NHS
Blood and Transplant

From Donor To Door

Caring Expert Quality

Aim

To provide basic knowledge on the processing, testing and issue of blood donations by NHSBT

<u>At the end of this session you will be aware of</u>:

- The stages of processing, testing and issue of blood
- NHSBT's range of blood components
- The storage specifications of those blood components

Taking the whole blood

450ml +/- 45ml into 63ml anticoagulant (CPD) within 15 minutes

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Whole Blood Donation

- Different blood pack types
- 450 ±45mL blood into 63mL of CPD anticoagulant (target volume typically 470mL)
- At least 3 blood samples taken - bar code labelled, together with the blood packs

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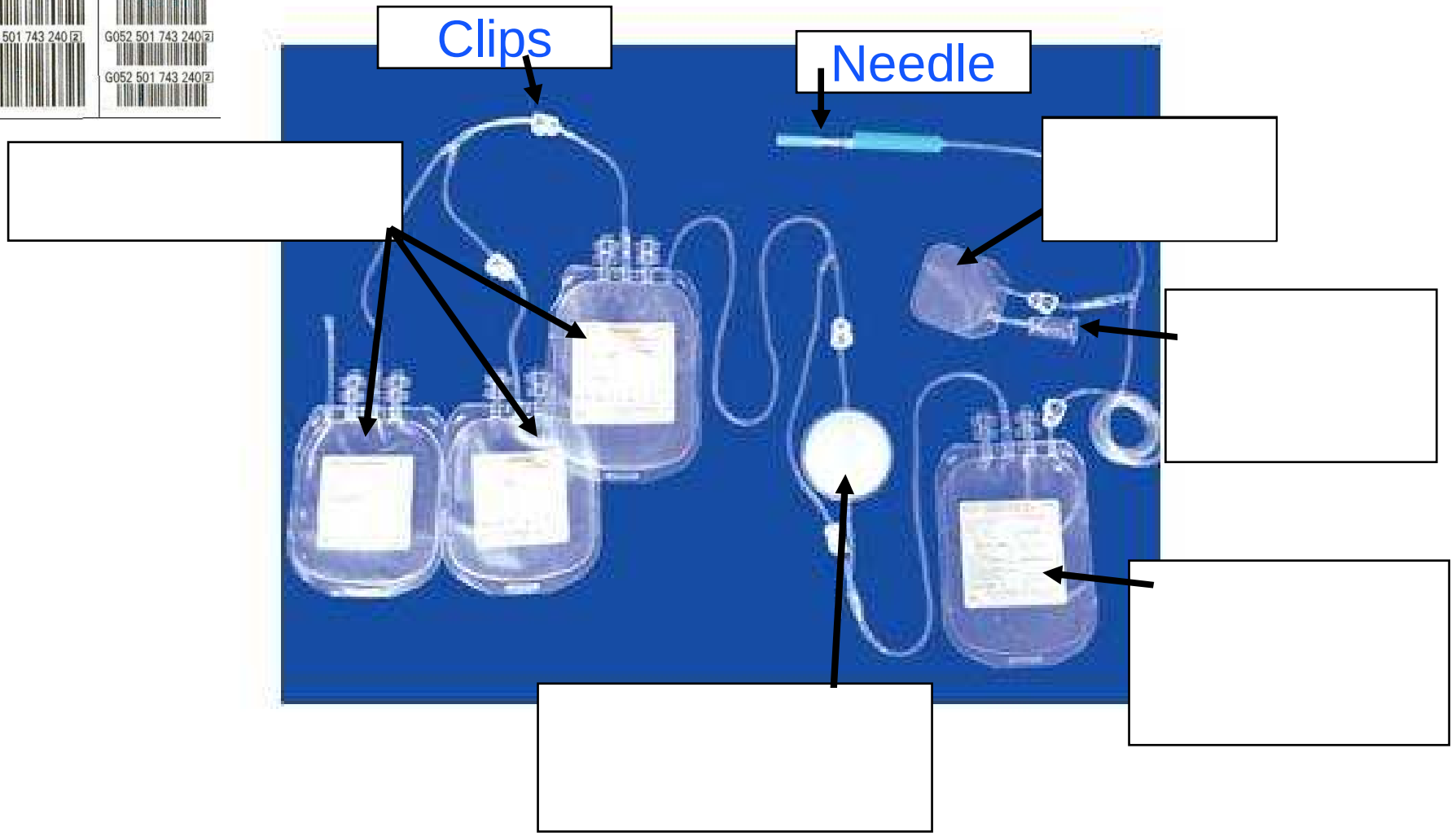
Multiple blood pack system



