NHS Blood and Transplant

The testing of Donated Blood and Components at NHSBT

Pete Rogan, Regional Testing Manager, North

- NHSBT is responsible for collecting all donated blood and platelets in England, then processing into components before issuing to client hospitals.
- It is highly regulated, working to national and international standards and compliant with GMP.
- Testing of donations falls under that Quality umbrella and is performed in two specialised laboratories, sited in Manchester and Filton.

What do we test for?

- All mandatory testing, as laid down in BSQR and the Guidelines for Transfusion Services in the UK ('Red Book') – required for every donation

- Secondary testing to improve safety or provide for hospital needs.

All donations are tested for (mandatory tests):-

- ABO and Rh D type
  - Anti-A, anti-B, Anti-D
  - Anti-A detects Ax
  - Anti-D detects Dvi
  - Antibody screen.
- Confirmation of known donors, result compared to historical computer record.

New donors

- No historical record so re-tested on a second, independent run to establish ABO and D type.
  - Anti-A (does not detect Ax)
  - Anti-B
  - Reverse group (A and B cells)
  - Anti-D (does not detect Dvi)

Significance of Dvi

- Commonest type of variant D
- May stimulate production of anti-D if transfused to D -ve recipient:- donations labelled Rh D positive
- May produce anti-D if transfused with D +ve red cells.:- patients treated as Rh D negative
- Important to identify so correctly labelled, correct records, samples for controls.

Antibody screen

- Crude screen using papain treated cells.
- Optimised to detect Rh and some K antibodies.
- Suitable for products for adult use – Antibodies diluted out on transfusion
- Not suitable for products for neonatal use.

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PK7300®

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Products for Neonatal use.

- TIGHTER GUIDELINES INCLUDING:
- Restricted by pack type:-
  Red cells not in SAGM for exchange or intra-uterine transfusion, platelets from single donor, donor must have previously donated within 2 years (micro neg)
- CMV antibody negative
- Irradiated
- ≤ 5 days old for exchange or intra-uterine transfusion

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Products for Neonatal use.

- Enhanced antibody screen negative:-
  2 or 3 cell anti-globulin test equivalent to patient antibody screen.
- HbS screen negative (red cell products only)
- High titre ABO antibody negative.

Phenotyped blood

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- All units typed for C, c, E, e and K.
- About 3,000 units per day will be further typed.
- Sufficient of each to maintain useful stock
- Provision of antigen negative blood for patients with pre-formed antibodies
- Profile matched blood for patients requiring long term transfusion support
- Identification of rare types suitable for freezing at NFBB
- Priority given to K- units negative for at least 2 other antigens
- Testing for M, S, s Jka, Jkb, Fya, Fyb, Cw (for reagents), HbS some Kpa, Lua.

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Transfusion Microbiology

- Responsible for performing all mandatory microbiology testing
- CMV antibody testing on selected donations
- Follow up of discrepant results with full liaison with independent reference laboratory
- Investigation of suspected post-transfusion infection.
- Discretionary testing of donors with extra risk.

Mandatory tests

- Hepatitis B (HBsAg)
- HIV (antibody to HIV1, HIV2, HIV1 sub-type O)
  - We use a test that detects HIV1 p24 antigen also.
- HCV (antibody and RNA)
- HTLV (antibody)
- Syphilis - TpPA performed in donor grouping for blood donations, EIA for SCATs
- SCATs also require anti-HBc

  All tests must comply with national standards of performance, using approved kits.
- Each run must include independent controls to prove compliance.

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CMV antibody test

- Approx. 28% of all donations tested daily
- 43% donor population positive (about 70% of whole population)
- Bank of CMV negative platelet and red cell products
- Filters that remove white cells also protect against CMV

SaBTO guidelines for CMV antibody tested products

- Leucodepleted products offer sufficient protection in most patients, including post-transplant.
- CMV antibody screened cellular products required for :-
  - Neonatal patients (<44 weeks post conception)
  - Pregnant women
  - Granulocyte or buffy coat products.

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NAT

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- Nucleic Acid Technology (since 1999)
- Currently only mandatory for HCV on blood donations
- Mandatory for all products with expiry >24hrs
- Can detect early infections 40 - 60 days before antibody test

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NAT section.

- Current test detects HCV, HIV, HBV
- Pools of 24. Reactives resolved down to individual donation.
- Has successfully detected serology negative HCV, HIV and HBV infections.

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Roche Cobas S201®

Investigations

- Confirmation of microbiology positive donors
- Follow up of donors giving non-specific reactions

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Investigation of Suspected Post-Transfusion Infection

- Frozen archive sample for at least 3 years
- Records of tests, controls, QC data for up to 30 years
- Look back procedure
  - Recovering and reviewing data
  - Re-testing donor
  - Re-testing archive sample

Discretionary testing

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- Malaria test - people visiting endemic areas >6mths < 12mths
- *T. cruzi* - people visiting endemic areas >6mths
- Piercers - tattoos, body piercing, acupuncture, semi-permanent make up > 4 months <12 months. (HBV window test – Anti-HBc)
- Donors with a history of hepatitis
- WNV in mosquito season:- visitors to continental North America and designated areas of Central and Eastern Europe.

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Quality monitoring

- Samples statistically significant numbers of all product types and measures set analytes to confirm compliance to specification:-
- RBC, Hct, WBC (post filtration), Plt count, Factor VIII levels
- Environmental monitoring of processing areas, Tissues Services clean rooms, Bacterial Arm Monitoring of donors

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Bacterial Monitoring of platelets

- BactALERT® automated test system
- Selection of platelets tested after 36 hours.
- Release after 6 hours
- Allows 7 day expiry date
- Monitoring continues until expiry of product.
- Each processing site has its own BSP laboratory

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Conclusion

- The Testing of blood donations is at the heart of NHSBT's core business function
- Major role in maintaining product quality and safety.
- Essential role in providing our hospitals with the products and services required.