FIGURES FROM THE ANNUAL SHOT REPORT 2019

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Figure 1.1: Risk of harm or death from blood transfusion in the UK

- 4248 reports submitted to SHOT in 2019
- 2.3 million blood components issued in the UK in 2019
- Risk of death approximately 1 in 135,705 and of serious harm 1 in 17,884 components issued in the UK

The risks of transfusion-transmitted infection are much lower than all other transfusion-related complications

Note: This is a representative image and not accurate to scale
Figure 2.1: Status of reports submitted to SHOT in the calendar year 2019

- **4248 total reports**
  - Included in the 2019 Annual SHOT Report: 3060
  - Withdrawn: 679
  - Incomplete on 31 December 2019: 461
  - Anti-D immunisation: 46

Note: 2 reports are not included on this figure as they were reported to Public Health England (PHE) and discussed in the 2018 SHOT Annual Report, but not reported to SHOT until 2019
Figure 2.2: Number of reports submitted to SHOT, and per 10,000 components issued 2010-2019

- **Number of reports**
- **Reports per 10,000 components**
Haemovigilance refers to the systematic surveillance of adverse reactions and adverse events related to transfusion with the aim of improving transfusion safety. The infographic below captures the flow of haemovigilance data and the process of gathering intelligence from the submitted reports to make recommendations to improve patient safety in transfusion.

**Who reports?**
Nominated person/s from Trusts/Health Boards (This is usually either the transfusion practitioner or transfusion laboratory manager)

**What to report?**
Serious adverse events or reactions relating to transfusion, categorised according to the SHOT definitions criteria which are reviewed and updated annually. Information relating to investigations of these incidents and the corrective and preventative actions instituted is also collected.

**How to report?**
Initial reports are submitted via the MHRA online portal (SABRE)

**What happens to these reports?**
Reports are transferred to SHOT automatically via the SABRE/SHOT interface, and reporters are asked to complete additional detailed questions.

**What happens next?**
On a monthly basis, completed reports are downloaded, collated, triaged and reviewed by the Haemovigilance Data Manager, Clinical Incidents Specialist and Laboratory Incidents Specialist at SHOT.

**Who evaluates these reports?**
SHOT Working Expert Group (WEG) members then review the cases, assess imputability and may either accept/withdraw/transfer cases or request further information as appropriate.

**What happens next?**
SHOT confirms all the SAR to MHRA which is the competent authority for BSQR. Urgent actions are recommended to improve patient safety in transfusion, as needed, after consultation with the wider SHOT SG/WEG group. All learning points, key SHOT messages with illustrative cases are included in the Annual SHOT Report released in July each year and available freely online. Key recommendations are made to improve transfusion safety and enable sustained change.

Collecting and reviewing reports helps identify safety risks and develop appropriate risk reduction measures more effectively. As haemovigilance is an ongoing exercise, SHOT can also monitor the effect of the implementation of its recommendations.
Figure 2.4: The last time a report was received on SABRE from an active SABRE account
Figure 2.5: Number of 2019 reports by reporting organisation and component usage level
Figure 2.6: Percentage of SHOT reports submitted by UK country
Figure 2.7: Trend of error reports from different departments

a. Emergency departments

b. Theatres

c. General wards

d. Adult critical care
Figure 3.1: Errors account for most reports: 2857/3397

- **Errors**: 84.1% (2857)
- **Not preventable**: 10.3% (349)
- **Possibly preventable**: 5.6% (191)
Figure 3.2: Deaths related to transfusion (with imputability) reported in 2019 n=17

Preventable deaths n=5/17 (29.4%)
Delays include 1 delay due to PCC in 2019; HTR includes 2 deaths due to ABO-incompatibility; “Other” includes 1 each for post-transfusion purpura, transfusion-associated graft-versus-host disease (2012) and anti-D related; there were 7 in the avoidable, over or undertransfusion category, 3 transfusion-transmitted infections, and 9 deaths related to other unclassified reactions.

TRALI=transfusion-related acute lung injury; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea; HTR=haemolytic transfusion reaction; FAHR=febrile, allergic and hypotensive reaction.
Figure 3.4: Summary data for 2019, all categories (includes RBRP and NM) n=3397

- NM: Near miss
- Anti-D: Anti-D immunoglobulin errors
- IBCT: Incorrect blood component transfused
- HSE: Handling and storage errors
- FAHR: Febrile, allergic and hypotensive reactions
- RBRP: Right blood right patient
- TACO: Transfusion-associated circulatory overload
- ADU: Delayed transfusion
- ADU: Avoidable transfusion
- HTR: Haemolytic transfusion reactions
- ADU: Over or undertransfusion
- CS: Cell salvage
- TAD: Transfusion-associated dyspnoea
- ADU: Prothrombin complex concentrates (PCC)
- UCT: Uncommon complications of transfusion
- TRALI: Transfusion-related acute lung injury
- TTI: Transfusion-transmitted infection
- PTP: Post-transfusion purpura
- TAGvHD: Transfusion-associated graft-vs-host disease

- Error
- Not preventable
- Possibly preventable

Total: 1314
Figure 3.5: Cumulative data for SHOT categories 1996-2019 n=23341

UCT: Uncommon complications of transfusion
PTP: Post-transfusion purpura
TTL: Transfusion-transmitted infection
CS: Cell salvage
FAHR: Febrile, allergic and hypotensive reactions
TAD: Transfusion-associated dyspnoea
TRALI: Transfusion-related acute lung injury
TACO: Transfusion-associated circulatory overload
TAGvHD: Transfusion-associated graft-vs-host disease
Allo: Alloimmunisation
HTR: Haemolytic transfusion reactions
ADU: Over or undertransfusion and PCC
ADU: Delayed transfusion
ADU: Avoidable transfusion
HSE: Handling and storage errors
Anti-D: Anti-D immunoglobulin errors
IBCT: Incorrect blood component transfused

