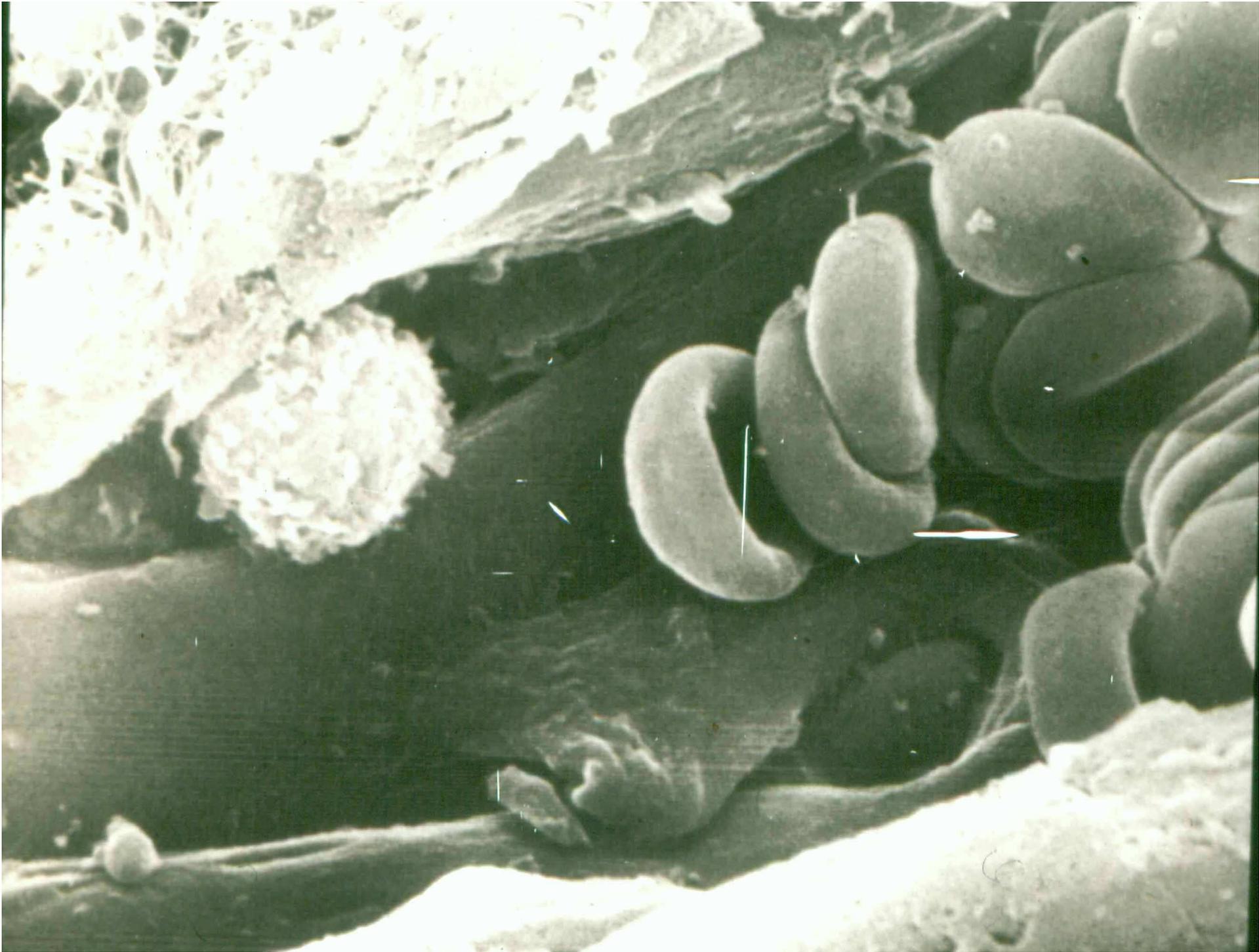


# CORD BLOOD BANKING

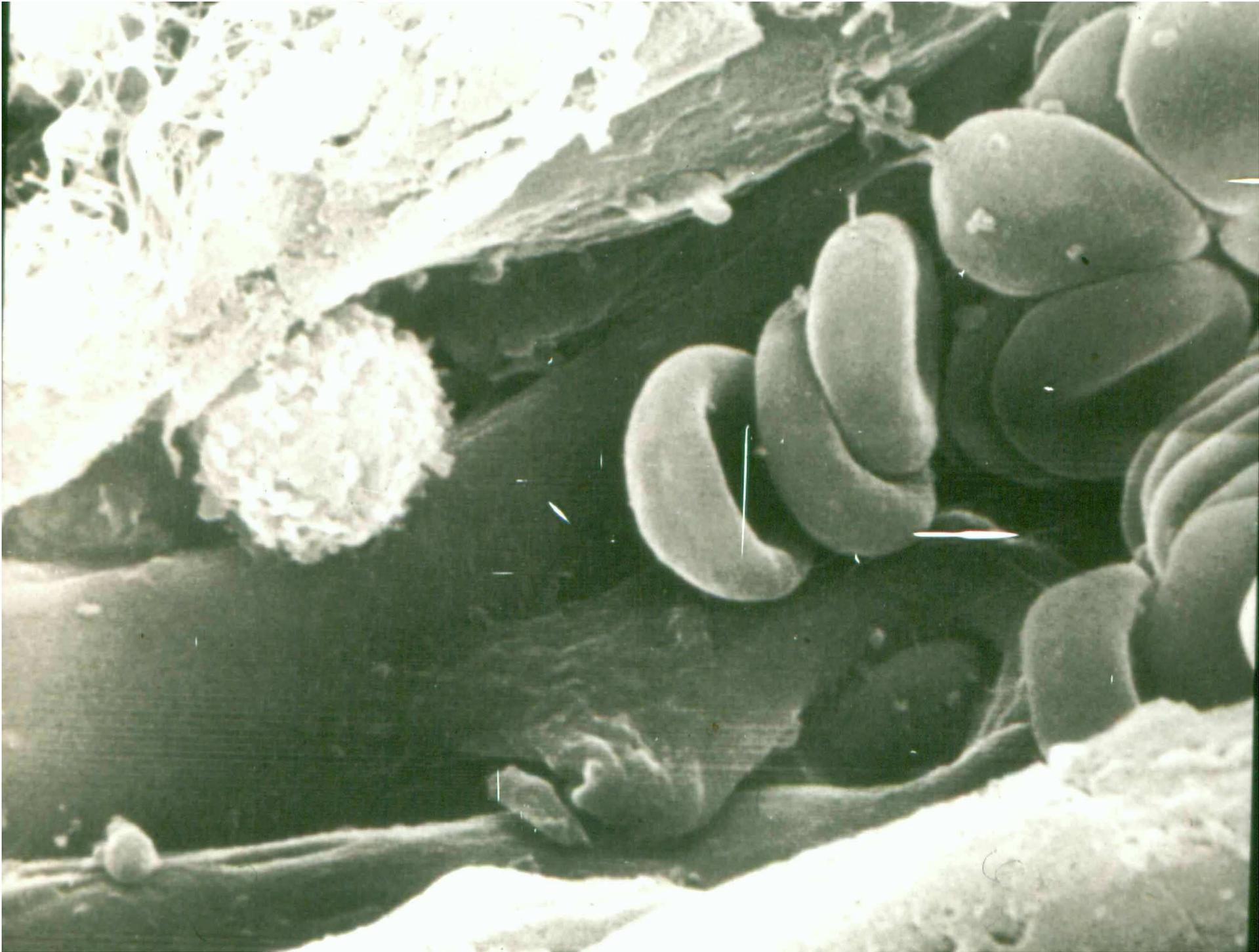
Vietnam 2011

*The European Group for Blood and Marrow Transplantation*









## The Charitable Way

The ANTHONY  
NOLAN Trust  *Taking back lives from leukaemia*



(LON-11) LONDON, Dec. 20 (AP) Mrs. Nolan, right, of Australia, campaigning with friends in Downing Street here today just before the arrival of Australian Prime Minister Gough Whitlam. She is trying to get British and Australian Government aid to help cure her son, Anthony, who is suffering from a rare bone disease. Mrs. Nolan has also started an Anthony Nolan Appeal Fund to assist Westminster Hospital to treat all child sufferers of blood and bone marrow diseases. (AP CABLEPHOTO)





