Highlights from the 2018 SHOT report

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Transfusion

DONOR

PATIENT
World Blood Donor Day – 14th June

By donating blood, you can save lives!

Everyone should have access to safe blood transfusions, when and where they need them.

Safe Blood For All
Trend in number of donations collected in the UK 2015-2018
SAED by category reported from the four UKBTS in 2018

SAED - Serious Adverse Event following Donation

- Arm pain >12/12 post donation: NHSBT 11, SNBTS 1, WBTS 2, NIBTS 2
- Hospital admission within 24 hours of donation: NHSBT 10, SNBTS 2
- Fracture: NHSBT 8, SNBTS 1, WBTS 1
- Other: NHSBT 1, SNBTS 1
- Road traffic collision <24 hours of donation: NHSBT 1
- Acute coronary syndrome: NHSBT 1
- Air embolism: NHSBT 1
- Donor death <7/7 of donation: NHSBT 1
Rate of Serious Adverse Events of Donation (SAED) reported per 10,000 donations in the UK from 2015-2018
Serious Adverse Events following Blood Donation reported to the UK Blood Services in 2018

In 2018 the UK Blood Services collected approximately 1.9 million donations. Forty three serious adverse events of donation (SAED) were reported (1 in 43,794 donations). Serious adverse events are very rare following blood donation but do occur and can have a significant impact on donor health and donor retention.

Breakdown of Serious Adverse Events in 2018

**SAED Categories n=43**

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute events</td>
<td>12</td>
</tr>
<tr>
<td>Fracture</td>
<td>9</td>
</tr>
<tr>
<td>Other,2</td>
<td></td>
</tr>
<tr>
<td>Death,1</td>
<td></td>
</tr>
<tr>
<td>Hospital Admission, 12</td>
<td></td>
</tr>
<tr>
<td>Other*</td>
<td></td>
</tr>
<tr>
<td>Misc. Infection, 10</td>
<td></td>
</tr>
<tr>
<td>Abnormal thiefology</td>
<td>3</td>
</tr>
<tr>
<td>FVC, 1</td>
<td></td>
</tr>
<tr>
<td>Other,3</td>
<td></td>
</tr>
</tbody>
</table>

**Key Messages**

- 2/43 SAED related to lower limb deep vein thrombosis following donation.
- 89 fractures were related to vasovagal reactions, 4 immediate and 4 delayed reactions.
- 1 report of a donor death 47 days of donation and 1 report of acute coronary syndrome 48 hours of donation.
- Complications during or following donation can happen despite the safety measures in place.
- Arm problems occurring to needle insertion persisting for more than a year and vasovagal events resulting in donor hospitalisation or injury continue to be the most frequently reported SAED.

**Summary**

- 15/43 SAED were as a direct result of a vasovagal reaction.
- 16/43 SAED were related to persistent arm problems 12/12 post donation.
- 7/40 donors who suffered an SAED were withdrawn from future donation.

**Key Themes**

- Improve donor safety
- Improve donor retention
- Improve donor experience
- Increase BAME donors
- Fragile donor base
Trend in the blood components issued in UK 2011-2018

Data from SHOT regarding blood components issued in UK between 2011-2018
Units of whole blood and red cells transfused per 1000 population in countries

Global status report on blood safety and availability 2016
ISBN 978-92-4-156543-1
Number of reports submitted to SHOT, and per 10,000 components issued 2010-2018
Summary data for 2018 all categories n=3326 (ranked by number)
Cumulative data for all SHOT categories 1996 to 2018; n=21474

- UCT: Unclassifiable complications of transfusion
- PTP: Post-transfusion purpura
- TTI: Transfusion-transmitted infection
- CS: Cell salvage
- FAHR: Febrile, allergic and hypotensive reactions
- TAD: Transfusion-associated dysproea
- TRALI: Transfusion-related acute lung injury
- TACO: Transfusion-associated circulatory overload
- TACvHID: Transfusion-associated graft-vs-host disease
- Abo: Alloimmunisation
- HTR: Haemolytic transfusion reactions

- ADU: Over or under transfusion and PCC
- ADU: Delayed transfusion
- ADU: Avoidable transfusion
- HSE: Handling and storage errors
- Anti-D: Anti-D immunoglobulin errors
- IBCT: Incorrect blood component transfused

Legend:
- Red: Cumulative to 2017
- Blue: 2018

- Transfusion reactions which may not be preventable
- Possibly or probably preventable by improved practice and monitoring