Cumulative to 2018
2019

Transfusion reactions which may not be preventable
Possibly or probably preventable by improved practice and monitoring
Adverse incidents due to mistakes

*Data on alloimmunisation has not been collected since 2015*
Figure 3.6: Reported errors triangle

- Large number of near misses (1314) and right blood right patient (216)  
  \( \frac{1530}{2857} = 53.6\% \)

- Medium number of incidents \( \frac{1323}{2857} = 46.3\% \)

- Small number of deaths \( \frac{4}{2857} = 0.1\% \)
Figure 3.7: Number of ABO-incompatible red cell transfusions 1996-2019
Figure 3.8: ABO-incompatible transfusions 2016-2019: few events (n=12) but many near misses (n=1236)
Figure 4.1: Ten ‘Rights’ for safe transfusions

- Right patient to be transfused
- Right investigations when things go wrong and right actions to be taken
- Right response to the transfusion and outcome
- Right advice based on right results and right information
- Right questions or challenges to get the right information
- Right knowledge and understanding of transfusion principles and processes
- Right blood component for transfusion
- Right amount to be transfused at the right rate
- Right time for the transfusion
- Right to refuse blood transfusion and actions needed

SHOT: Serious Hazards of Transfusion
Figure 4.2: 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/Communication (adequate patient information—both verbal and written) to patients and where appropriate to families and carers
Correctable factors to be addressed like bleeding, haematinic deficiency

D
Do not forget other measures (vitamin K, tranexamic acid, cell salvage, etc)
Do not hesitate to question colleagues regarding decisions made and ask for rationale
Do not forget to document in patient’s notes and in discharge summaries

E
Ensure timely communications to laboratory- need to be clear, concise and accurate
Ensure all relevant transfusion checklists including TACO risk assessment and actions arising thereafter have been completed
Evidence based decisions made weighing risks, benefits and options available
Ensure patient receives adequate post transfusion information if transfusion given as a day case
System Building Blocks

- Service delivery
- Health workforce
- Health information systems
- Access to essential medicines
- Financing
- Leadership/Governance

Overall Goals/Outcomes

- Improved health (LEVEL AND EQUITY)
- Responsiveness
- Social and financial risk protection
- Improved efficiency

Figure 4.3: The WHO health system framework
Figure 5.1: Critical elements of a safety culture

- Reporting culture
- Just culture
- Flexible culture
- Learning culture
- Questioning culture

Safety culture in practice - key aspects
Figure 6.1: Rate of SAED reported per 10,000 donations in the UK from 2015-2019
Figure 6.2: Trend in number of donations collected in UK Blood Services 2015-2019

- **Whole blood donations**
- **Apheresis/component donations**
Figure 6.3: Summary of serious donor adverse events in the UK in 2019
Figure 7.1: Factors identified for one change likely to reduce recurrence of the incident (970 responses)

Factors identified in question responses:

- Staff member: 34.7% (337 responses)
- Environment: 36.3% (352 responses)
- Organisation: 26.9% (261 responses)
- Government/regulatory: 2.1% (20 responses)
Figure 7.2: Assessment of whether multiple contributory factors were assigned HF scores

- 4 factors: 513 (18.0%)
- 3 factors: 446 (15.6%)
- 2 factors: 607 (21.2%)
- 1 factor: 973 (34.1%)
- No score given: 318 (11.1%)
Figure 7.3: Evaluation of uptake of self-learning opportunity and comparative percentages of scores for human and organisational factors.
To improve patient safety, a combined approach using both Safety-I and Safety-II principles is essential.

- **Safety-I (Reactive)**
  - Respond when something happens or is categorised as an unacceptable risk.
  - As few things as possible go wrong.
  - Humans seen as a liability or hazard.
  - Investigation purpose: identify causes and contributory factors.

- **Safety-II (Proactive)**
  - Continuously trying to anticipate developments and events.
  - As many things as possible go right.
  - Humans seen as a resource for system flexibility and resilience.
  - Investigation purpose: understand how things usually go right to explain how things occasionally go wrong.

[Figure 7.4: Overview of Safety-I and Safety-II]
Figure 8.1: Distribution of anti-D Ig related error reports 2019 n=413

- Omission or late administration of anti-D Ig: 271
- Anti-D Ig handling and storage errors: 31
- Anti-D Ig given to the mother of a D-negative infant: 29
- Anti-D Ig given to a woman with immune anti-D: 24
- Anti-D Ig given to a D-positive woman: 19
- Miscellaneous: 14
- Anti-D Ig given to the wrong woman: 11
- Wrong dose of anti-D Ig given: 10
- Right product right patient: 4
Figure 8.2: The three main areas for late administration or omission of anti-D Ig 2019 n=271

- Following PSE n=129: 47.6%
- Post delivery n=79: 29.2%
- RAADP n=63: 23.2%
Figure 8.3: Location and time of errors associated with anti-D Ig administration
Figure 8.4: Overview of late administration or omission of Anti-D Ig

**RAADP n=63/271 (23.2%)**
- **Group and antibody screen at booking**: Administer anti-D Ig 1500IU at 28-30 weeks
- **Opportunity for error**: Dose incorrectly omitted after PSE
- **Corrective and preventative action**: Avoid transcription errors by printing results and placing those in the hand-held record

**Delivery n=79/271 (29.2%)**
- **Anti-D Ig should be administered within 72 hours of delivery if baby is D-positive**: Maternal blood and cord blood should be tested to confirm baby’s D-status
- **Opportunity for error**: Early discharge OR results not checked before discharge OR samples incorrectly labelled
- **Corrective and preventative action**: Review discharge protocols and arrange for anti-D Ig prophylaxis on day 2 when required for D-negative blood groups

