HAEMOVIGILANCE, NATIONAL AUDIT AND EXTERNAL QUALITY ASSESSMENT

WORKING TOGETHER TO IMPROVE TRANSFUSION PRACTICE

A woman with many hats!
UK National Organisations

- **What is the right thing to do?**
  - Guidelines **BCSH**
- **What goes wrong and why?**
  - UK Haemovigilance **SHOT**
- **How good are we at achieving national standards and ‘doing the right thing’?**
  - National audits **NCABT**
- **How good are we at getting the tests right?**
  - Proficiency Testing **UK NEQAS**

**Working together to improve practice**

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**BCSH Guidelines**

*British Committee for Standards in Haematology Transfusion Taskforce*

- Produces and updates technical and clinical guidelines based on evidence where available and expert opinion
- **SHOT, NCABT and UK NEQAS**
  - promote BCSH guidelines as the basis for best practice
  - Participate in BCSH guideline development
Haemovigilance in the UK

Serious Hazards of Transfusion
- Records actual events
- Analyses root cause and trends
- Shared learning
- Recommendations to hospitals
- Influences guidelines
- Not all events are recorded

National Audit in the UK

National Comparative Audit of Blood Transfusion
- Audit of practice against national standards based on BCSH guidelines
- Benchmarking practice against peers
- Choice of topics determined by professionals
- Participation promoted by Department of Health/NHS England through Quality Accounts
- Only a snapshot – and not always possible to access a representative sample
- Shows potential for error, not actual errors
### National Comparative Audit of Blood Transfusion

<table>
<thead>
<tr>
<th>Audit</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of Fresh Frozen Plasma</td>
<td>2009</td>
</tr>
<tr>
<td>Bedside Transfusion Practice (re-audit)*</td>
<td>2009 and 2011</td>
</tr>
<tr>
<td>Blood Collection from the Issue Fridge*</td>
<td>2009</td>
</tr>
<tr>
<td>Use of Red Cells in Neonates and Children</td>
<td>2010</td>
</tr>
<tr>
<td>Use of O Negative Red Cells (re-audit)</td>
<td>2010</td>
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<tr>
<td>Platelet Transfusions in Haematology (re-audit)</td>
<td>2010</td>
</tr>
<tr>
<td>Use of Red Cells in Medical Patients</td>
<td>2011</td>
</tr>
<tr>
<td>Blood Sample Collection and Labelling*</td>
<td>2012</td>
</tr>
<tr>
<td>Anti-D Immunoglobulin Prophylaxis</td>
<td>2013</td>
</tr>
<tr>
<td>Patient Information and Consent*</td>
<td>2014</td>
</tr>
<tr>
<td>National Red Cell Survey</td>
<td>2014</td>
</tr>
<tr>
<td>Transfusion in Sickle Cell Disease</td>
<td>2014</td>
</tr>
<tr>
<td>Surgical Patient Blood Management</td>
<td>2015</td>
</tr>
</tbody>
</table>

**UK NHS Hospital participation rate is very high-usually >90%**

Comparison to standards and to other participating sites nationally, regionally and locally.

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### AFFINETE project

- NCA working with behavioral psychologists
- Evaluating the most effective way of using audit and feedback to influence practice
- 2 paired audits with hospitals randomised to receive different reports and feedback tools to try and improve change
  - Audit of Surgical Patient Blood management
  - Audit of Transfusion In Haematology Patients
- Potential to work with SHOT to see if improved practice impacts on adverse patient events

NIHR-funded Programme Grant
PI Dr. Simon Stanworth
Proficiency Testing in the UK

UK NEQAS for Blood Transfusion Laboratory Practice
- Regular assessment of blood group serology and associated processes
- Simulated patient samples with ‘unknown’ results but designed to test the range seen by hospital transfusion laboratories
- Errors in external quality assessment (EQA) provide a ‘free lesson’ for all participants – no patient harm
- Paper exercises and questionnaires used to understand trends in practice

Two Transfusion Pathways……..

……where there is some room for improvement

- Giving the right blood to the right patient
  - Prevention of ABO incompatible transfusion

- Giving anti-D Ig prophylaxis to RhD negative pregnant women
  - Prevention of HDFN due to immune anti-D
The Transfusion Pathway

- Decide to transfuse and consent the patient
- Test blood group and sensitivity screen
- Collect blood from main fridge
- Monitor patient for adverse effects
- Issue compatible blood
- Check and administer blood
- Record outcome of transfusion
ABO-incompatible RBC transfusion

- Causes potentially fatal haemolytic transfusion reaction
- One of the most serious but preventable errors of transfusion
- National Patient Safety Agency - Safer Practice Notice made recommendations with the aim of reducing these events by 50%
  - Correct identification of patient, sample and unit at all stages of the transfusion process
- Included in DH list of ‘Never Events’
Last Year’s SHOT Recommendation

All ABO-incompatible red cell transfusions to be included as ‘never events’: ABO-incompatible red cell transfusions may be fatal and are absolutely preventable. The two thirds that do not result in harm should be included as reportable ‘never events’.