Adverse incidents due to mistakes
Categorisation of reports analysed in 2018

- Total reports: 3326
- Incidents: 1659
  - Near miss: 1451 (87.3%)
    - RBRP: 216
      - All errors: 1238 (74.6%)
  - Pathological reactions: 396 (23.9%)
  - Others (CS & UCT): 25 (1.5%)

RBRP = right blood right patient; CS = cell salvage; UCT = unclassifiable complications of transfusion
Errors account for the majority of reports in 2018: 2905/3326 (87.3%)
Mortality and major morbidity data by reporting category in 2018

<table>
<thead>
<tr>
<th></th>
<th>Death definitely related</th>
<th>Death probably related</th>
<th>Death possibly related</th>
<th>Major morbidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delayed transfusion</td>
<td>2</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overtransfusion</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>FAHR</td>
<td></td>
<td></td>
<td></td>
<td>60</td>
</tr>
<tr>
<td>HTR</td>
<td></td>
<td></td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>IBCT-WCT (clinical)</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>IBCT-WCT (laboratory)</td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>IBCT-SRNM (laboratory)</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>UCT</td>
<td></td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>TACO</td>
<td>2</td>
<td></td>
<td>3</td>
<td>36</td>
</tr>
<tr>
<td>TAD</td>
<td></td>
<td></td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>TRALI</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>TTI</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>0</strong></td>
<td><strong>8</strong></td>
<td><strong>12</strong></td>
<td><strong>109</strong></td>
</tr>
</tbody>
</table>

FAHR = febrile, allergic and hypotensive reactions; HTR = haemolytic transfusion reaction; IBCT-WCT = incorrect blood component transfused; IBCT-SRNM = IBCT-specific requirements not met; UCT = unclassifiable complications of transfusion; TACO = transfusion-associated circulatory overload; TAD = transfusion-associated dyspnoea; TRALI = transfusion-related acute lung injury; TTI = transfusion-transmitted Infection
Deaths related to transfusion (with imputability) reported in 2018
n=20

Preventable deaths n=14/20 (70.0%)
Transfusion-related deaths 2010 to 2018 n=156

- Delays: 39 (25.0%)
- Other: 18
- HTR: 13 (11.6%)
- Febrile/allergic reactions: 5 (3.2%)
- Pulmonary complications: 81 (51.9%)
- TACO: 65 (41.7%)
- TAD: 10 (6.4%)
- TRALI: 6 (3.8%)

HTR = haemolytic transfusion reaction; TRALI = transfusion-related acute lung injury; TACO = transfusion-associated circulatory overload; TAD = transfusion-associated dyspnoea

SHOT - Serious Hazards of Transfusion
Reports of pulmonary complications by year: 2008-2018

TRALI=transfusion-related acute lung injury; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea
Number of confirmed TRALI cases and deaths at least possibly related to TRALI by year of report

TRALI = transfusion-related acute lung injury
# Updated TACO pre-transfusion checklist

<table>
<thead>
<tr>
<th>TACO Checklist</th>
<th>Red cell transfusion for non-bleeding patients</th>
<th>If ‘yes’ to any of these questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Heart]</td>
<td>Does the patient have a diagnosis of ‘heart failure’ congestive cardiac failure (CCF), severe aortic stenosis, or moderate to severe left ventricular dysfunction?</td>
<td></td>
</tr>
<tr>
<td>![Lungs]</td>
<td>Is the patient on a regular diuretic?</td>
<td></td>
</tr>
<tr>
<td>![Water Droplet]</td>
<td><strong>Does the patient have severe anaemia?</strong></td>
<td></td>
</tr>
<tr>
<td>![Lungs]</td>
<td>Is the patient known to have pulmonary oedema?</td>
<td></td>
</tr>
<tr>
<td>![Water Droplet]</td>
<td>Does the patient have respiratory symptoms of undiagnosed cause?</td>
<td></td>
</tr>
<tr>
<td>![Water Droplet]</td>
<td>Is the fluid balance clinically significantly positive?</td>
<td></td>
</tr>
<tr>
<td>![Water Droplet]</td>
<td>Is the patient on concomitant fluids (or has been in the past 24 hours)?</td>
<td></td>
</tr>
<tr>
<td>![Water Droplet]</td>
<td>Is there any peripheral oedema?</td>
<td></td>
</tr>
<tr>
<td>![Water Droplet]</td>
<td>Does the patient have hypoalbuminaemia?</td>
<td></td>
</tr>
<tr>
<td>![Water Droplet]</td>
<td>Does the patient have significant renal impairment?</td>
<td></td>
</tr>
</tbody>
</table>

1. **Review the need for transfusion (do the benefits outweigh the risks)?**
2. **Can the transfusion be safely deferred until the issue can be investigated, treated or resolved?**
   - Consider body weight dosing for red cells (especially if low body weight)
   - Transfuse one unit (red cells) and review symptoms of anaemia
   - Measure the fluid balance
   - Consider giving a prophylactic diuretic
   - Monitor the vital signs closely, including oxygen saturation

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Due to the differences in adult and neonatal physiology, babies may have a different risk for TACO. Calculate the dose by weight and observe the notes above.