**PSE n=129/271 (47.6%)**
- **Administer anti-D Ig within 72 hours of PSE**: Take bloods for Kleihauer then administer minimum of 500IU anti-D Ig prophylaxis
- **Opportunity for error**: Anti-D Ig can be administered within 10 days of PSE
- **Corrective and preventative action**: Ensure those with D-negative blood groups are aware of the risks associated with PSE

**RAADP n=63/271 (23.2%)**
- **Group and antibody screen at booking**: Administer anti-D Ig 1500IU at 28-30 weeks or 500IU at 28 weeks and 34 weeks
- **Opportunity for error**: Results incorrectly transcribed into the hand-held record
- **Corrective and preventative action**: Never use handwritten results to inform treatment decisions

**Corrective and preventative action**
- **Avoid transcription errors by printing results and placing those in the hand-held record**
- **Pre-plan for clinics and pre order anti-D Ig**
- **Review internal pathways to ensure timely administration of anti-D Ig at the first visit. Do not put the onus on the individual to return**
- **Review protocols in conjunction with the laboratory for notifying of sample issues, and timely supply of anti-D Ig**
Figure 9.1: Overview of reports where an incorrect blood component was transfused in 2019 n=329

Incorrect blood component transfused n=329 (100%)

- Clinical: 131 (39.8%)
- Laboratory: 198 (60.2%)

Wrong component transfused n=70
- Blue: 29 (41.4%)
- Green: 41 (58.6%)

Specific requirements not met n=259
- Blue: 102 (39.4%)
- Green: 157 (60.6%)
Figure 9.2: Total incorrect blood component transfused errors categorised by the step where the error occurred n=329

- **Request**: 83 errors (SRNM 3, WCT 3)
- **Sample taking**: 10 errors (SRNM 5, WCT 5)
- **Collection**: 11 errors (SRNM 3, WCT 10)
- **Prescription**: 3 errors (SRNM 3, WCT 8)
- **Administration**: 8 errors (SRNM 1, WCT 7)
- **Sample receipt and registration**: 26 errors (SRNM 4, WCT 22)
- **Testing**: 80 errors (SRNM 26, WCT 54)
- **Component selection**: 42 errors (SRNM 30, WCT 12)
- **Component labelling, availability and HSE**: 2 errors (SRNM 2, WCT 0)
- **Miscellaneous**: 9 errors (SRNM 3, WCT 6)

WCT=wrong component transfused; SRNM=specific requirements not met; HSE=handling and storage errors
Figure 9.3: WCT errors categorised by urgency of request n=70

- 60.0% Routine requests (n=42)
- 17.1% Urgent (n=12)
- 14.3% Emergency (n=10)
- 8.6% Unknown (n=6)
Figure 9.4: ABO-incompatible red cell transfusions from 2010-2019

- **Error unable to be identified at administration step**
- **Error had potential 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
Figure 9.5: Clinical errors resulting in IBCT-WCT categorised by stage the error occurred and patient impact n=29

- **Wrong ABO/D group to HSCT patient**: 2 Request, 3 Miscellaneous
- **ABO-incompatible red cells**: 2 Request, 1 Collection
- **WBIT**: 4 Sample
- **D-mismatch**: 1 Request, 2 Collection
- **Wrong component**: 3 Collection, 2 Administration
- **Wrong patient**: 1 Request, 3 Collection, 5 Administration

**Abbreviations**
- HSCT = haemopoietic stem cell transplant
- WBIT = wrong blood in tube

**Note**
- The figure shows the distribution of clinical errors by stage and patient impact.
Figure 9.6: Clinical errors resulting in IBCT-SRNM categorised by patient impact and stage the error occurred n=102

SD-FFP=solvent detergent fresh frozen plasma; HLA=human leucocyte antigen; CMV=cytomegalovirus

SD-FFP           Blood warmer  Incorrect phenotype  HLA-matched  CMV-screened  Irradiated
                                      1              3              3 2             7           73

- Green box: Miscellaneous
- Red box: Request
- Pink box: Collection
- Light pink box: Prescription
- Blue box: Administration
Figure 9.7: Laboratory errors resulting in WCT n=41

- **Miscellaneous**: 1
- **ABO-incompatible**: 3
- **D-mismatch**: 2
- **Wrong ABO/D to transplant patient**: 10
- **Wrong patient**: 1
- **Wrong component**: 1

Legend:
- Orange: Sample receipt and registration
- Beige: Testing
- Green: Component selection
Figure 9.8: Laboratory errors resulting in SRNM n=157

- Inappropriate El: 2, 4
- Incomplete testing: 48
- Sampling not valid: 4, 5, 1
- Pathogen-inactivated: 1, 7
- Paediatric specification: 2
- K-negative: 5, 1
- Irradiated: 15, 2, 5
- Incorrect phenotype: 3, 23, 13, 1
- HLA-matched: 1, 5
- CMV-screened: 7
- Blood warmer: 1

Colors represent:
- Sample receipt and registration
- Testing
- Component selection
- Component labelling
- Miscellaneous
Figure 10.1: Breakdown of 2019 handling and storage error (HSE) reports $n=306$

- **Handling and storage errors $n=306$**
  - **Clinical**
    - Excessive time to transfuse $n=80$
      - Transfused $n=78$
    - Expired unit transfused $n=19$
      - 12
      - 7
    - Technical administration error $n=89$
      - 89
  - **Laboratory**
    - Reservation period exceeded $n=15$
      - 15
    - Cold chain errors $n=103$
      - 20
      - 83
Figure 11a.1: Delayed transfusion reports by year 2010 to 2019
Figure 11a.2: Factors contributing to delayed transfusion in 16 cases

- Communication: 15 cases
- Failure to follow MHP correctly: 11 cases
- Porter availability: 6 cases
- Staff shortages: 4 cases
- Poor knowledge: 4 cases
- Equipment: 4 cases
- Assumptions: 2 cases
- Sample issue: 1 case

MHP = major haemorrhage protocol
Activated partial thromboplastin time (APTT) tests for deficiency of factors (single or multiple) in the blue box.