# CORD BLOOD APPROACH

- Today global network of public cord blood banks - 500,000 cord blood units.
- Nearly 30,000 transplants reported to WMDA to date
- 2009 cord blood became second most common source of transplant stem cells.
- Clinical trials using UCB Stem Cells
  - - wide variety of conditions including stroke, spinal injuries, cerebral palsy and a wide variety of other degenerative conditions.

# The Anthony Nolan Cord Blood Programme

Register



Cell Pharmacy

Cord Blood Bank

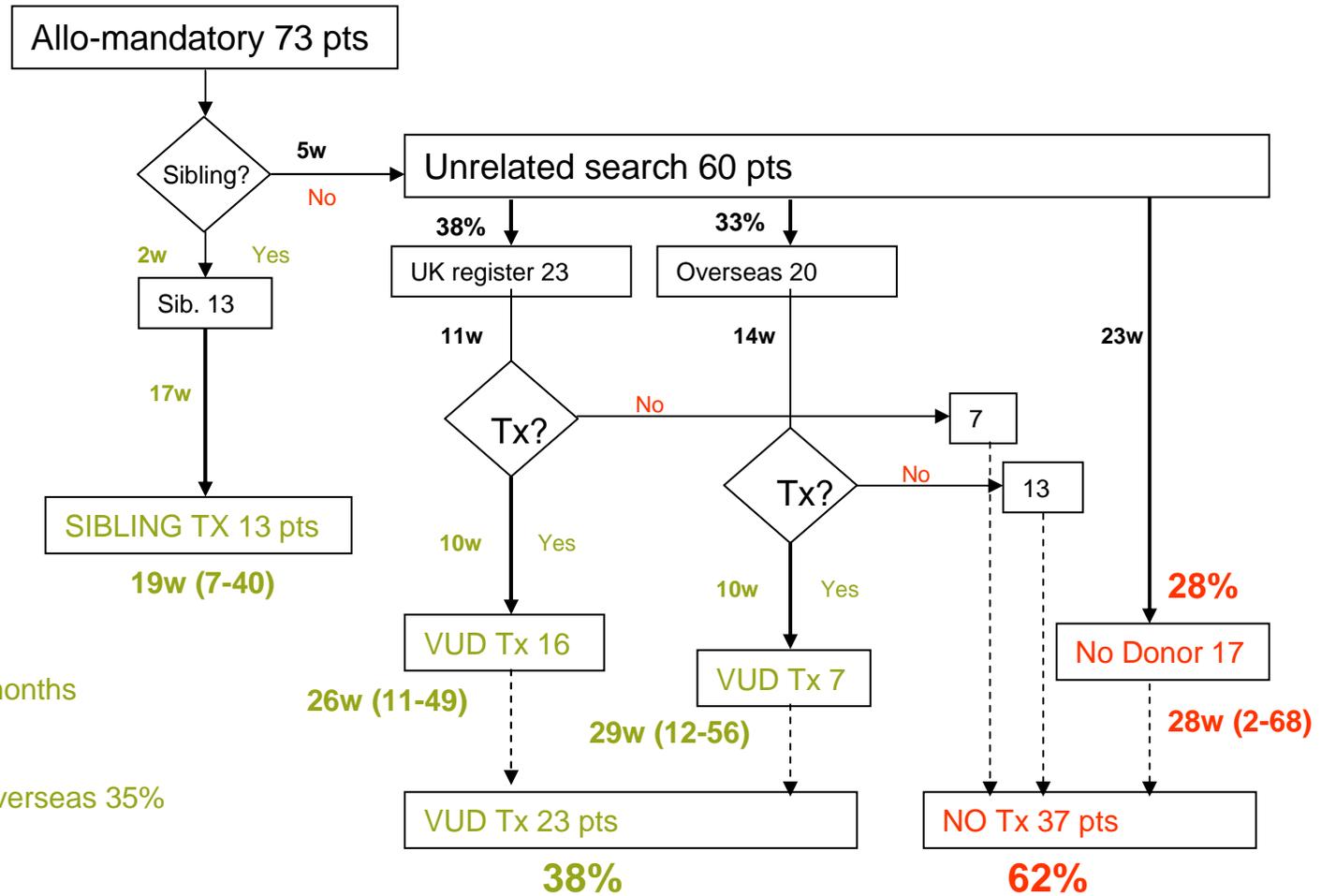
Cord Blood Pharm

FIT FOR THE FUTURE  
Name of meeting here

**ANTHONY  
NOLAN**  
BE A MATCH, SAVE A LIFE

# **Why Cord Blood?**

# SOME PATIENTS DO NOT HAVE SUITABLE ADULT DONORS



- Estimated time delay: 2 months
- Access failure: 28%
- UK self-sufficiency: 38%
- Efficiency: UK 70% vs. Overseas 35%
- Total allo-therapies: 38%

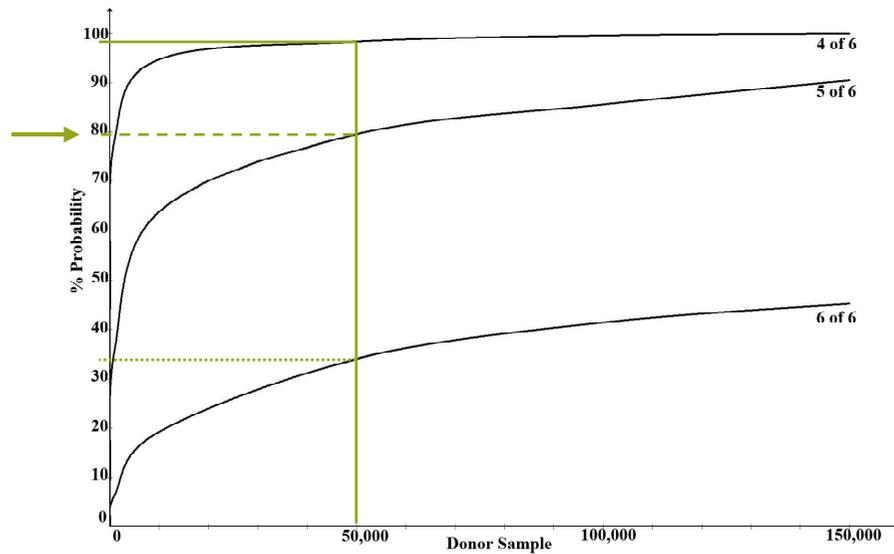
# CORD BLOOD PROS AND CONS

- Advantages:
  - Donor safety/attrition
  - ‘Off-the-shelf’= time
  - Reduced match stringency= equitable access
  - Long-term Sustainability
- Disadvantages:
  - (Speed) Engraftment
  - DLI

How many Cord blood Units we need to store?