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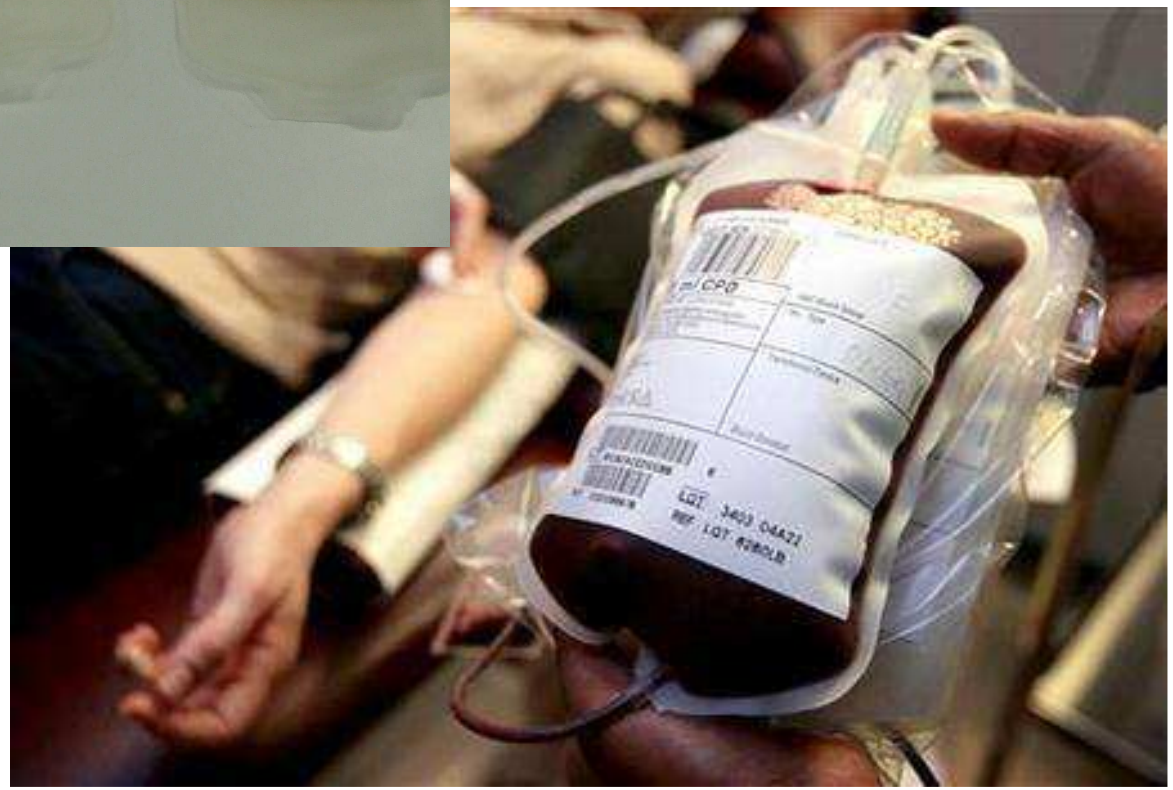
Donated Whole Blood – ready to be processed

What happens next?



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Processing, Testing and Issue

Processing (> Manufacturing)

- Very few units are used as whole blood
- Reduces wastage

Testing

- Every donation no matter how often the donor has given

Issue

- Includes validation, storage and despatch

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Advantages

Provides a concentrated form of a clinically effective product for the patient:

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But.....

- Patient may be exposed to more donors (especially pooled products) - increases potential risk of disease transmission

- Manufacturing costs

- Practical problems of supply and demand for ‘off-the-shelf’ products - wastage due to expiry

‘Manufacturing’ Department

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What they do:

- Blood component “processing”
- Monitor the quality of the components
- Product storage

Licensed by MHRA

- Subject to Good Manufacturing Practice (GMP)

Produce:

- Red cell donations
- Platelet concentrates
- Fresh Frozen Plasma
- Cryoprecipitate
- (Granulocytes)

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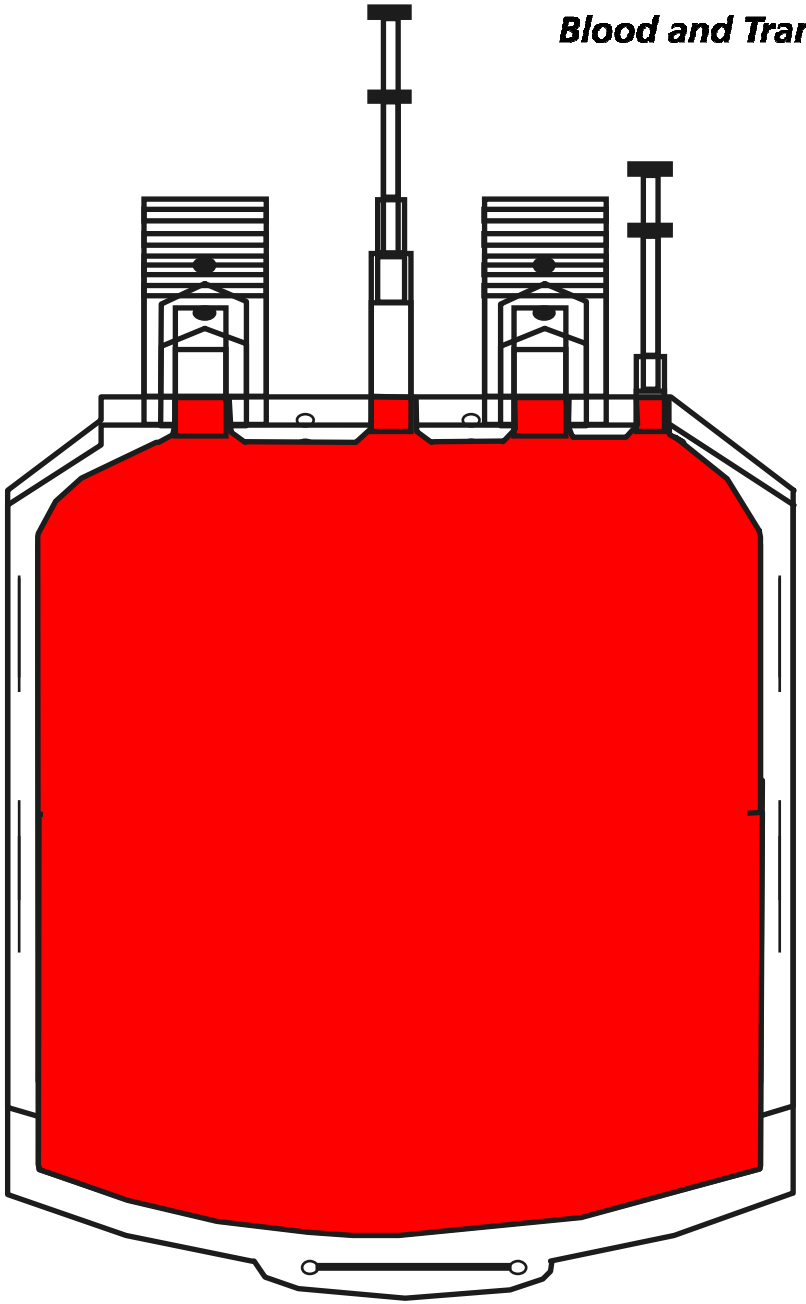
Fresh Frozen Plasma