Prothrombin time (PT) tests for deficiency of factors in the red box.

VIII  IX  XI  XII

V, X Calcium and phospholipids

PROTHROMBIN → THROMBIN

FIBRINOGEN → FIBRIN CLOT

Thrombin time only looks at this final conversion and depends on adequate amount of fibrinogen.
Prothrombin time | Activated partial thromboplastin time | Thrombin time | Interpretation
---|---|---|---
Abnormal | Normal | Normal | Factor VII deficiency
Normal | Abnormal | Normal | Deficiency of FXII, XI, IX, VIII (single or multiple)
Abnormal | Abnormal | Normal | Deficiency in the common pathway, isolated V or X deficiency. Multiple factors e.g. liver disease, warfarin therapy

Notes: many sick patients have disturbances of coagulation tests that do not predict bleeding (and in some cases are associated with a thrombotic risk). These tests were introduced in the 1960s to screen for congenital factor deficiencies. The PT is very sensitive to FVII deficiency and is used for warfarin monitoring but note that the APTT will also be prolonged (because FIX is reduced) but to a lesser extent. The sample must be taken carefully (good venepuncture, free flow) to avoid activation and in the correct volume (as it is taken into a specific volume of anticoagulant citrate) to avoid erroneous and misleading results.

Isolated prolongation of the APTT can be due to haemophilia A (FVIII deficiency) or B (FIX deficiency,) where the need for diagnosis and treatment is urgent. It is also prolonged in FXII deficiency (common but of no clinical significance) and factor XI deficiency (uncommon and usually not associated with serious bleeding). The thrombin time does not depend on other coagulation factors as thrombin is added to the test system. Many laboratories measure the amount of fibrinogen rather than the thrombin time. (Prolongation of standard coagulation tests can also be caused by inhibitors).

Vitamin K results in increased synthesis of factors II, VII, IX and X so will correct the PT but not FVIII, FXI, V or X deficiency. Normal ranges are different in childhood and any hospital with paediatric patients must use an age-appropriate normal range to avoid unnecessary investigation and treatment.
Figure 11b.1: Example of a blood gas result illustrating the difference between total Hb (A) and O2Hb (B) (not the actual case described above)

<table>
<thead>
<tr>
<th>Results</th>
<th>Crit. Low</th>
<th>Reference Low</th>
<th>Crit. High</th>
<th>Reference High</th>
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<td><strong>Measured (37.0°C)</strong></td>
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<td>pH</td>
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<td>[7.20 7.35 7.45 7.60]</td>
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<td>$\rho CO_2$</td>
<td>↑ 6.8 kPa</td>
<td>[2.6 4.3 6.4 9.3]</td>
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<tr>
<td>$\rho O_2$</td>
<td>↓ 9.0 kPa</td>
<td>[6.0 11.0 14.4 --]</td>
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<td>Na⁺</td>
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<tr>
<td>K⁺</td>
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<td>Ca²⁺</td>
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<td>Hct</td>
<td>↓ 35 %</td>
<td>[18 37 50 60]</td>
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<tr>
<td>Glu</td>
<td>↑ 14.4 mmol/L</td>
<td>[2.5 3.6 5.3 25.0]</td>
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<td>Lac</td>
<td>↑ 2.3 mmol/L</td>
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**CO-Oximetry**

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<td>$tHb$</td>
<td>↓ 110 g/L</td>
<td>[70 117 174 200]</td>
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<tr>
<td>$O_2Hb$</td>
<td>92.5 %</td>
<td>[-- 90.0 95.0 --]</td>
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<tr>
<td>COHb</td>
<td>1.3 %</td>
<td>[-- 0.0 3.0 10.0]</td>
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</tr>
<tr>
<td>MetHb</td>
<td>0.8 %</td>
<td>[-- 0.0 1.5 --]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HHb</td>
<td>↑ 5.4 %</td>
<td>[-- 1.0 5.0 --]</td>
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<tr>
<td>$sO_2$</td>
<td>94.5 %</td>
<td>[-- 94.0 98.0 --]</td>
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**Derived**

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<td>BE(B)</td>
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<tr>
<td>$HCO_3^{-}$std</td>
<td>27.3 mmol/L</td>
<td>[10.0 21.0 28.0 40.0]</td>
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↑↓  Outside Reference Range
Figure 12a.1: Reports of WBIT 2010 to 2019

- **Number of WBIT**
- **% of near misses**
- **% of total error incidents**

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<th>Year</th>
<th>Number of WBIT</th>
<th>% of near misses</th>
<th>% of total error incidents</th>
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<td>2010</td>
<td>386</td>
<td>469</td>
<td>505</td>
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<td>469</td>
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<tr>
<td>2019</td>
<td>780</td>
<td>780</td>
<td>643</td>
</tr>
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</table>
Figure 12a.2: Staff groups responsible for taking the WBIT samples reported to SHOT (n=728) compared with staff groups who take transfusion samples in Oxford Hospitals November 2019 to January 2020 (n=17593)
Patient identification errors