# SIZE FOR UK

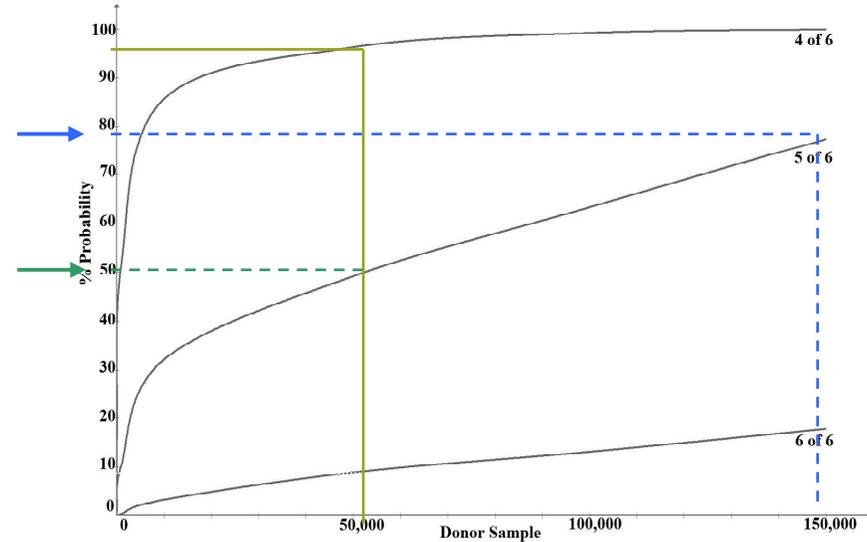
Probability to find a least 1 HLA-A,B low and DRB1 high match



All patients

2,000

80% chance for 5/6 (50% non-predominant)  
 ≈ 50,000



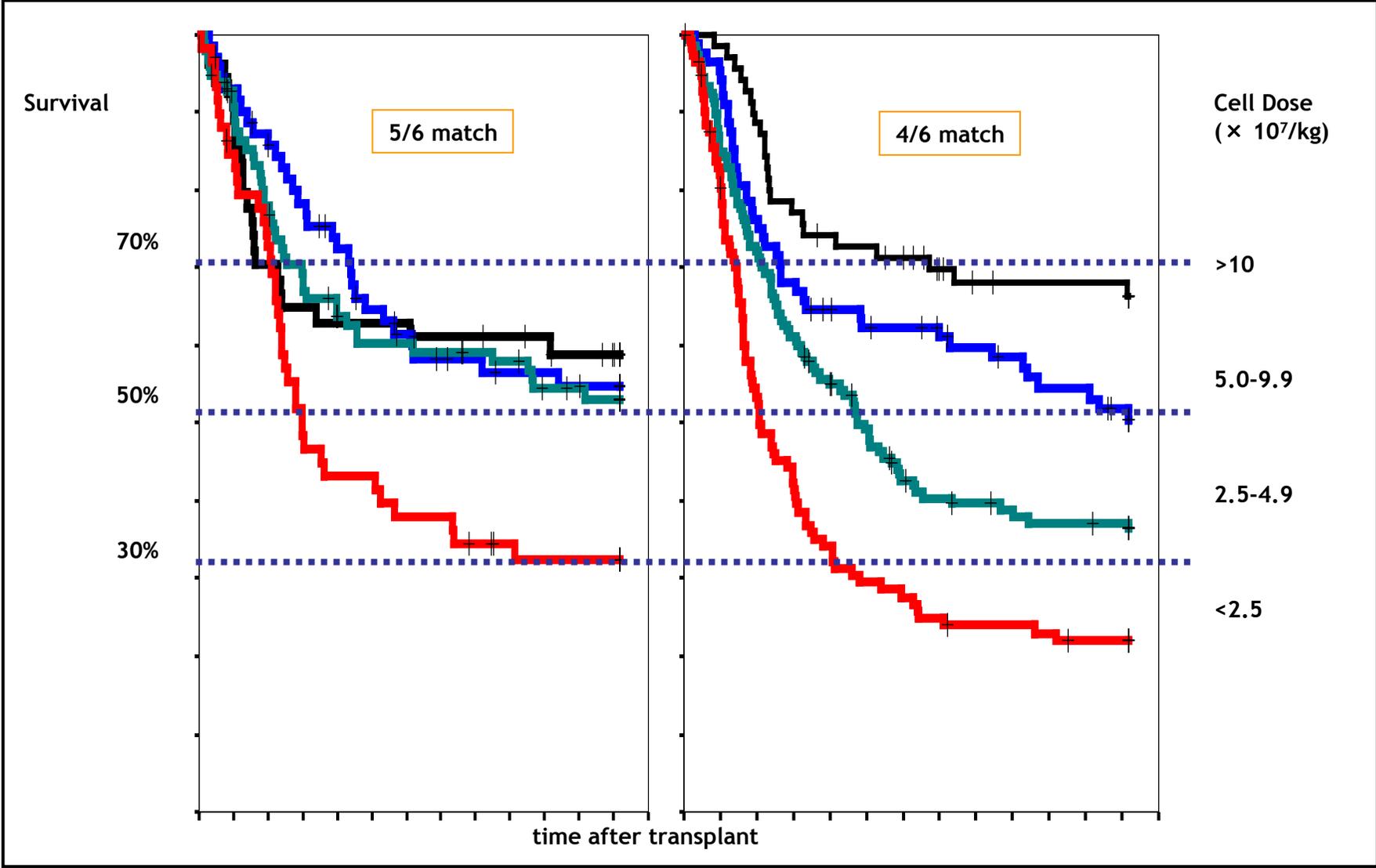
Non north western european patients

722

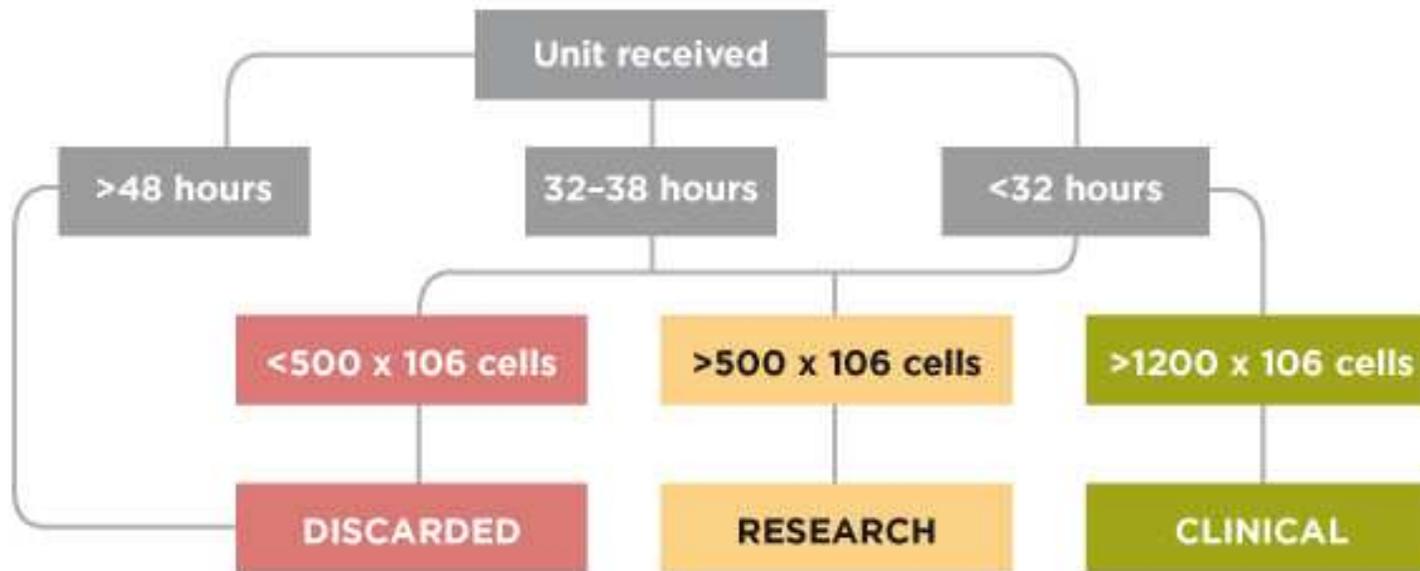
Raise to 80% chance for 5/6 to non-predominant  
 ≈ 150,000