Cryoprecipitate

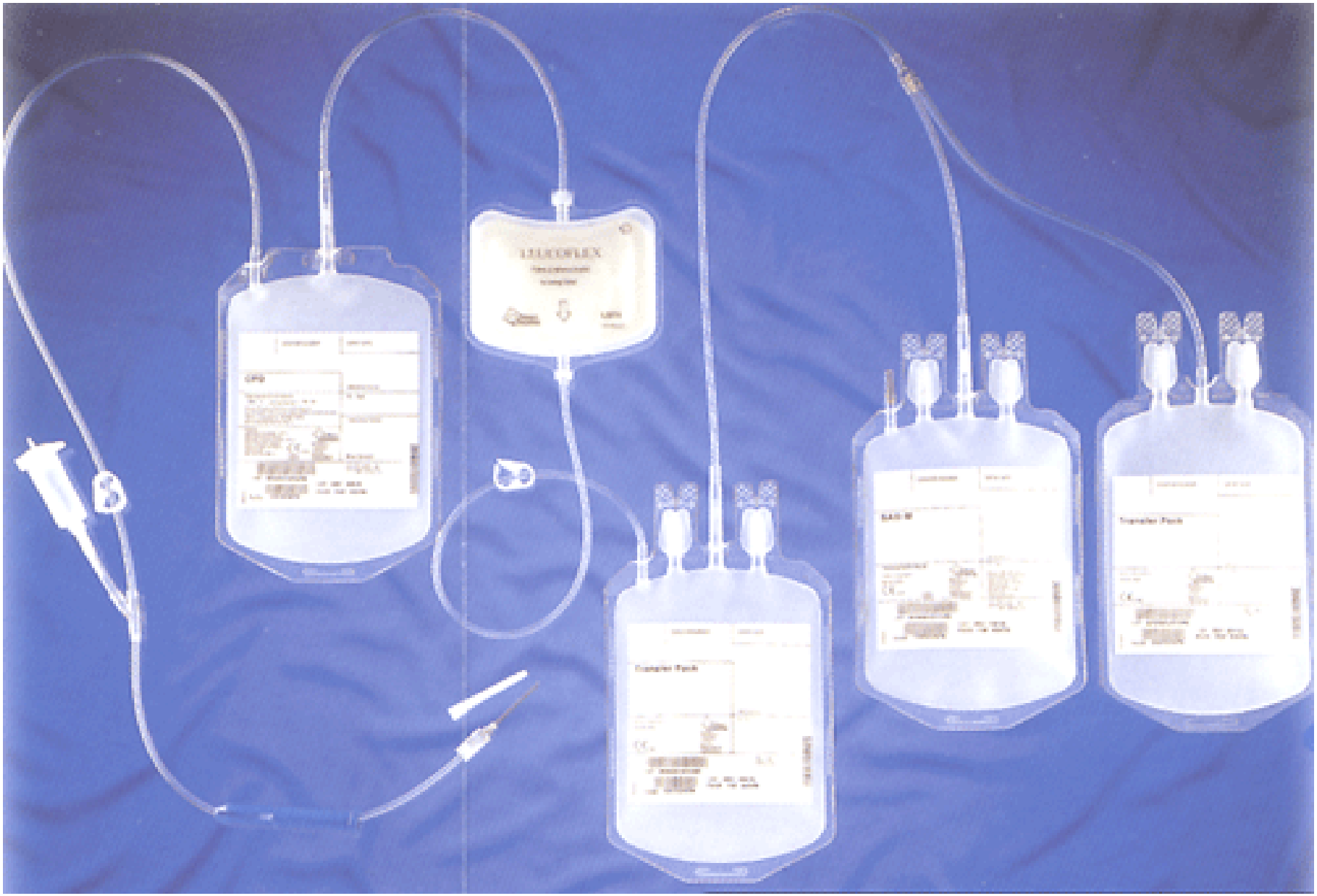
Red cells

Platelets

(Granulocytes)