**TACO** = transfusion-associated circulatory overload
TACO and TRALI update in 2019


Delayed transfusion reports by year 2010-2018

In 13 cases delays were experienced during MHP activation and in a further 6 cases with major haemorrhage but without MHP activation.

Delays can contribute to patient death. Every second counts!
Location of major haemorrhage incidents

- Emergency department: 13
- Theatre: 13
- Ward: 2
- Delivery suite: 3
- Medical admissions unit: 3

76.5% in Theatre & ED
Poor communication is the most common factor contributing to errors in MHP-related reports (results as %)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>88.2%</td>
</tr>
<tr>
<td>Procedures not followed</td>
<td>47.1%</td>
</tr>
<tr>
<td>Lack of knowledge</td>
<td>38.3%</td>
</tr>
<tr>
<td>Porter availability</td>
<td>17.6%</td>
</tr>
<tr>
<td>Equipment failure</td>
<td>14.7%</td>
</tr>
<tr>
<td>Assumptions</td>
<td>8.8%</td>
</tr>
<tr>
<td>Staff shortages</td>
<td>8.8%</td>
</tr>
<tr>
<td>IT issues</td>
<td>8.8%</td>
</tr>
<tr>
<td>Sample errors</td>
<td>5.9%</td>
</tr>
</tbody>
</table>

*IT = information technology*
ABO-incompatible transfusions
ABO- incompatible blood transfusions

Never Events

Red category events
ABO- incompatible blood transfusions

Preventable
ABO incompatible transfusions in 2018
n=7

- Red cells: 4
- FFP: 2
- Cryoprecipitate: 1
ABOi transfusions in UK as reported to SHOT 2010-2018

Majority (60 out of 74, 81%) were ABOi red cell transfusions
Number of ABO-incompatible red cell transfusions where the first error occurred or had the potential to be identified at the administration step 2010-2018

55 reported cases
41 administration errors

Error had potential to be identified at administration step
Error unable to be identified at administration step

Actions to improve bedside checks
2015-2017 SHOT recommendation to use a bedside checklist
2017 DH CAS alert
2018 administration video released

DH=Department of Health; CAS=central alerting system
Number of ABO-incompatible red cell transfusions
1996-2018
Transfusion process (nine steps)

1. REQUEST
2. SAMPLE TAKING
3. SAMPLE RECEIPT
4. TESTING
5. COMPONENT SELECTION
6. COMPONENT LABELLING
7. COMPONENT COLLECTION
8. PRESCRIPTION
9. ADMINISTRATION

Note: Once a decision to transfuse is made, the authorisation or prescription may be written at variable times during this sequence, but must be checked at the final stage.
ABO-incompatible red cell transfusions
2016 to 2018

8 ABO-incompatible red cell transfusions

907 ABO-incompatible near miss events
Reports of WBIT 2010 to 2018
Overview of reports where an incorrect blood component was transfused in 2018 n=272

Incorrect blood component transfused n=272 (100%)

- Clinical: 112 (41.2%)
- Laboratory: 160 (58.8%)

Wrong component transfused n=78
- Clinical: 32 (41.0%)
- Laboratory: 46 (59.0%)

Specific requirements not met n=194
- Clinical: 80 (41.2%)
- Laboratory: 114 (58.8%)
Laboratory incidents and near misses by category of outcome n=885

WCT = wrong component transfused; SRNM = specific requirements not met; HSE = handling and storage errors; RBRP = right blood right patient; Ig = immunoglobulin
SHOT laboratory data (n=530) showing at which stage in the transfusion process the primary error occurred.
SHOT near miss laboratory errors (n=355) showing at which stage in the transfusion process the primary error occurred with outcome.

WCT = wrong component transfused; SRNM = specific requirements not met; HSE = handling and storage errors; RBRP = right blood right patient; Ig = immunoglobulin.
Key SHOT messages from laboratory errors

- Many of the incidents reported appeared to result from failure to follow correct procedures, inadequate processes, omitting steps or wrong procedure being performed.