Outcome: NHS England, patient safety domain has published a revised ‘Never Events’ list (March 27th 2015).
Relevant Guidelines

- **BCSH Administration Guidelines**
  - Importance of 4 core patient identifiers at all stages of identification of patient, samples and blood bags
  - Positive patient identification for sampling and bedside checking

- **BCSH Pre-Transfusion Testing Guidelines**
  - Most important test is assigning correct ABO/D group and robust and accurate antibody screening
  - 2 methods of establishing compatibility before issuing blood with emphasis on the ‘group check’ or ‘2-sample rule’

SHOT: ABO incompatible RBC transfusions

- 9 ABO-incompatible red cell transfusions in 2013, 12 in 2012, 10 in 2014
- 2014 – all 10 were **clinical** errors
  - often multiple errors
    - 7 due to failure in correct patient identification, no bedside checks
    - 7 red cell transfusions of group A were given to group O patients; 2 were given in ‘emergency’ situations in theatre and 3 others were ‘urgent’.
Key Findings: Bedside Transfusion Practice

- 2.3% of patients were not wearing wristbands
  - 99.4% of wristbands contained the four core identifiers
- 85% of patients had all four pre-transfusion observations
  - 87% had observations within 30 minutes following the start of the transfusion

**Worst-case scenario**
- 3 cases had a transfusion with no wristband and no observations before, during or after transfusion (0.03% of all audited cases)
- 24 cases were given a transfusion with no wristband and no pre-transfusion observations (0.3% of all audited cases)

EQA error rates in UK are very low

Error Rates by Analyte in UK NEQAS Exercises 2011–2014

- During this period 40–88% of ABO errors were due to transcription/transposition (i.e. non-technical)
Annual UK NEQAS Questionnaire
(return rate 2014 = 77%)

- Manual testing is prone to error, automated testing is more secure
  - Test tube and microplates have been replaced by CAT other technologies
  - Transposition and transcription errors occur where there are manual steps
- Laboratory information management system (LIMS), analyser software and the computer interfaces between the analyser have to be robust and fully validated for the processes they support
  - Electronic issue is safe and efficient but not all IT systems are compliant with the regulations and automation is essential

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Automation for G&amp;S</td>
<td>86%</td>
<td>84%</td>
<td>74%</td>
<td>68%</td>
<td>41%</td>
</tr>
<tr>
<td>Electronic issue</td>
<td>53%</td>
<td>55%</td>
<td>46%</td>
<td>37%</td>
<td>10%</td>
</tr>
<tr>
<td>CAT for ABO/D</td>
<td>85%</td>
<td>86%</td>
<td>82%</td>
<td>77%</td>
<td>33%</td>
</tr>
<tr>
<td>CAT for AS</td>
<td>89%</td>
<td>91%</td>
<td>90%</td>
<td>90%</td>
<td>85%</td>
</tr>
<tr>
<td>CAT for XM</td>
<td>97%</td>
<td>98%</td>
<td>96%</td>
<td>96%</td>
<td>77%</td>
</tr>
</tbody>
</table>

Some definitions.....

A ‘near miss’ event: any error which if undetected, could result in the determination of a wrong blood group or transfusion of an incorrect component, but was recognised before the transfusion took place

A ‘wrong blood in tube’ incident: Blood is taken from the wrong patient and is labelled with the intended patient’s details or blood is taken from the intended patient, but labelled with another patient’s details
Key Findings: Sampling and Labelling of Pre-Transfusion Samples

- 2.99% of samples were mislabelled
  - 99 miscollected samples – not possible to state the WBIT rate
- 70% had ‘zero tolerance’ policy
  - 23% allowed deviations from their own policy
- Doctors were most likely to mislabel specimens
  - 38% could not be traced to a member of staff
- Commonest reasons for mislabelled samples were
  - transcription errors (33%) and distraction (24%)
- 64% had been competency assessed
  - phlebotomists (82%) healthcare assistants (73%) nurses (72%) doctors (49%)

Mislabelled samples cost time and money (estimated at £19 per rejected sample) so 38,570 from 220 sites over 3 months would result in an annual cost of nearly £3 million. This figure could be balanced against the cost of any system put in place to reduce transcription errors.