Against 150,000 Anthony Nolan Donors

Querol S, Mufti GJ, Marsh SG, Pagliuca A, Little AM, Shaw BE, Jeffery R, Garcia J, Goldman JM, Madrigal JA. Cord blood stem cells for hematopoietic stem cell transplantation in the UK: how big should the bank be? Haematologica. 2009, 94(4):536-41



# DECISION FLOW CHART



# DOSE

- Preference of bigger units make obsolete many units stored in the cord blood banks (internal competition)
- Prospective thresholds could raise until a level that makes new units highly competitive:
  - NC12x10<sup>8</sup> and CD34 4x10<sup>6</sup>
- Unfortunately, this makes necessary large collection programmes that are highly inefficient (up to 80% of units are discarded)

# COLLECTION



# COLLECTION



- Raised platform
- Adapted shelf
- Hole for specially adapted bowl
- Paperwork holder
- Wheels for manoeuvrability

# COLLECTION



- Place the placenta in adapted bowl
- Pull cord through and hang

# COLLECTION



- Clean the cord with sterile solution and sterile swabs
- Reduces risk of cross contamination

# COLLECTION



- Insert cannula
- Close to birth clamp to maximise collection
- PATIENCE!!!

# COLLECTION



- **DRAINED!!**

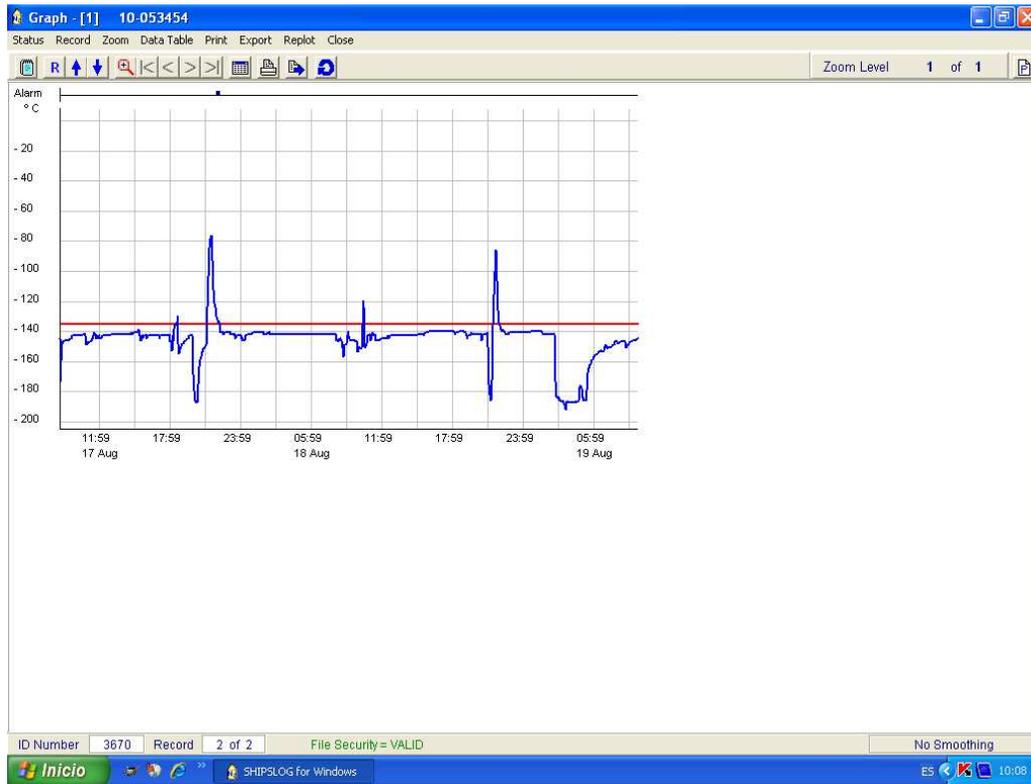