- Robust root cause analysis using ergonomics/human factors approach should be undertaken to identify quality management systems (QMS) improvements to mitigate these errors.

- All laboratory staff must complete annual good manufacturing practice (GMP) training (European Commission 2015).

- Key SHOT messages from the 2017 Annual SHOT Report for laboratory staff on knowledge and skills, shared responsibility and information technology (IT) remain pertinent (Bolton-Maggs et al. 2018).
## Anti-D errors in 2018

<table>
<thead>
<tr>
<th>Error Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omission or late administration of anti-D Ig</td>
<td>272</td>
</tr>
<tr>
<td>Anti-D Ig handling and storage errors</td>
<td>111</td>
</tr>
<tr>
<td>Anti-D Ig given to a D-positive woman</td>
<td>20</td>
</tr>
<tr>
<td>Anti-D Ig given to a woman with immune anti-D</td>
<td>17</td>
</tr>
<tr>
<td>Anti-D Ig given to the mother of a D-negative infant</td>
<td>17</td>
</tr>
<tr>
<td>Wrong dose of anti-D Ig given</td>
<td>13</td>
</tr>
<tr>
<td>Right product right patient</td>
<td>8</td>
</tr>
<tr>
<td>Anti-D Ig given to the wrong woman</td>
<td>5</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>5</td>
</tr>
</tbody>
</table>
Hyperhaemolysis remains a cause of transfusion-related mortality and major morbidity. Patients with haemoglobinopathies should be monitored for signs and symptoms of haemolysis following transfusions and diagnosis of hyperhaemolysis considered early. It is important that patients are educated about signs and symptoms they might develop when discharged home so they can present early should any of these occur.

Hyperhaemolysis can also occur in non-haemoglobinopathy patients therefore it is important that all clinicians involved in the transfusion process have an awareness of the signs and symptoms of hyperhaemolysis and that any suspected cases are followed up and investigated - two cases reported in 2018 in non-sickle patients resulting in patient death.
Cumulative data for adverse events in transfusion for patients with haemoglobin disorders 2010 to 2018
Sickle cell disease n=228

HTR=haemolytic transfusion reaction; SRNM=specific requirements not met; FAHR=fabrile, allergic and hypotensive reaction; ADU=avoidable, delayed and under or overtransfusion; IBCT=incorrect blood component transfused; TACO=transfusion-associated circulatory overloaded; TAD=transfusion-associated dyspnoea; TTI=transfusion-transmitted infection
Cumulative data for adverse events in transfusion for patients with haemoglobin disorders 2010 to 2018
Thalassaemia n=52

FAHR 40.4%

HTR=haemolytic transfusion reaction; SRNM=specific requirements not met; FAHR=febrile, allergic and hypotensive reaction; ADU=avoidable, delayed and under or overtransfusion; IBCT=incorrect blood component transfused; TACO=transfusion-associated circulatory overload;
Transfusion-associated graft-v-host disease

Irradiation of cellular components was missed in 81 patients in 2018. In 64/81 (79.0%) cases the error was made in clinical areas and 17 in the laboratory. The cumulative number of reports of patients known to have missed irradiation is now 1478 since 1999.

No case of TaGVHD reported in 2018
The number of cases of PTP with confirmed HPA alloantibodies reported annually to SHOT since 1996, a total of 57 reports. Cumulative data 1996 to 2018.
Bacterial transmissions 1996-2018

- **Diversion pouch** 2003
- **Bacterial screening** 2010

2016: No bacterial transmissions  
4 near misses  
2017: 1 possible transmission  
2018: 1 probable TTI and 1 late detection but no evidence of TTI
Outcome of reports of suspected TTI made to the NHSBT/PHE Epidemiology Unit in 2018

TTI=transfusion-transmitted infection; HAV=hepatitis A virus; HBV=hepatitis B virus; HSV=herpes simplex virus; HIV=human immunodeficiency virus; HEV=hepatitis E virus

*The Bact/ALERT system flagged as positive after the associated platelets had been issued and transfused however no evidence of a TTI was found

**Reported based on a clinical diagnosis of HAV, but this was not confirmed by further laboratory testing

***Due to the time elapsed since transfusion archive samples were not available for half of the implicated donations
Summary of paediatric reports by category and age for 2018

IBCT = incorrect blood component transfused; FAHR = febrile, allergic and hypotensive reactions; HSE = handling and storage errors; TACO = transfusion-associated circulatory overload; TTI = transfusion-transmitted infection; UCT = unclassifiable complications of transfusion.
One death was reported secondary to TACO, in part attributable to an error in the process of performing an exchange transfusion.