Multiple Blood Pack System



Leucodepletion

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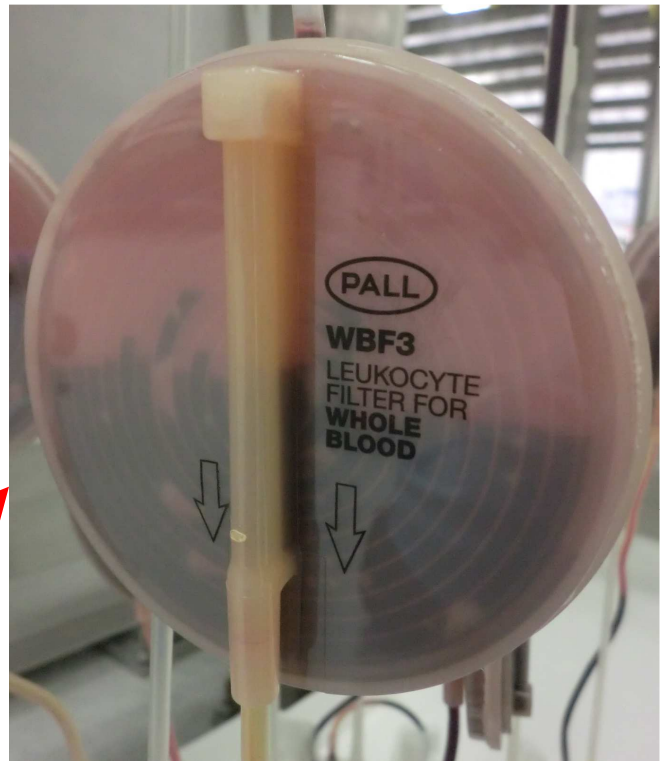
- All products are routinely leucocyte depleted by filtration (WBC count of $<5x10^6$/unit)

- Timing is dependant on the component produced (whole blood pre-processing or component post-processing)



Mandatory:-

Minimise risk of

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Basic Methodology

Centrifugation of the donation

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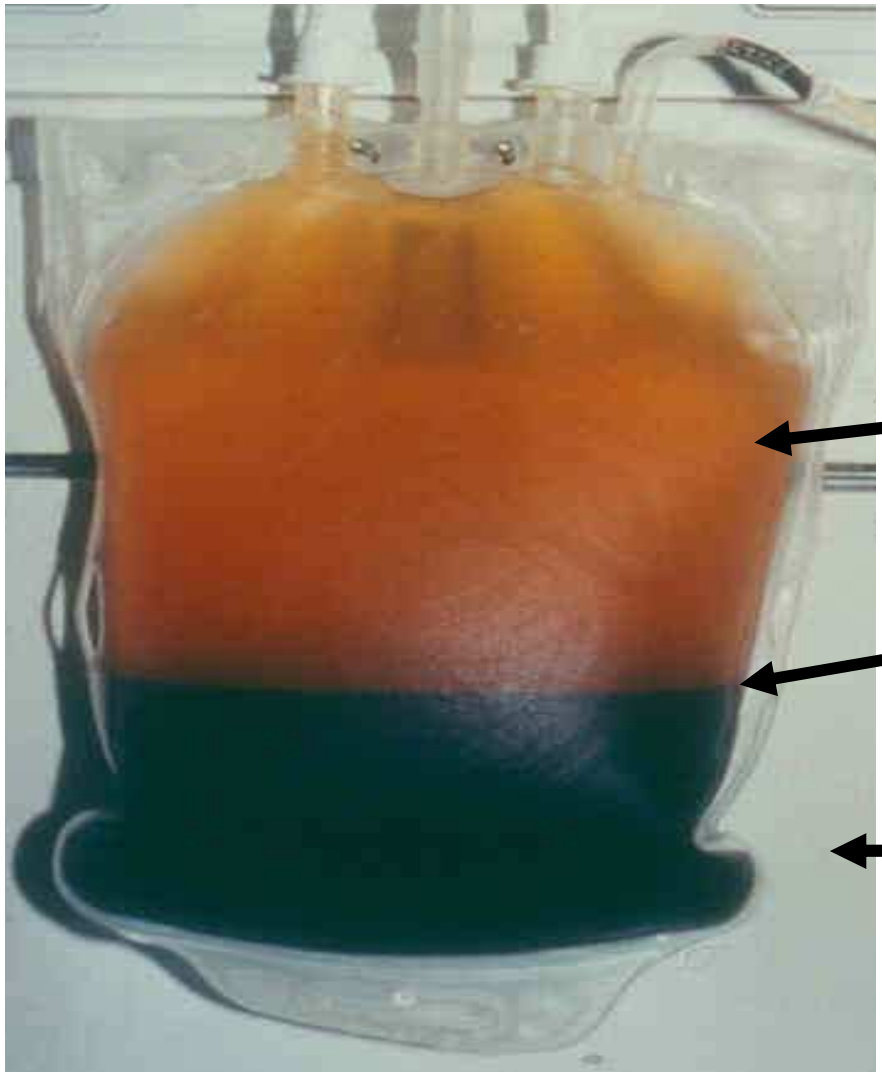
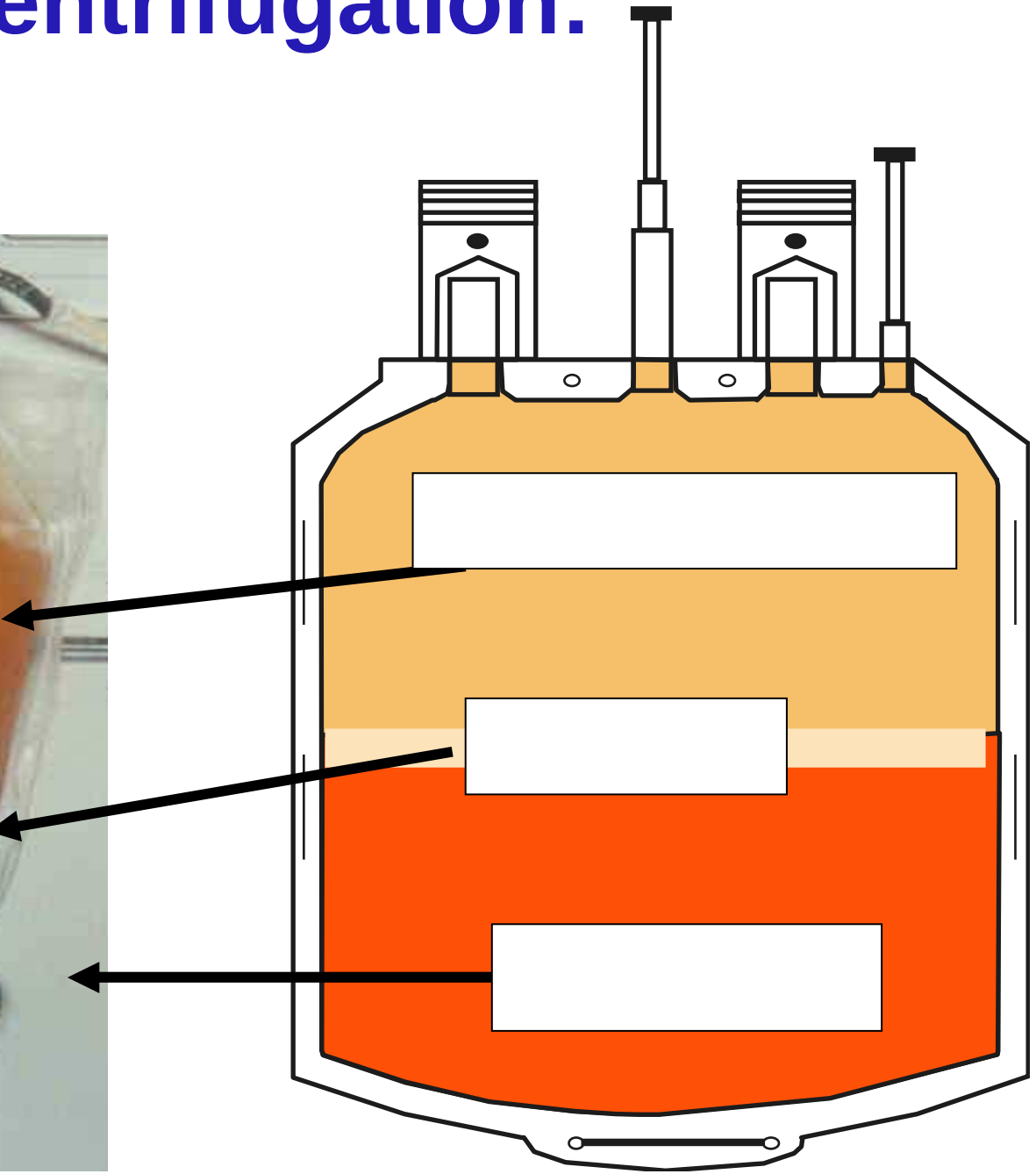
Post-centrifugation:





Under pressure the components are expressed into different satellite bags

Bag separation by heat sealing

Product labelling - all critical stages of processing are under computer control

Red Cell Products

General

Types

- Most Red cells in SAGM

Storage:

- Time : 35 days
- Temperature : 4 ^{o}C ± 2^{o}C
- Storage monitored

Red Cell Products

Specialist

- Red cells, thawed and washed (rare phenotypes)
- Washed red cells (history of severe allergic / febrile reactions to transfusion)

<u>Neonatal / infant components</u>

- Red cells in SAGM for large volume transfusion (not exchange) a.k.a. “LVT”
- Red cells in SAGM for neonatal transfusion (LVT split into 6 equal components)
- Red cells for neonatal exchange transfusion (in plasma)
- Red cells for intra-uterine transfusion (IUT) (in plasma but higher haematocrit)

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Platelet Concentrate Products

- Automated Component Donation
- Pooled

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Platelets

- Routinely produced : ‘off-the-shelf’ products
- ABO identical blood group transfused where possible
- RhD negative products for RhD negative women
- CMV negative and / or irradiated where appropriate

Component Donation (Apheresis)

- Donor blood passes through centrifuge
- Separates components
- 2-3 Adult Therapeutic Doses (ATD)
- 12 ‘baby’ doses
- Red cells are returned
- Can donate more frequently
- Takes about 90 minutes

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Automated Component Donation

Can be used also for provision of directed platelet products

Advantages:

- Amount collected
- Frequency of donation
- Increased reliability / control
- [redacted]

Disadvantages:

- Time consuming for donors
- Expensive

Apheresis Platelet Concentrate :