# COLLECTION

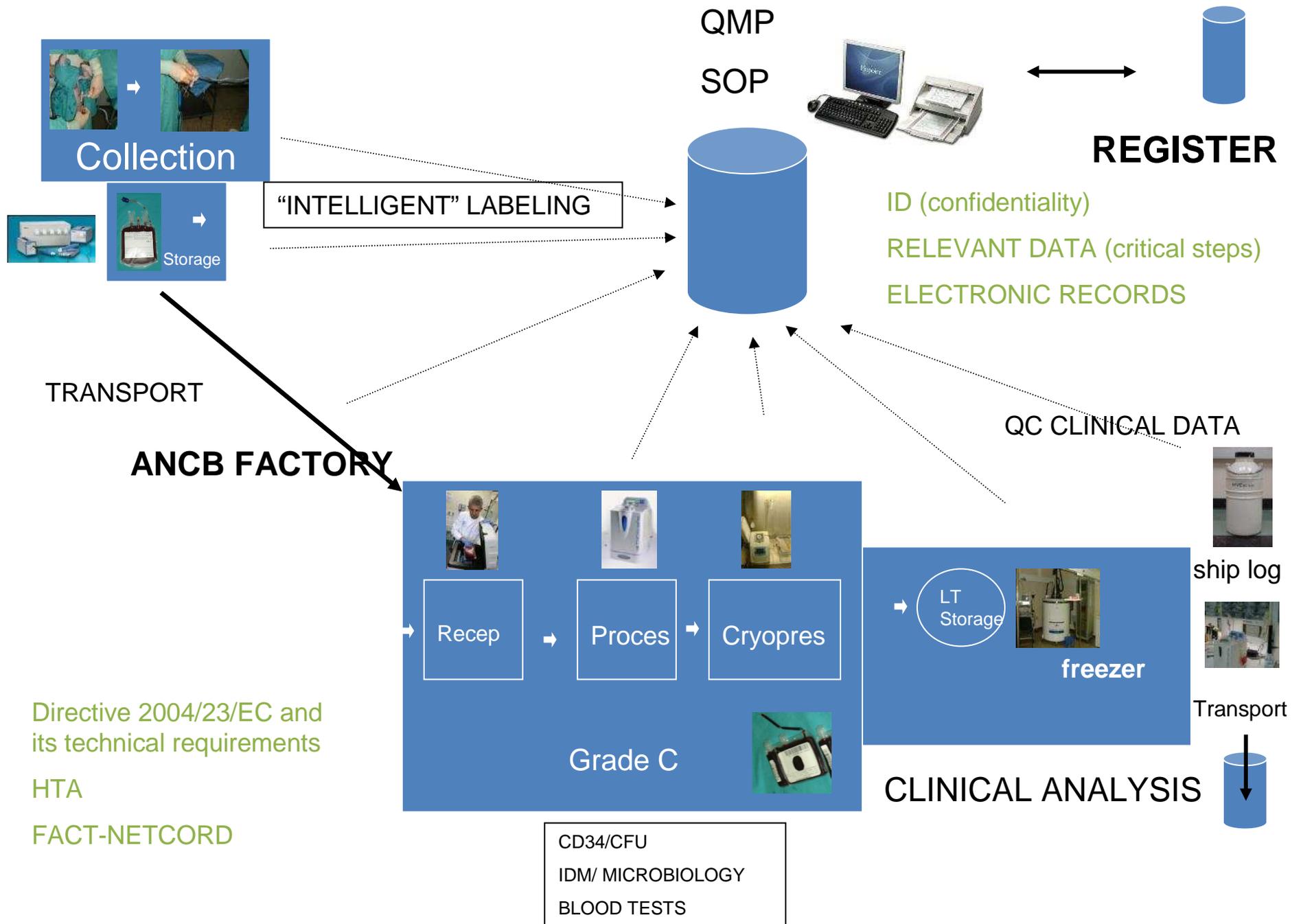


- Life saving cord blood

i.e. Transport issues

MVE IATA Shipper



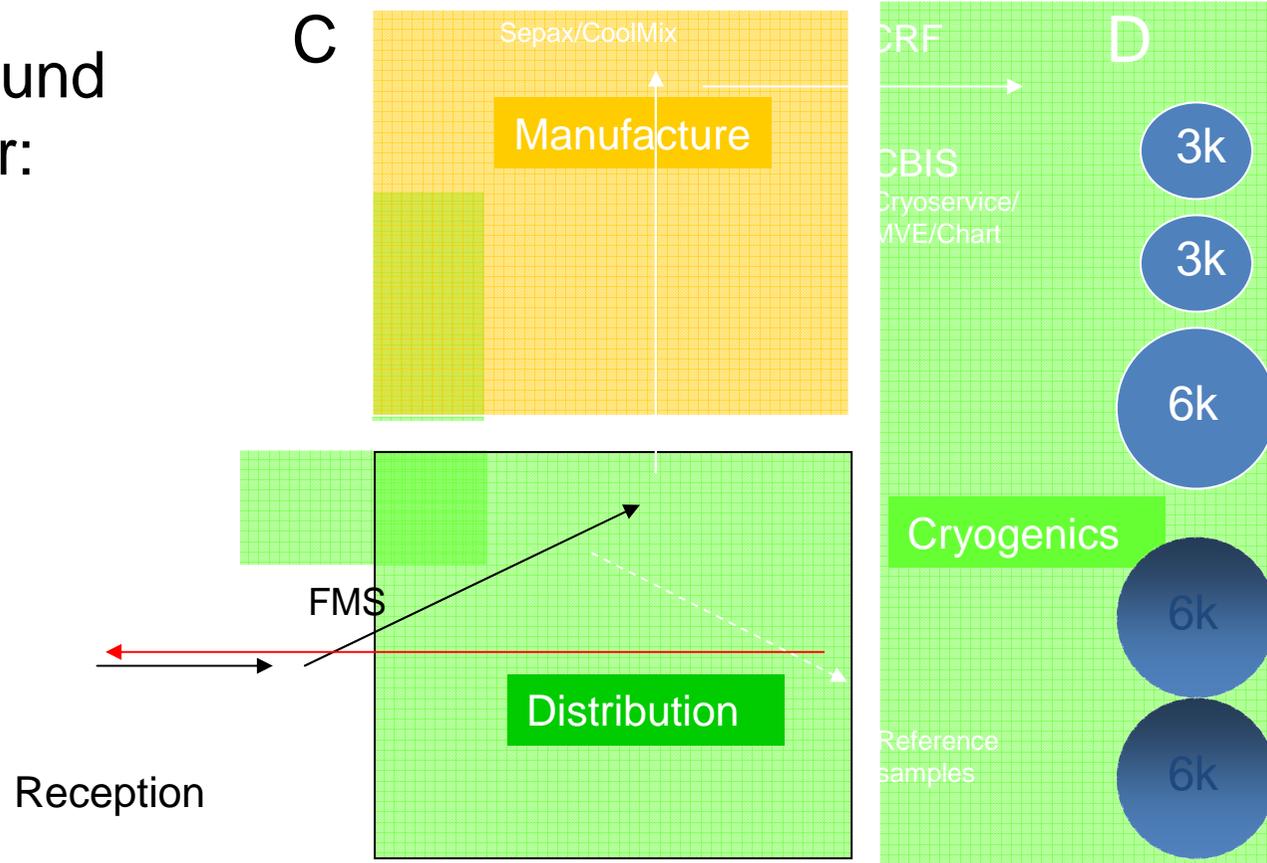


Directive 2004/23/EC and its technical requirements  
HTA  
FACT-NETCORD

CD34/CFU  
IDM/ MICROBIOLOGY  
BLOOD TESTS

# PROCESSING FACILITY

Ground floor:



# RECEPTION

The sample is received in the cord blood bank.

The paperwork and sample are checked.

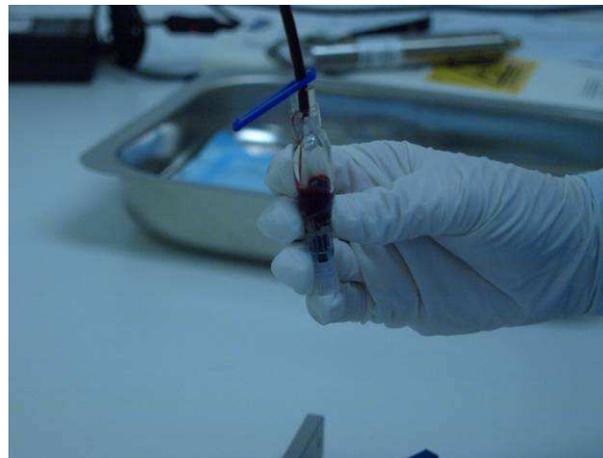
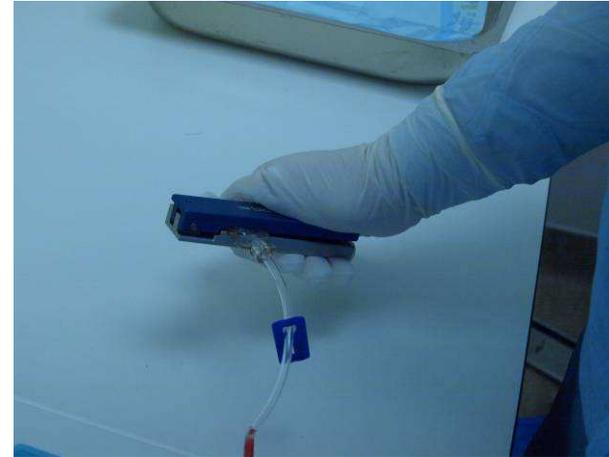
Check none of the packs are leaking

Monitor the data logger



# INITIAL SAMPLE

An initial 1ml sample to be taken for total nucleated cells counts



# PROCESSING

The cord blood bag is attached to SEPAX® kit using a sterile connection.

All the procedure is performed in a close system.



# PROCESSING

Our process utilises the SEPAX<sup>®</sup> cell separation device which is a fully automated and turn-key system that allows safe and efficient processing of blood and its components for various applications in stem cell banking

The kit is placed on the SEPAX<sup>®</sup> machine and an automated programme to perform a volume reduction is carried out

The SEPAX<sup>®</sup> process takes approx. 35 minutes.