Preventing ABO incompatible transfusion

- BCSH Administration Guidelines
  - Importance of 4 core patient identifiers at all stages of identification of patient, samples and blood bags
  - Positive patient identification for sampling and bedside checking
- BCSH Pre-Transfusion Testing Guidelines
  - Most important test is assigning correct ABO/D group and robust and accurate antibody screening
  - 2 methods of establishing compatibility before issuing blood with emphasis on the ‘group check’ or ‘2-sample rule’
# Annual UK and ROI NEQAS Questionnaire

(returns rate 2014 = 77%)

<table>
<thead>
<tr>
<th>ABO check performed on a second sample?</th>
<th>2015</th>
<th>2014*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, for all patients</td>
<td>54%</td>
<td>44%</td>
</tr>
<tr>
<td>Yes, but only for EI</td>
<td>-</td>
<td>5%</td>
</tr>
<tr>
<td>No, but in process of implementing a group-check policy</td>
<td>20%</td>
<td>23%</td>
</tr>
<tr>
<td>No</td>
<td>26%</td>
<td>28%</td>
</tr>
</tbody>
</table>

*This varies according to UK country.

In 2014 the proportion of respondents stating that they had implemented, or were planning to implement, a ‘group-check’ policy was:

- England 74%
- Scotland 55%
- Wales 83%
- NI 75%
- ROI 36%

See the 2 related posters in main ISBT meeting; Milkins et al. and Watt et al.

![Bar chart showing near miss WBITs and WBITs leading to IBCI over the years](chart.png)
Anti-D prophylaxis

Impact of anti-D immunoglobulin prophylaxis on neonatal deaths

Improved obstetric and neonatal intensive care

800,000 pregnancies per year
15 - 20 deaths per year
SHOT 2014 Anti-D Administration Errors

359 case reports, 273 (76.0%) related to the omission or late administration of anti-D Ig

- There is still lack of knowledge and understanding about anti-D Ig prophylaxis (clinicians and laboratories)
  - E.g. RAADP incorrectly omitted if given for recent sensitising event

- Manual procedures result in mistakes
  - Transcribing blood grouping results onto maternity notes and care plans - IT systems should be used to transmit results
  - IT systems can also be used to control who should (and should not) get anti-D

- BCSH has just re-issued guidance on Anti-D Ig prophylaxis and RCOG have endorsed these guidelines and archived their own
National Audit of Anti-D Prophylaxis 2013

AUDIT STANDARDS
ROUTINE ANTENATAL ANTI-D PROPHYLAXIS, POST-DELIVERY PROPHYLAXIS and for POTENTIALLY SENSITISING EVENTS
Did all eligible RhD negative women receive anti-D Ig prophylaxis at the correct dose and the correct time?
(includes use of a Kleihauer/FMH test after 20 weeks and post delivery)

CONSENT and PATIENT INFORMATION
Were all RhD negative women given information about anti-D Ig prophylaxis and was consent to receive the injections documented?

Standards from BCSH and NICE guidelines

Comparison of the year RAADP was introduced in audited hospitals compared to when evidence and guidelines were published

Organisational questionnaire, 147 sites
Audit Results: 161 sites (232 maternity units) participated in the audit, 5972 clinical cases audited in one month of bookings, median cases audited per site = 33 (IQR 19-49), estimated 78% of eligible RhD negative deliveries were audited.

<table>
<thead>
<tr>
<th>Indication (number of eligible RhD - women)</th>
<th>% given anti-D Ig prophylaxis</th>
<th>% given right dose at right time</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAADP (5276) – 39 women did not get any RAADP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-dose 1500 IU at 28-30 weeks*</td>
<td>99.0%</td>
<td>89.9%</td>
</tr>
<tr>
<td>Two-dose 500 IU at 28 and 34 weeks</td>
<td>98.7%</td>
<td>58.6%</td>
</tr>
<tr>
<td>POST DELIVERY (3392) – 19 women did not get any PD anti-D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard dose Anti-D Ig**</td>
<td>98.5%</td>
<td>91.6%</td>
</tr>
<tr>
<td>Kleihauer?</td>
<td>Yes in 97%</td>
<td></td>
</tr>
<tr>
<td>POTENTIALLY SENSITISING EVENTS (924)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard dose Anti-D Ig**</td>
<td>95.7%</td>
<td>79%</td>
</tr>
<tr>
<td>Kleihauer after 20 weeks?</td>
<td>Yes in 87%</td>
<td></td>
</tr>
</tbody>
</table>

*95% of maternity units use 1500 IU for RAADP, 5% use 500 IU twice.
**33% of units use 1500 IU for PD prophylaxis and PSE after 20/40 (covers 12mL FMH), 66% use 500 IU (cover 4mL FMH).