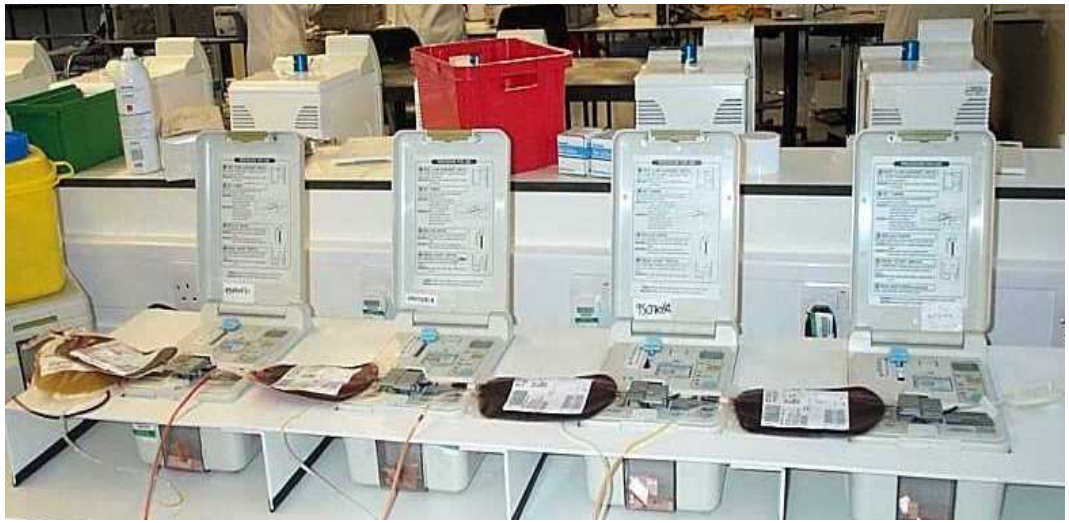
Split For Neonatal / Paediatric Patients

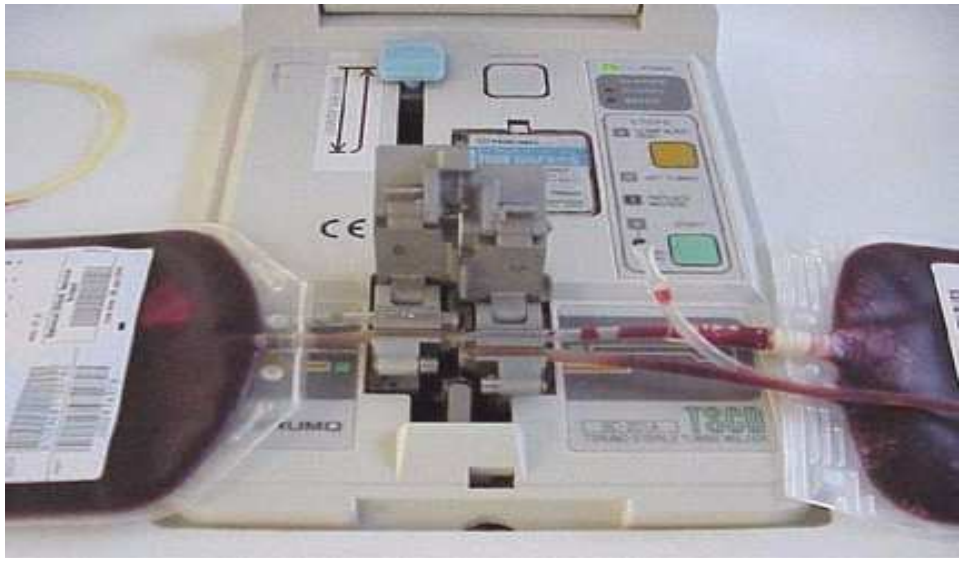
One adult dose is ‘split’ into four smaller packs

Making A Platelet Pool

‘Buffy coat’ extracted by centrifugation

Four units connected with sterile connecting device





The platelets are expressed through a filter into the special platelet pack

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Platelet Storage

- Maintained / recorded temperature of [ ] $^{o}C \pm 2^{o}C$
- Up to 7 days (if bacterial monitoring)
- Constantly mixed

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Plasma Products

Fresh-Frozen plasma

- Processed and frozen to below [ ] °C within 8 hrs
- Shelf life : 3 years at below [ ] °C
- ABO group specific FFP transfused
- Methylene Blue treated imported plasma for :-under 16's WHY?

Plasma Products

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Cryoprecipitate

- Preparation : 'Cryoglobulin' fraction produced by controlled thawing of FFP at 4°C ± 2°C
- Contains various coagulation factors e.g. Fibrinogen, Factor VIII
- Isolated, resuspended in a small volume of plasma and re-frozen (<2 hours)
- Processed and frozen immediately to below -30°C
- Shelf life : 3 years at -25°C or colder

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Pooled Granulocytes

- Supportive therapy for patients with life threatening bacterial / fungal infection due to:
  - Bone marrow failure
  - Neutrophil dysfunction
- Clinically effective adult dose : ~$2x10^{10}$ cells
  - 2 pooled components
  - Derived from 20 whole blood donations
- Prepared for individual patients (must be discussed with an NHSBT Consultant before ordering)
- Use : ASAP expires midnight on day 1

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Blood Product Summary

PRODUCT	STORAGE TIME	STORAGE TEMP	STORAGE NOTES
RED CELLS	35 days	4°C +/- 2°C	Air temp : 2°C - 8°C
PLATELETS	7 days Bacterial Monitored	22°C +/- 2°C	Gently mixed
FFP / CRYO	3 years	below -25°C	Use within 4 hrs of thawing
GRANULOCYTE	< 24 hrs	22°C +/- 2°C	Not agitated Use within 24hrs