# PROCESSING



# ADDING DMSO

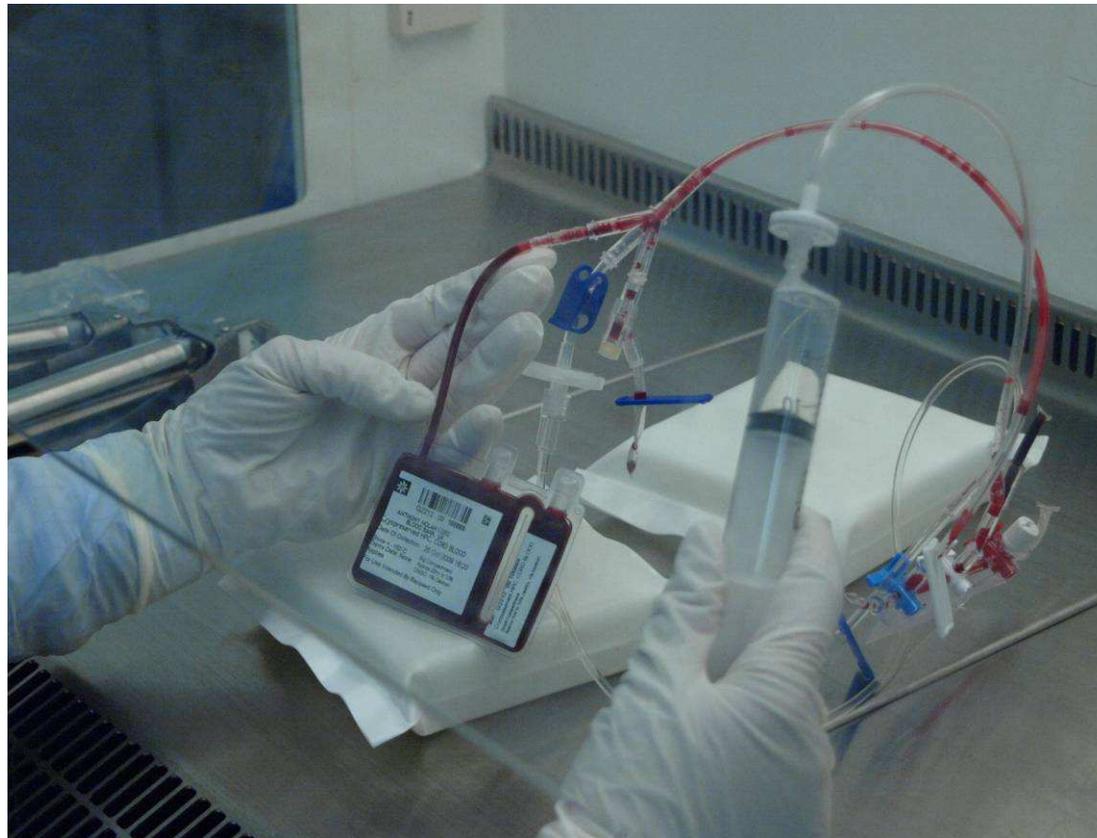
A pre-cooling of the stem cell bag is carried out whilst mixing using the CoolMix to bring the cells to 4 C before the addition of the cryoprotectant.

The DMSO-dextran (5ml) is added over 10 minutes using a syringe pump whilst on the CoolMix



# SEALING

Remove air and fill the whole tube so as 3 segments can be made and utilised for post thaw analysis



# PROCESSING

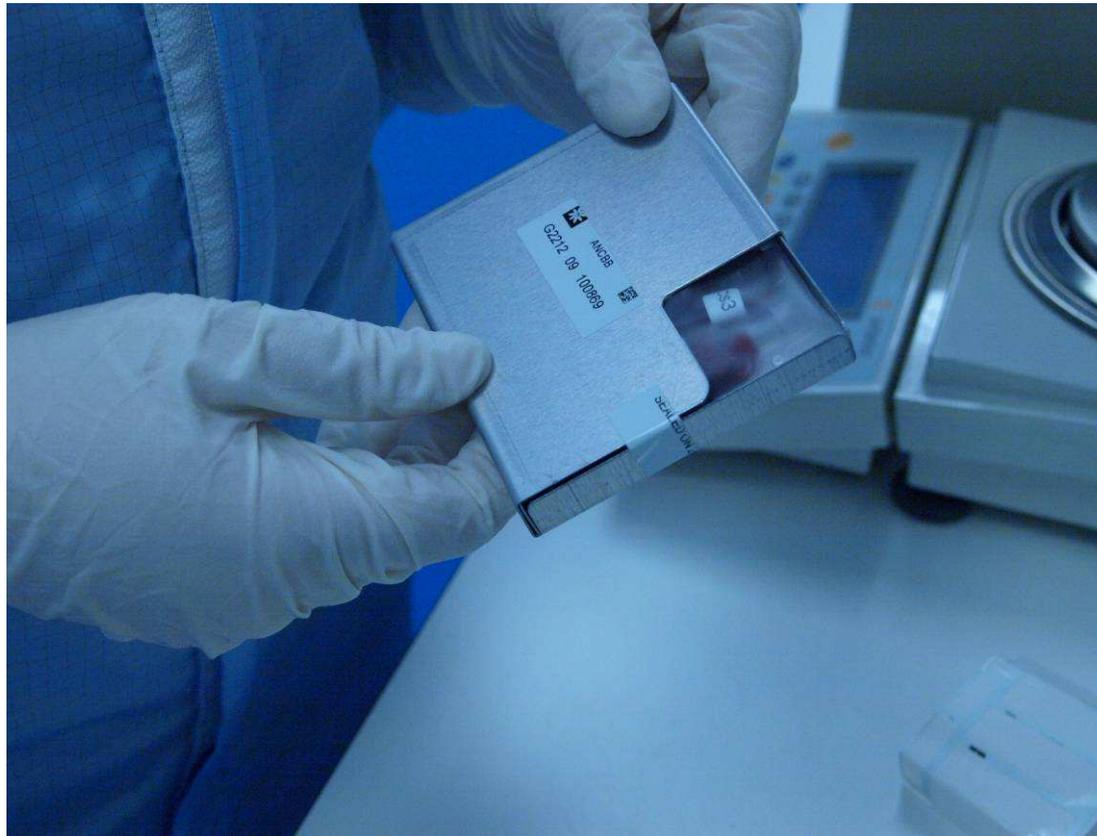
Weigh the bag, in order to calculate final volume.





# FREEZING

Use the canister for the cryotank adding the corresponding labels.