42.6% Patient not identified correctly at phlebotomy n=310
28.2% Sample not labelled at the bedside n=205
5.6% Sample not labelled by the person taking the blood n=41
0.7% Pre-labelled sample tube used n=5
16.8% Other n=122
6.2% Unknown n=45

Figure 12a.3: Primary sampling errors
Figure 13.1: Breakdown of 2019 RBRP reports n=216

Right blood right patient n=216

Clinical Laboratory Other

153 62 1

Patient identification errors n=140

Prescription errors n=20

Labelling errors n=44

Miscellaneous n=5

No bedside check performed n=7
Figure 14.1: Laboratory component labelling and exit check

**Component check**

1. ✔ Type of component
2. ✔ ABO- and D-compatible with patient's blood group
3. ✔ Donation number matches component issued on LIMS and on compatibility label
4. ✔ Patient demographics on compatibility label identical to request form/LIMS
5. ✔ Within expiry period (up to anticipated time of transfusion end)
6. ✔ Patient specific requirements met (if applicable)
7. ✔ Required phenotype met (if applicable)
8. ✔ Component quality (e.g. no leaks, tears or clots)

**Storage check**

2. ✔ Storage requirements met
3. ✔ Storage equipment within temperature control

**Component ready for collection**

3. ✔ Inform clinical area (verbally or electronically)
Figure 14.2: Laboratory incidents and near misses by category of outcome n=796
Figure 14.3: SHOT laboratory data showing at which stage in the transfusion process the primary error occurred n=495

Numbers <4 are too small to be annotated on the figure: Testing: RBRP=1, overtransfusion=1; Component selection: HSE=2, RBRP=1, Delay=3; Component labelling, availability and HSE: SRNM=2, avoidable=1; Miscellaneous: RBRP=1
Figure 14.4: UPTAKE areas to be covered in a robust competency assessment

- Understands procedure being assessed
- Performs task accurately
- Takes heed of limits of procedure
- Applies knowledge of scientific background and rationale for procedure
- Knows and considers risks of not following process
- Explains exceptions and where to find further advice if needed
Figure 14.5: SHOT near miss laboratory errors showing at which stage in the transfusion process the primary error occurred with outcome n=301

WCT=wrong component transfused; SRNM=specific requirements not met; HSE=handling and storage errors; RBRP=right blood right patient; PCC=prothrombin complex concentrate; Ig=immunoglobulin

Numbers <2 are too small to be annotated on the figure. All segments with no data label=1
Figure 16.1: Reactions by component type


Granulocytes (1) - Hypotensive: 1, Mixed allergic/febrile: 1.

Multiple components (14) - Hypotensive: 2, Mixed allergic/febrile: 4, Anaphylactic/severe allergic: 7, Moderate allergic: 1, Febrile: 1.

HLA=human leucocyte antigen; cryo=cryoprecipitate
Figures 16.2: Percentage of reactions to apheresis and pooled platelets 2014 to 2019

a: Febrile-type reactions

b: Allergic reactions

<table>
<thead>
<tr>
<th>Year</th>
<th>Apheresis</th>
<th>Pooled</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>0.0112</td>
<td>0.0039</td>
</tr>
<tr>
<td>2015</td>
<td>0.0133</td>
<td>0.0066</td>
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<tr>
<td>2016</td>
<td>0.0065</td>
<td>0.0024</td>
</tr>
<tr>
<td>2017</td>
<td>0.0102</td>
<td>0.0048</td>
</tr>
<tr>
<td>2018</td>
<td>0.0066</td>
<td>0.0033</td>
</tr>
<tr>
<td>2019</td>
<td>0.0071</td>
<td>0.0081</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>Apheresis</th>
<th>Pooled</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>0.0185</td>
<td>0.0117</td>
</tr>
<tr>
<td>2015</td>
<td>0.0135</td>
<td>0.0068</td>
</tr>
<tr>
<td>2016</td>
<td>0.0065</td>
<td>0.0024</td>
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<tr>
<td>2017</td>
<td>0.0102</td>
<td>0.0048</td>
</tr>
<tr>
<td>2018</td>
<td>0.0066</td>
<td>0.0033</td>
</tr>
<tr>
<td>2019</td>
<td>0.0071</td>
<td>0.0081</td>
</tr>
</tbody>
</table>

0: Febrile-type reactions
0: Allergic reactions

Apheresis
Pooled
Figure 17.1: Reports of pulmonary complications by year 2008-2019

TRALI=transfusion-related acute lung injury; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea
Figure 17a.1: Number of confirmed TRALI cases and deaths at least possibly related to TRALI by year of report.
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
Figure 17b.2: Number of surveillance criteria versus number of accepted TACO cases

Minimum TACO criteria not met

Number of TACO criteria met

TACO=transfusion-associated circulatory overload
Figure 17b.3: Use of the TACO checklist to identify patients at risk of TACO and implementation of mitigations

<table>
<thead>
<tr>
<th>Action</th>
<th>Performance</th>
<th>TACO Identified</th>
<th>No Risk Identified</th>
<th>Evidence of Risk for TACO following review of report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performed</td>
<td>15.8% (22/139)</td>
<td>81.8% (18/22)</td>
<td>18.2% (4/22)</td>
<td>Evidence of mitigating action being performed</td>
</tr>
<tr>
<td>Not performed</td>
<td>76.3% (106/139)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not answered</td>
<td>7.9% (11/139)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Action</th>
<th>Evidence</th>
<th>TACO</th>
<th>No Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>No action taken</td>
<td>38.9% (7/18)</td>
<td>42.2%</td>
<td>29.0%</td>
</tr>
<tr>
<td>Mitigating action identified as being required</td>
<td>61.1% (11/18)</td>
<td>57.8%</td>
<td>71.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Action</th>
<th>Evidence of Mitigating Action Being Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>All assigned actions performed</td>
<td>54.5% (6/11)</td>
</tr>
<tr>
<td>Actions partially performed</td>
<td>36.4% (4/11)</td>
</tr>
<tr>
<td>No evidence of actions performed</td>
<td>9.1% (1/11)</td>
</tr>
</tbody>
</table>
Figure 17c.1: Summary of transfers and categorisation of cases included under TAD