Finished Components awaiting ‘Validation’

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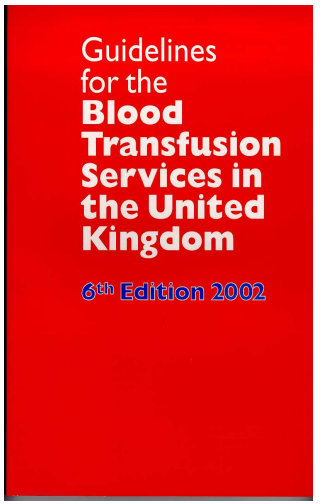
Quality Monitoring

Selection of each component type sampled to ensure stated specifications are met ('Red Book')



- Checks volume, white cell contamination, clotting factors, platelet counts
- Also includes various in-process controls, worker assessment, equipment monitoring and reagent controls
- Sample 1% of products
- >75% must meet specification

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Testing

Grouping and Transfusion Microbiology

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Testing

- Responsible for all mandatory testing of donations
- Mandatory tests required for every donation
- 2 Testing Departments nationally. Between them they test over 9000 samples /day
- Responsible for non-mandatory testing of donations (selected donations)
- Responsible for investigating discrepancies

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“Grouping” Tests

The following tests are performed on every donation

- ABO and RhD (mandatory)
  - New donors tested twice before release
- Antibody screen (mandatory)
- High Titre ABO antibodies
- Extended phenotype (c, C, e, E, K)

The system:-

- Automated blood grouping system:-

  PK series (all UK Blood Centres)

- Positive sample ID, machine interpretation of results, electronic transfer of results to Pulse

- Nationally approved settings (NHSBT)

- Centrally produced reagents

- National monitoring of performance

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Grouping
Discretionary Tests

- Phenotyped Units
  - Used to provide antigen negative blood for patients with pre-formed antibodies
  - Patients with antibodies to several antigens may be particularly challenging
  - Example = requirement for up to 10 units/week of O RhD pos E- S- K- Fya- Jkb- CMV-
- Enhanced antibody screen for neonatal use
- Sickle (HbS) testing

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Mandatory

Transfusion microbiology:-

Mandatory testing

- HBsAg
- Anti-HIV1 and 2
- Anti-HCV
- Syphilis antibodies (Olympus)
- Anti-HTLV I/II
- HCV RNA (NAT lab)
- “Bacterial Monitoring” (for 7 day platelets)

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Microbiology

What types of tests?

Serological tests

- Detect antigens and/or antibodies
- Performed in testing departments

Nucleic acid tests

- Detect viral nucleic acid
- Performed in specialised NAT laboratories

Abbott Prism Test system

- Same principles as ELISA but uses Chemiluminescence instead of enzyme

- Easy system to run

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Nucleic Acid Technology

- Direct detection of virus nucleic acid
- Allows reduction in window period
  - 40-60 days for HCV
  - 5-7 days for HIV
  - 7-14 days for HBV
- Currently only mandatory for HCV on blood donations with expiry >24hrs
- Current test detects HCV, HIV, HBV
- Very sensitive:- allows use of pools
- Mini-pools allows resolution to individual donation

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Bacterial Screening of Platelets

- Sample each platelet unit for bacterial growth
- SHOT reported 28 cases in 12 years (8 fatal)
- Bacterial screening of platelet components implemented in January 2011
  - 100% testing established by March 2011
- Increases shelf-life to 7 days

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Bacterial Monitoring of platelets

In addition to arm cleansing and donation diversion pouch

- BactALERT automated test system
- All platelets now tested
- Platelets tested up to expiry
- 7 day expiry (increased from 5 days)

Bacterial Monitoring of platelets

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- All platelets sampled into a pouch using sterile docking
- Sampled from pouch in laminar flow cabinet
- Tested Aerobically and Anaerobically at 36^{o}C
- After 6 hrs results downloaded to PULSE
- Monitoring continues until expiry of product, not removed until Day 8

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Hospital Services

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Responsible for:

- All post-production handling of product
  - validation
  - stock control
  - receipt, issue, despatch of orders
  - reconciliation
- Daily contact with hospitals
- Inter-site stock transfers

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Product Validation

- PULSE computers system links donation testing and blood pack labelling
- The system depends upon the use of machine-readable barcode labels

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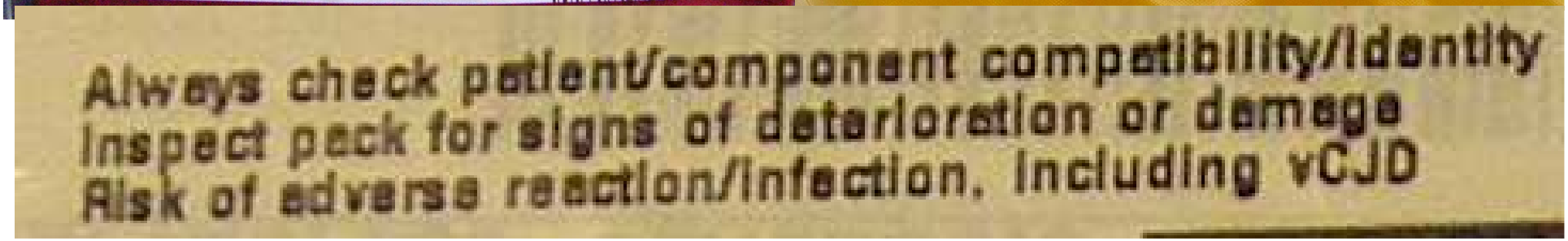
Ready to go