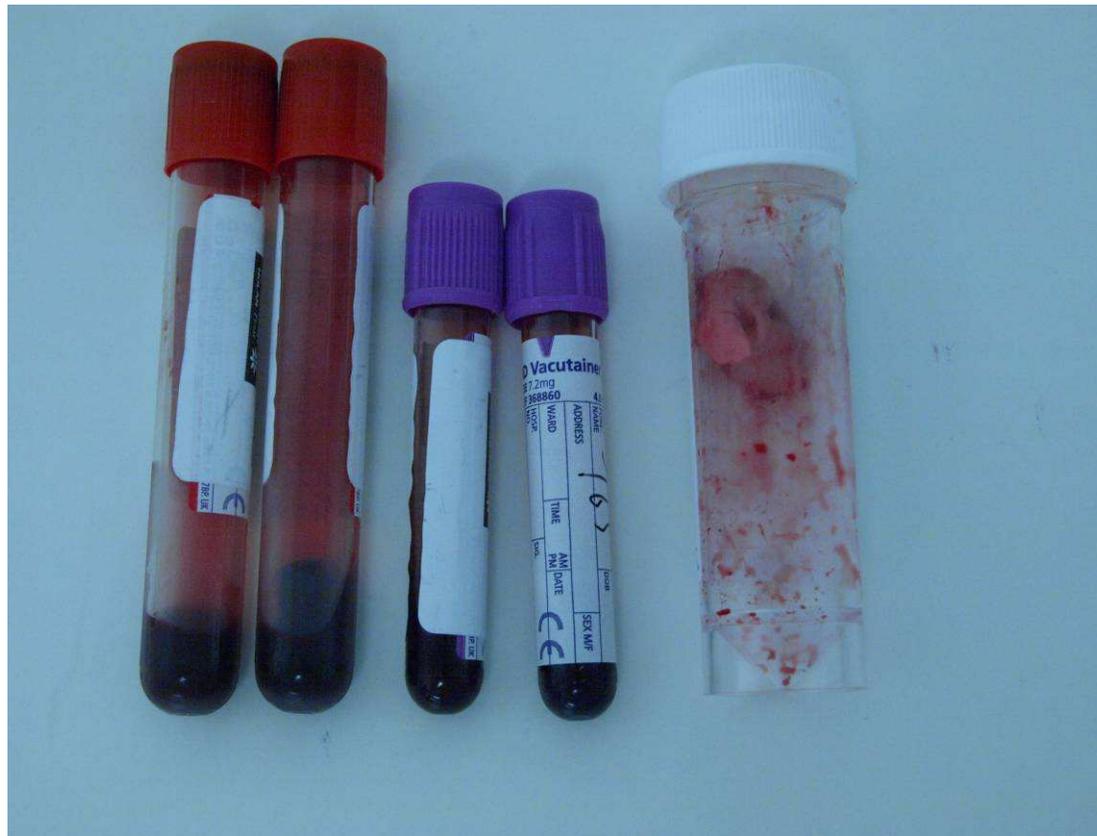
# FREEZING

Put the final sample in the cryotank for its long term storage

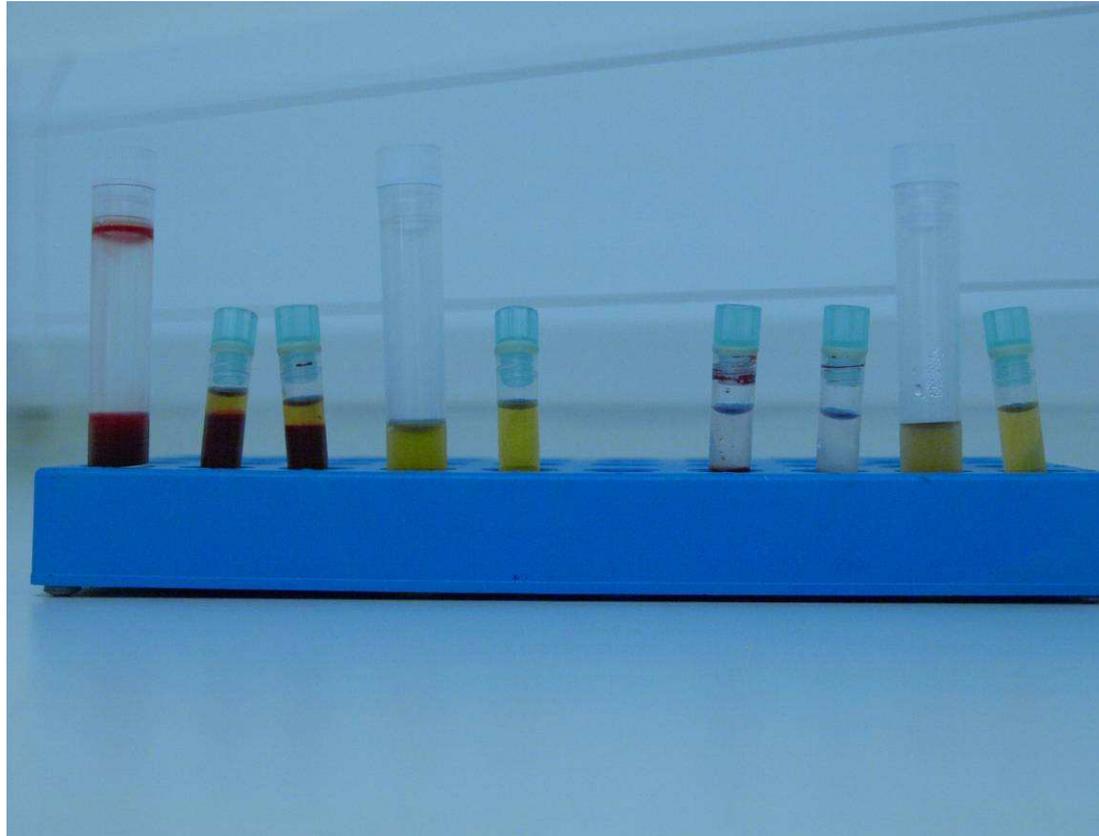


# DIAGNOSTIC SAMPLES

Mother's blood and a cord fragment is processed and stored for virology tests, blood group and HLA typing.