Paediatric FAHR most often occurred following platelet transfusions (21/30; 70.0%), the usual FAHR pattern for paediatrics.

Four errors were caused by acting on inaccurate or old blood results.

Communication errors continue to be an issue across categories.

Errors related to transfusion volumes remain an issue (6 cases).

Paediatric reports = 7.2% of total cases reported in 2018.
Human factors approach...
Since 2016, reporters to SHOT have been asked to score (0-10) the extent to which the cause of incidents can be attributed to key factors – staff, environmental, organisational and government/regulatory which helps recognise the key factors identified while investigating these incidents.
SHOT Human Factors Investigation Tool (since 2016...)

Staff asked to score 0-10 under each category as being key factors identified whilst investigating incidents.
Healthcare Challenges

Changes in structure and functioning of the NHS

Social, Economic and political factors

Changes in education & training

Workforce challenges

Variation in practice, patient experiences, outcomes
The Four Varieties of Human Work

Work-as-Imagined

Work-as-Disclosed

Work-as-Prescribed

Work-as-Done

Designing for work as done
User centred/
human centred processes
Essentially...

Make it easier to do the right thing/follow the right process

Make it difficult to deviate or do the wrong thing

Safer system

Safety is not just about checklists, team work or human factors

It is about checklists AND teamwork AND human factors – and many other things besides

Situation Awareness
Decision making
Leadership
Resilience
Coping with stress
LEAP TO Transfusion safety

- Strong, supportive, shared, authentic leadership
- Adding the ‘why’ to the ‘what’ and ‘how’ in education
  - Interprofessional learning, interactive, technology enhanced learning
- Everyone counts
  - Appropriate resource allocation
  - Design processes that are easy to follow and build safer systems
- Learning culture
  - Just culture
  - Empowered and engaged staff

Safer transfusion practices and improved patient safety

SHOT: Serious Hazards of Transfusion
Learning from near misses is vital to prevent future incidents

Investigating incidents should be thorough and systematic and identify systemic issues

Rethinking transfusion education - technology enhanced learning, learning in teams, non-technical skills training, patient safety training and human factors awareness is needed

Staffing challenges including staff shortages, gaps in skill mix need to be addressed to improve safety

Standard operating procedures need to be simple, clear, easy to follow and explain the rationale for each step - this will help engage staff and improve compliance
All clinical and laboratory Standard Operating Procedures (SOP) must be CLEAR

| C | • Clear and concise |
| L | • Logical and meaningful |
| E | • Easy to follow and effective |
| A | • Always workable and simple |
| R | • Realistic and relevant |
All NHS organisations must move away from a blame culture and towards a just and learning culture.

All clinical and laboratory staff should be encouraged to become familiar with human factors and ergonomics concepts.

All transfusion decisions must be made after carefully assessing the risks and benefits of transfusion therapy. Collaboration and co-ordination among staff are vital.
Just Culture

Patients and families must be given a complete explanation of what has gone wrong.

Both the organisation and its people are held accountable while focussing on risk, systems design, human behaviour and patient safety.

Deliberate neglect/wilful harm by health care professionals should certainly mean that they are held accountable by the law.

Health care professionals must be enabled to truly learn and understand errors and be encouraged to admit them. The system should be equally scrutinised as judgements are often made when under pressure/lack of resources.
The A-E Decision Tree to facilitate decision making in transfusion

A
- Assess patient
- Any avoidable blood loss (frequent, unnecessary tests/interventions)

B
- Blood results (all) reviewed including trends - valid and reliable
- Best treatment option - is transfusion the best treatment option? If yes, what components needed, how many, what order and any specific requirements needed?

C
- Consent for transfusion
- Correctable factors - address all correctable factors like bleeding, haematinic deficiency

D
- Do not forget other measures (vitamin K, tranexamic acid, cell salvage)
- Do not hesitate to challenge
- Do not forget to document

E
- Ensure communications with laboratory
- Evidence-based decisions
Further steps.....

Culture matters! Encourage reporting, investigate thoroughly, identify and address systemic issues

Simplified processes
Clear SOPs

Transfusion teams

Adequate staffing and other resources

Improving transfusion education,
Multiprofessional learning,
Improved communication
Non-technical skills training
Human factors awareness

Share lessons learnt
Celebrate successes

Culture matters! Encourage reporting, investigate thoroughly, identify and address systemic issues
Acknowledgements

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• The UK Forum for funding

For further information visit: www.shotuk.org