Dealing with orders

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- Trained staff
  - Orders by Online Blood Ordering System (OBOS)
  - Fax back-up and phone for an emergency
  - Stock Control and first in first out to minimise wastage
- Annual issues (National 2014/15)
  - Red cells 1,651,237
  - Platelets 229,589
  - FFP 181,841
  - Cryo 27,409
- Distribution
  - Daily routine deliveries
  - Ad hoc
  - Emergency

Blood Supply Distribution Structure (2017)

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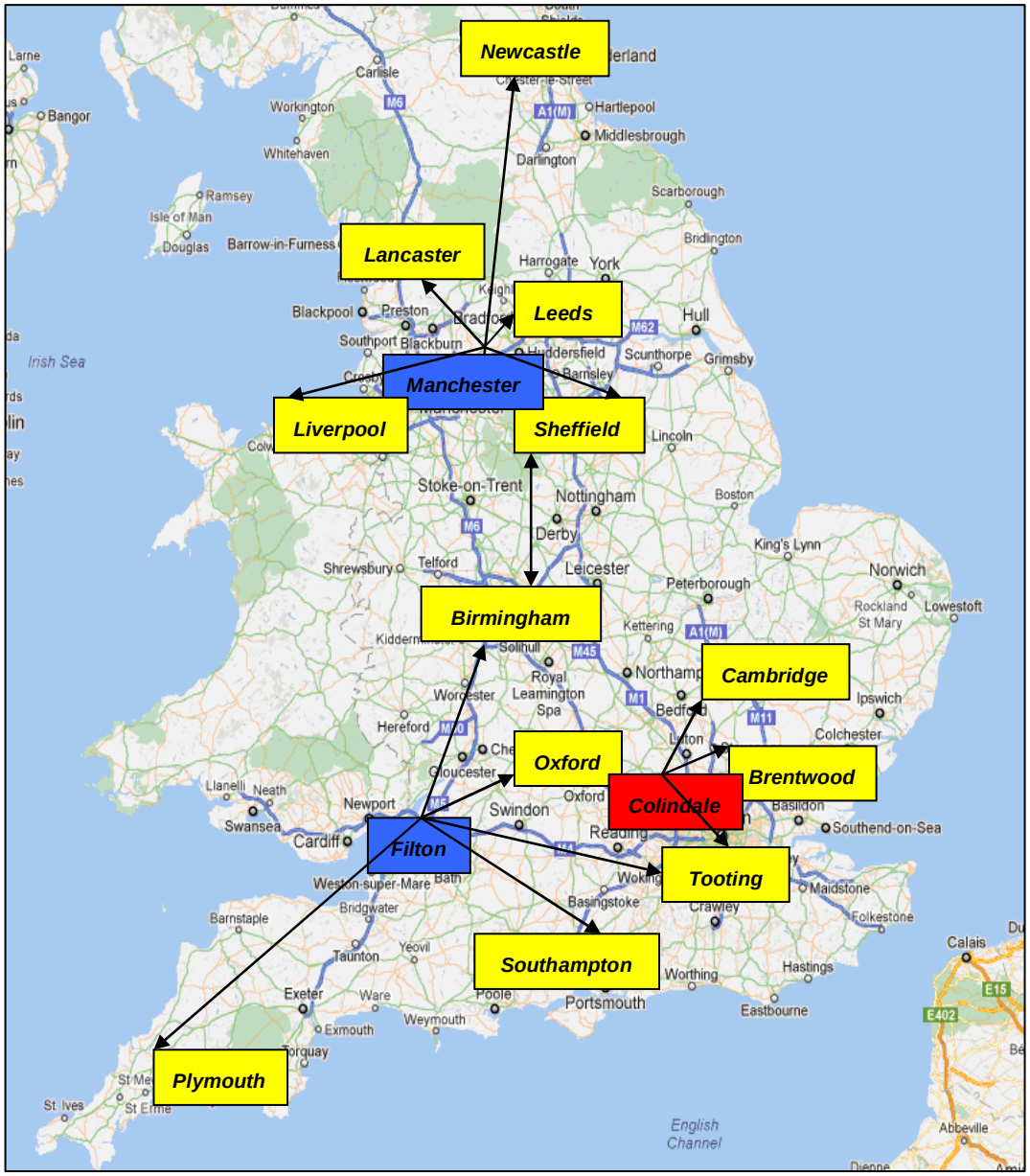

Key

Testing and Manufacturing and SHU Centres

- Manchester
- Filton

Manufacturing and SHU Centres

- Colindale

Stock Holding Units (SHU)

- Lancaster
- Leeds
- Liverpool
- Newcastle
- Sheffield
- Birmingham
- Oxford
- Southampton
- Plymouth
- Tooting
- Brentwood
- Cambridge

Aim

To provide basic knowledge on the processing, testing and issue of blood donations by NHSBT

Further information:

- NHSBT Portfolio of Blood Components (via our “Hospitals & Science” website)
- Guidelines for the Blood Transfusion Services in the United Kingdom (“Red Book”)
- Your hospital’s blood bank
- robin.coupe@nhsbt.nhs.uk