Total number of cases submitted or transferred to TAD from other categories n=31

Reviewed by SHOT pulmonary WEG

Categorised as TAD n=18 (does not include those categorised as possible TRALI type II)
- TAD-C: TAD with adequate clinical details provided n=8
- TAD-IC: TAD with inadequate clinical details available n=10

Recategorised as TACO, TRALI type II or FAHR as appropriate n=8
- Recategorised as TRALI type II based on recent consensus redefinition n=3

Withdrawn - other causes thought to be mainly contributing to patient’s clinical features n=5
- Transferred to TACO n=3
- Transferred to FAHR n=2
Figure 18.1: Overview of HTR cases n=49

**Haemolytic transfusion reactions**

- Total reported in 2019 **n=49**
- Deaths **n=0**
- Major morbidity* **n=11**
- Age range: 9 to 91 (median 55)

*All reported cases of probable hyperhaemolysis where there is a significant fall in Hb are considered as major morbidity

**Types of HTR**

- Acute HTR **n=22**
- Delayed HTR **n=23**
- Hyperhaemolysis **n=4**

**Key clinical findings**

- Typical clinical features reported including fever, dyspnoea, rigors, tachycardia, reports of pain and haemoglobinuria
- No clinical symptoms of transfusion reaction reported in 12/23 cases
- 3/4 cases seen in patients with sickle cell disease, in one of these, patient had DHTR followed by hyperhaemolysis
- One case was in a patient with myelodysplastic syndrome and cold agglutinin disease

Deaths **n=0**

Major morbidity* **n=11**

Age range: 9 to 91 (median 55)
Key findings from laboratory investigations reported in HTR

- DAT post transfusion was not available in 4 cases.
- In 25 cases the DAT was not repeated on the pre-transfusion sample. 16/25 of these cases were due to the sample being no longer available in DHTR however in 6 cases of AHTR no pre-transfusion DAT was tested.
- In 8/49 haemolytic reactions reported no eluate had been tested despite the patient developing a positive DAT post transfusion, and in 5 of these cases the patient also had a new antibody detectable in the post-transfusion sample.
Figure 18.3: Antibodies implicated in DHTR
Figure 20.1: Outcome of UK reports of suspected TTI made to the NHSBT/PHE Epidemiology Unit in 2019

- **Reports for investigation**: 152
  - **Suspected bacterial incidents investigated**: 139
    - **Post-transfusion reactions with no evidence of bacteria on investigation**: 130
    - **Not TTI**: 9
  - **Suspected viral incidents reported and investigated**: 13
    - **Not TTI**: 11 (1 HBV, 4 HCV, 2 HEV, 2 HIV, 2 CMV)
    - **Probable TTI**: 1 (1 HBV)
    - **Confirmed TTI**: 1 (1 HEV)

*TTI=transfusion-transmitted infection; CMV=cytomegalovirus; HBV=hepatitis B virus; HCV=hepatitis C virus; HEV=hepatitis E virus; HIV=human immunodeficiency virus*
Figure 21.1: Cell salvage incidents by type of report 2010-2019
Figure 22.1: Percentages of paediatric and total reports in each category
Uncommon complications of transfusion (UCT)

Cell salvage (CS)

Haemolytic transfusion reactions (HTR)

Transfusion-associated circulatory overload (TACO)

Handling and storage errors (HSE)

Anti-D immunoglobulin errors (Anti-D Ig)

Febrile, allergic and hypotensive reactions (FAHR)

Incorrect blood component transfused (IBCT)

Under or overtransfusion

Delayed

Avoidable

Figure 22.2: Summary of paediatric cases by category and age 2019
Figure 22.3: Trends in paediatric cases from 2009-2019

- ≤28 days
- >28 days to <1 year
- 1 to <16 years
- 16 to <18 years

<table>
<thead>
<tr>
<th>Year</th>
<th>≤28 days</th>
<th>&gt;28 days to &lt;1 year</th>
<th>1 to &lt;16 years</th>
<th>16 to &lt;18 years</th>
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</thead>
<tbody>
<tr>
<td>2009</td>
<td>110</td>
<td>60</td>
<td>19</td>
<td>16</td>
</tr>
<tr>
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<td>122</td>
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<td>20</td>
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<tr>
<td>2019</td>
<td>132</td>
<td>69</td>
<td>17</td>
<td>22</td>
</tr>
</tbody>
</table>
Figure 22.3 b. Paediatric reports where specific requirements were not met (SRNM)
Figure 22.3 c. Paediatric febrile, allergic and hypotensive reactions by component type

- **Multiple components**
- **Granulocytes**
- **Plasma**
- **Platelets**
- **Red cells**

Mild reactions excluded

<table>
<thead>
<tr>
<th>Year</th>
<th>Multiple components</th>
<th>Granulocytes</th>
<th>Plasma</th>
<th>Platelets</th>
<th>Red cells</th>
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<tbody>
<tr>
<td>2009</td>
<td>1</td>
<td>13</td>
<td>19</td>
<td>37</td>
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<td>3</td>
<td>26</td>
<td>28</td>
<td>17</td>
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<tr>
<td>2011</td>
<td>48</td>
<td>3</td>
<td>53</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>2012</td>
<td>28</td>
<td>22</td>
<td>22</td>
<td>26</td>
<td>2</td>
</tr>
<tr>
<td>2013</td>
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<tr>
<td>2019</td>
<td>38</td>
<td>23</td>
<td>23</td>
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</table>
### Figure 22.4: Breakdown of incorrect blood component transfused reports