# DIAGNOSTIC SAMPLES

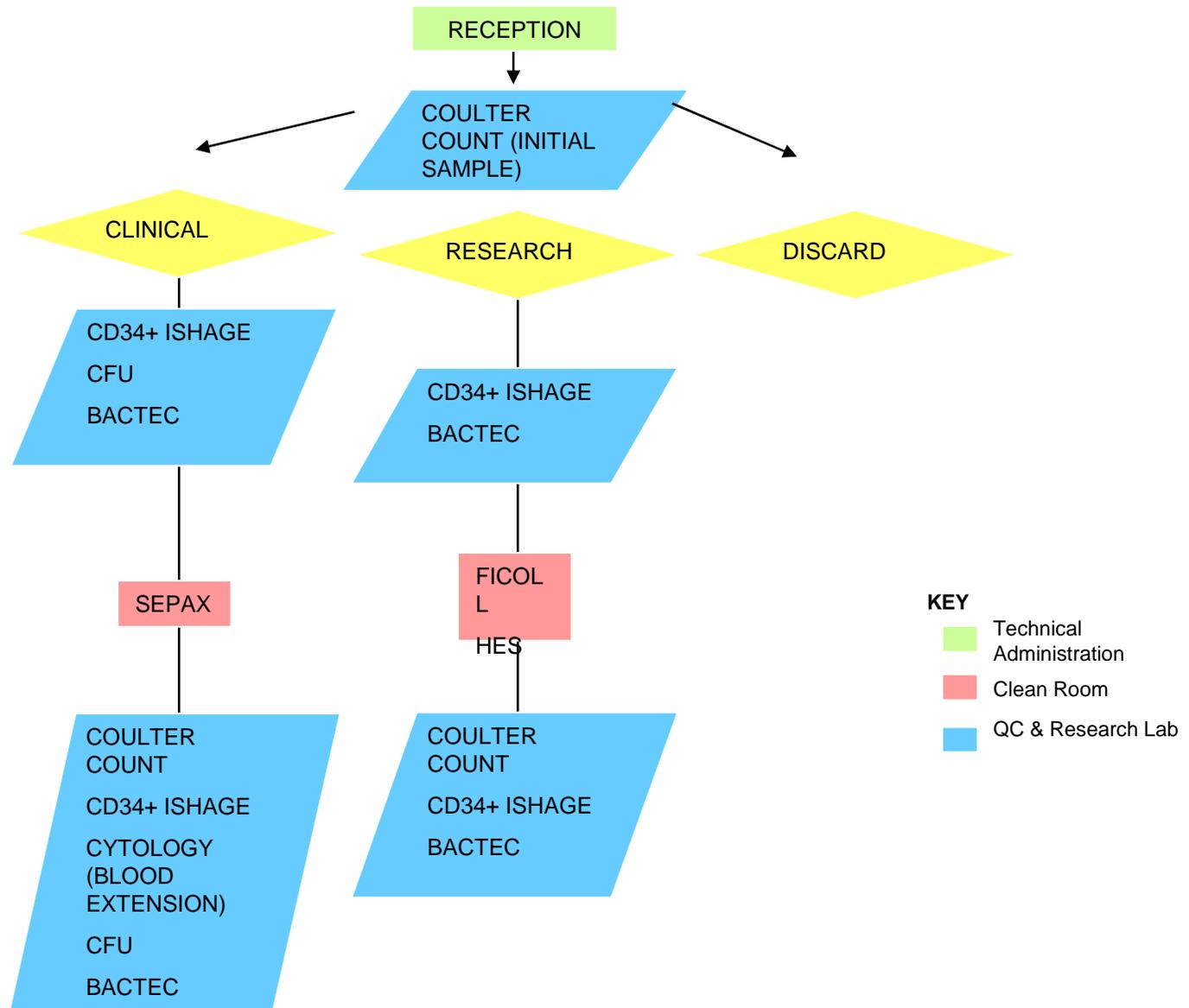


# BACTERIOLOGY

From cord plasma and red blood cells (waste product) inoculate volume to perform bacteriology tests.



# QUALITY CONTROL ASSAYS



# QUALITY CONTROL ASSAYS

We evaluate the results so as to obtain, the NC/ml, TNC, TNC yield, CD34+/ml, total CD34+ and CD34+ yield, to constantly monitor and evaluate the performance of our procedures.

We regularly partake in national NEQAS and international proficiency testing schemes to ensure the quality of our assays.

Virology:

- Hep B, Hep C, HIV, HTLV I-II, Syphilis, CMV, Toxo

HLA typing & blood group

Haemoglobinopathies

## WHY NATIONAL PROGRAMMES?

- Meeting National Regulations
- Pre-defined Quality
- Easy Logistics
- Better Feedback
- R&D using CB surplus
- Economic control (auto-sufficiency)

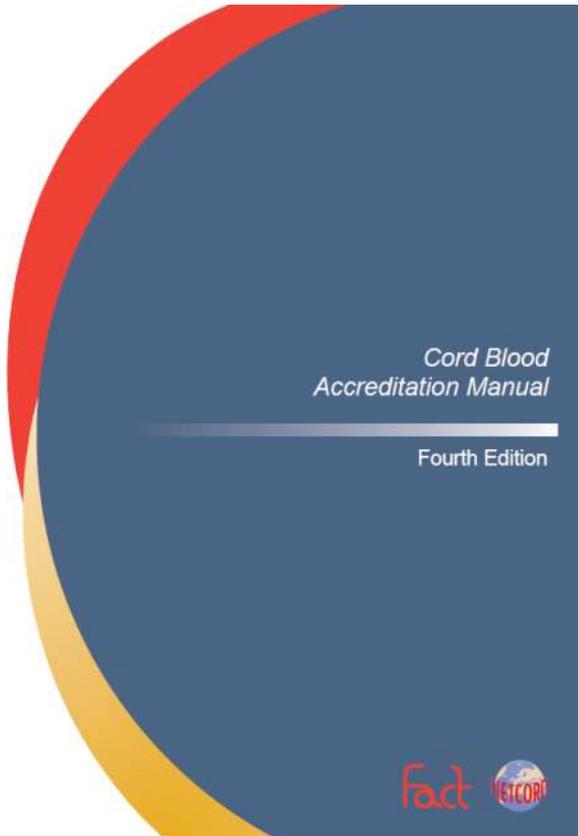
## PRIVATE vs PUBLIC CORD BLOOD BANKS

Same concept but different targets:

- Public CBB: A new allogeneic network, focused in the product and in the recipient safety
- Private CBB: First speculative application of the Regenerative Medicine principle, focused in the donor

# BUT, WHAT IS A CORD BLOOD BANK?

2010: Standards for Cord  
Blood Services



INTERNATIONAL STANDARDS FOR CORD  
BLOOD COLLECTION, BANKING, AND RELEASE  
FOR ADMINISTRATION  
**ACCREDITATION MANUAL**



Guidance to Accompany the  
**NetCord-FACT International Standards for Cord Blood Collection,  
Banking, and Release for Administration, Fourth Edition**

**Fourth Edition  
January 2010**

**NOTICE**

These Standards are designed to provide minimum guidelines for Cord Blood Banks, facilities, and individuals performing cord blood collection, processing, testing, banking, listing, search, selection, reservation, release, and distribution, or providing support services for such procedures. These Standards are not intended to establish best practices or include all procedures and practices that a Cord Blood Bank, facility, or individual should implement if the standard of practice in the community or Applicable Law establishes additional requirements. Each Cord Blood Bank, facility, and individual should analyze its practices and procedures to determine whether additional standards apply. The Foundation for the Accreditation of Cellular Therapy and NetCord disclaim any responsibility for setting maximum standards and expressly do not represent or warrant that compliance with these Standards is an exclusive means of complying with the standard of care in the industry or community.

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FOUNDATION

# BIOETHICS AND CORD BLOOD

- AUTONOMY: Each individual has the right to freely choose their own course of action and to choose what happens to them.
- NON-MALEFICENCE: Do not harm!
- BENEFICENCE: Actions taken should do good

## Women's Will and Midwife-Obstetrician's Responsibility



# COMMERCIAL BANK PITFALLS

(Fox et al, 2007)

- 1) Commercial CBB should not represent the service they sell “doing everything possible”
- 2) More than 95% allogeneic searches find a potential donor
- 3) Few cases of really autologous transplantation has been reported (mainly there are related)
- 4) If stored publicly, 90% of units are available after a 10-years period
- 5) Collection in a non-trained environment could increase the risk of neonatal anemia (early clamping)
- 6) Collectors should disclose any benefit received from the company
- 7) Commercial bank for Regenerative Medicine relies on expansion technology still unsuccessful

## CONCLUSION: THE CORD BLOOD MOVEMENT

- Cord blood represents an actual (**real**) product (**not virtual lists**)
- Ethical (**naturally discarded product**)
- Cost-benefit (**lower inventories, less maintenance, highest efficiency and self-sufficiency**)
- Potential to expand access, improve outcomes and open new doors in therapy (**new paradigm**)
- Potential to develop a biotechnological and biopharmaceutical platforms (**biotechnology/biopharmacy**)
- Reconcile public and private interests (**same answer to different questions**)



**THANK YOU**

**Prof Alejandro Madrigal**

**Dr Sergio Querol**

**Susana Garcia Gomez**

**Robert Davy**

**Dr Roger Horton**

**Daniel Gibson**

**Pam Sami**

**Chris Leonforte**

**Laura Fry**

**Kieran Herrity**

**Guy Parkes**

**Terie Duffy & dedicated collectors at Kings**

**Linda Moss & dedicated collectors at Leicester**

**All Anthony Nolan Cord Blood Programme donors**