Reasons for omission of Post–delivery anti-D

<table>
<thead>
<tr>
<th>ANTI-D OMISIONS</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Declined anti-D Ig</td>
<td>9</td>
<td>27%</td>
</tr>
<tr>
<td>Hysterectomy or sterilisation post delivery</td>
<td>3</td>
<td>9%</td>
</tr>
<tr>
<td>Immune anti-D at delivery</td>
<td>2</td>
<td>6%</td>
</tr>
<tr>
<td>Acceptable reason for omission of anti-D</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>No postnatal bloods taken</td>
<td>1</td>
<td>3%</td>
</tr>
<tr>
<td>Did not attend for anti-D Ig injection</td>
<td>2</td>
<td>6%</td>
</tr>
<tr>
<td>Recent anti-D Ig for PSE so anti-D ‘not deemed necessary’</td>
<td>3</td>
<td>9%</td>
</tr>
<tr>
<td>Laboratory error</td>
<td>2</td>
<td>6%</td>
</tr>
<tr>
<td>Omission investigated but reason unknown</td>
<td>7</td>
<td>22%</td>
</tr>
<tr>
<td>No comment on omission of anti-D</td>
<td>4</td>
<td>12%</td>
</tr>
<tr>
<td>Anti-D should have been given and wasn’t</td>
<td>19</td>
<td></td>
</tr>
</tbody>
</table>
Kleihauer (FMH) test

Post delivery:
97% had a FMH test
- 88.1% < 2mL of fetal cells
- 3% had a confirmed FMH of >4mL
- 0.5% (15 cases) needed additional anti-D Ig

PSEs >20 weeks:
87% had a FMH test
- 1.6% (11 cases) had a confirmed FMH of more than 4mL

Booking weight

Data from 5430 women
- Range 29-186 Kg
- Mean = 70.4 Kg
- Median = 66.6 Kg
- Greater than or equal to
  - 100 Kg = 6.5% (353)
Data from 5263 women

23% of deliveries were after 40 weeks of gestation

UK NEQAS for Fetomaternal Haemorrhage

- 2 simulated FMH samples every 2 months
- Test by your usual method: by acid elution and/or flow cytometry
- Accuracy of FMH estimation (compared to method median)
- Decision-making and clinical significance of results
  - Significantly outlying results [Deviation Index <2.5 or >3.5]
  - Was the sample quantified?
  - Would you refer the sample for flow cytometry?
  - Would you request a follow-up sample
  - How much anti-D Ig would you give?

Analytical performance score <80 = satisfactory, >80<100 = borderline, >100 = unsatisfactory
Performance in FMH EQA in UK

 Participating Laboratories
141 quantify FMH by acid elution (AE), 43 ‘screen only’ – no quantification
14 quantify by FMH flow cytometry (FC), 19 test by AE and FC

<table>
<thead>
<tr>
<th>Category of unsatisfactory performance</th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score &gt;100</td>
<td>17</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Outlying results – underestimation</td>
<td>48</td>
<td>27</td>
<td>27</td>
</tr>
<tr>
<td>Outlying results - overestimation</td>
<td>14</td>
<td>27</td>
<td>11</td>
</tr>
<tr>
<td>Risk of sensitisation – screen only labs</td>
<td>1</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>Risk of sensitisation – quantification labs</td>
<td>3</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Non return</td>
<td>1</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Scoring system was revised

SHOT Anti-D Sensitisation Study

- Immunisation to the D antigen in women of childbearing potential continues to occur
  - Anti-D audit showed 39 women (0.65%) with immune anti-D at booking/before 28 weeks and another 2 at delivery
  - Anti-D Ig errors reported to SHOT include mistakes in decision making, communication and testing but outcome is not known
  - EQA errors, if translated to clinical practice, could result in incorrect or inadequate anti-D Ig doses
- SHOT set up this study to collect and analyse the reason for sensitisation (2012-2014)
  - “All cases of anti-D immunisation detected for the first time in pregnancy should be reported to SHOT”
Summary

- We have fantastic support from hospitals who participate in SHOT, NCA and EQA
- The purpose of these initiatives is to progressively improve patient care through understanding what is best and sharing what goes wrong
- Despite the increasing burden of participation and pressure on resources at a hospital level we are making progress

Acknowledgements

National Comparative Audit
Chair Steering Group: Prof. Mike Murphy
Manager: John Grant Casey
Project Leads: All my NHSBT patient-facing consultant colleagues (at one time or another!)

UK NEQAS for Blood Transfusion Laboratory Practice
Chair Steering Group: Peter Baker
Manager and Deputy Director: Clare Milkins
Deputy Manager: Jenny White

BCSH Transfusion Taskforce
Chair: Shubha Allard

SHOT: the Office, the Working Expert Group and the Steering Group

And, of course, all of you who participate in these initiatives – without you it wouldn’t happen!