<table>
<thead>
<tr>
<th>Category</th>
<th>≤28 days</th>
<th>&gt;28 days to &lt;1 year</th>
<th>1 to &lt;16 years</th>
<th>16 to &lt;18 years</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td><strong>IBCT-WCT Totals</strong></td>
<td>7</td>
<td>1</td>
<td>2</td>
<td>10</td>
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<tr>
<td><strong>Laboratory</strong></td>
<td>3</td>
<td>2</td>
<td></td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>Clinical</strong></td>
<td>4</td>
<td>1</td>
<td></td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>IBCT-SRNM Totals</strong></td>
<td>8</td>
<td>6</td>
<td>6</td>
<td>2</td>
<td>22</td>
</tr>
<tr>
<td><strong>Irradiated</strong></td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>MB- or SD-plasma</strong></td>
<td>2</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td>5</td>
<td>5</td>
<td>5</td>
<td></td>
<td>15</td>
</tr>
</tbody>
</table>

IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; MB=methylene blue-treated; SD=solvent-detergent treated
Figure 22.5: Paediatric febrile, allergic and hypotensive reaction (FAHR) reports
a. Comparison of proportions of adult and paediatric FAHR related to different components
Figure 22.5: Paediatric febrile, allergic and hypotensive reaction (FAHR) reports
b. Percentages of reaction types of each component for paediatric reports
Figure 23.1: Cumulative data for adverse events in transfusion for patients with haemoglobin disorders 2010 to 2019

a. Sickle cell disease n=260

- HTR & SRNM: 98 (72.7%)
- SRNM: 91 (34.6%)
- HTR: 91 (34.6%)
- FAHR: 34 (13.1%)
- ADU: 24 (9.2%)
- IBCT: 9 (3.5%)
- TACO: 2 (0.8%)
- TAD: 1 (0.4%)
- TTI: 1 (0.4%)

b. Thalassaemia n=58

- FAHR: 24 (41.4%)
- SRNM: 14 (24.6%)
- HTR: 5 (8.6%)
- IBCT: 5 (8.6%)
- TACO: 4 (6.9%)
- ADU: 1 (1.7%)
- TTI: 1 (1.7%)

SRNM=specific requirements not met; HTR=haemolytic transfusion reactions; FAHR=febrile, allergic and hypotensive reactions; ADU=avoidable, delayed or under or overtransfusion; IBCT=incorrect blood component transfused; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea; TTI=transfusion-transmitted infection
### Figure 24.1: Number of reports of anti-D immunisation in pregnancy by year, 2012-2019

<table>
<thead>
<tr>
<th>Year</th>
<th>Previous Pregnancy</th>
<th>No Previous Pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>4</td>
<td>2</td>
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<tr>
<td>2013</td>
<td>14</td>
<td>9</td>
</tr>
<tr>
<td>2014</td>
<td>32</td>
<td>5</td>
</tr>
<tr>
<td>2015</td>
<td>34</td>
<td>17</td>
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<tr>
<td>2016</td>
<td>31</td>
<td>9</td>
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<tr>
<td>2017</td>
<td>50</td>
<td>16</td>
</tr>
<tr>
<td>2018</td>
<td>31</td>
<td>8</td>
</tr>
<tr>
<td>2019</td>
<td>37</td>
<td>17</td>
</tr>
</tbody>
</table>
Figure 24.2: Summary of 2019 NPP data n=17

- 17 NPP
  - 12 received RAADP
  - 3 no RAADP received
  - 2 did not provide information

- RAADP
  - 4/12 PSE
    - 3 x fall
    - 1 x APH

- PSE
  - 12 live births
    - 8 no treatment
    - 4 treatment for HDFN

- Outcome of pregnancy
  - 2 live births
    - 1 IUD
    - 2 treatment for HDFN
  - 2 live births
    - 1 no treatment
    - 1 treatment for HDFN

Note: The 4 PSE cases did not result in treatment for HDFN
NPP=no previous pregnancy; RAADP=routine antenatal anti-D Ig prophylaxis; PSE=potentially sensitising event; APH=antepartum haemorrhage; HDFN=haemolytic disease of the fetus and newborn; IUD=intruterine death
Figure 24.3: Summary of 2019 PP data n=37

When anti-D detected

37 PP

10 in first trimester

20 later in pregnancy

7 at delivery

RAADP in preceding pregnancy

6 live births
1 stillbirth, 1 miscarriage
2 unknown

5 treatment for HDFN
4 no treatment
1 unknown

RAADP in index pregnancy

18 received RAADP
9 did not receive RAADP

6/27 PSE, 3 x APH
2 x PV bleeding
1 x fall

PSE in index pregnancy

27 live births
12 treatment for HDFN
13 no treatment
2 unknown

PSE in preceding pregnancy

3/10 PSE
1 x termination
1 x miscarriage
1 x APH

Outcome of index pregnancy

6 live births
1 stillbirth, 1 miscarriage
2 unknown

5 treatment for HDFN
4 no treatment
1 unknown

PP=previous pregnancy; RAADP=routine antenatal anti-D Ig prophylaxis; TOP=termination of pregnancy; PSE=potentially sensitising event; APH=antepartum haemorrhage; PV=per vaginum; HDFN=haemolytic disease of the fetus and newborn
Figure 25.1: Total cases of incorrect ABO, D and specific requirement not met (SRNM) HSCT-related transfusion errors reported to SHOT 2012-2019; n=325
Figure 25.2: Numbers of errors according to type 2012-2019 (including near miss) n=325

- Irradiated not provided: 84 errors (45 near misses)
- ABO group errors: 76 errors (37 near misses)
- D group errors: 33 errors (14 near misses)
- Other: 15 errors (1 near miss)
- HEV-screened not provided: 8 errors (4 near misses)
- CMV-screened not provided: 4 errors (4 near misses)

HEV = hepatitis E virus; CMV = cytomegalovirus

"Other" includes inappropriate electronic issue, failure to supply human leucocyte antigen (HLA)-matched components and a case where a neonate was given the wrong component.

Of irradiated not provided errors, 6 included failure to also supply HEV (1 of these was near miss); 2 included failure to also supply CMV-screened products (1 of these was near miss).
Figure 25.3: Source of the HSCT-related error n=324*

*Excludes 1 case of wrong component transfused to a neonate
SRNM=specific requirements not met

- ABO/D clinical: Error 33, Near miss 10
- SRNM clinical: Error 86, Near miss 29
- ABO/D laboratory: Error 76, Near miss 41
- SRNM laboratory: Error 24, Near miss 25
Figure 25.4: Types of error, includes ABO/D and SRNM n=325

- Clinical communication: 152
- Laboratory understanding: 22
- Laboratory communication: 20
- Clinical decision making: 7
- LIMS flags not heeded or updated: 122
- Other: 2

LIMS = laboratory information management system
Figure 25.5: Point of detection of near miss incidents n=105

- **Bedside check**: 52.4% detected at the bedside
- **Component selection**: 6
- **Testing**: 11
- **Component collection**: 4
- **Other or unknown**: 29
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.
Figure 25.7: Important steps in ensuring safe transfusion practice in HSCT

- Patient and family informed and educated about new transfusion requirements
- Everyone involved in patient care (other local hospitals and primary care) also informed of patient's transfusion requirements
- Local hospital informed
- Confirmation of updated LIMS
- Laboratory to update LIMS
- Inform transfusion laboratory of transplant details

HSCT = haemopoietic stem cell transplant; LIMS = laboratory information management system
Figure 26.1: Submitted confirmation reports 2010-2019

- Serious adverse event
- Serious adverse reaction
- Total
Figure 26.2: 2019 SAE confirmation reports by deviation and specification

Whole blood collection
Apheresis collection
Testing of donations
Processing
Distribution/HSE
Donor selection
Storage/HSE
Other

- Equipment failure
- Human error
- Product defect
- Other defect
Figure 26.3: Human error sub-categories of the two most increased storage errors

- Lapsed/no training: 2
- Ineffective training: 1
- Incorrect procedure: 1
- Inadequate training: 1
- Inadequate QMS – staffing and workload: 4
- Procedure performed incorrectly: 8
- Procedural steps omitted/wrong procedure performed: 14
- Inadequate process: 40

QMS=quality management system
Figure 26.4: Incorrect storage of component by specification

- Inadequate process: 2
- Procedure performed incorrectly: 3
- Ineffective training: 3
- Inadequate QMS – staffing and workload: 3
- Lapsed/no training: 12
- Inadequate training: 16
- Ineffective training: 19
- Procedural steps omitted/wrong procedure performed: 23
- Inadequate process: 24

QMS=quality management system
<table>
<thead>
<tr>
<th>Error Description</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect blood component accepted (IBCA)</td>
<td>1</td>
</tr>
<tr>
<td>Handling damage (HD)</td>
<td>1</td>
</tr>
<tr>
<td>Incorrect blood component ordered (IBCO)</td>
<td>5</td>
</tr>
<tr>
<td>Failed recall (FR)</td>
<td>6</td>
</tr>
<tr>
<td>Expired component available for transfusion (ECAT)</td>
<td>9</td>
</tr>
<tr>
<td>Unspecified (UNSPEC)</td>
<td>9</td>
</tr>
<tr>
<td>Component available for transfusion past dereservation (CATPD)</td>
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</tr>
<tr>
<td>Data entry error (DEE)</td>
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<tr>
<td>Component labelling error (CLE)</td>
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</tr>
<tr>
<td>Component collection error (CCE)</td>
<td>117</td>
</tr>
<tr>
<td>Pre-transfusion testing error (PTTE)</td>
<td>119</td>
</tr>
<tr>
<td>Sample processing error (SPE)</td>
<td>142</td>
</tr>
<tr>
<td>Incorrect blood component issued (IBCI)</td>
<td>190</td>
</tr>
</tbody>
</table>
Inadequate supervision: 15
Lapsed/no training: 27
Incorrect procedure: 52
Inadequate training: 58
Inadequate QMS – staffing and workload: 90
Ineffective training: 140
Procedural steps omitted/wrong procedure performed: 199
Inadequate process: 282
Procedure performed incorrectly: 310

Figure 26.6: Human error sub-category

NOTE: These numbers should be used as guidance only. The quality of this data is limited by several factors. QMS=quality management system
Figure 26.7: Other Sub-category and root cause for all SAE other than procedural steps omitted/wrong procedure performed and procedure performed incorrectly

<table>
<thead>
<tr>
<th>Category</th>
<th>Inadequate process</th>
<th>Inadequate QMS – staffing and workload</th>
<th>Inadequate supervision</th>
<th>Inadequate training</th>
<th>Incorrect procedure</th>
<th>Ineffective training</th>
<th>Lapsed/no training</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBCO</td>
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</tr>
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<td></td>
<td></td>
</tr>
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</tr>
<tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>2</td>
<td>3</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLE</td>
<td>10</td>
<td>14</td>
<td>2</td>
<td>4</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPE</td>
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<td>3</td>
<td>7</td>
<td>4</td>
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</tr>
<tr>
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<td>9</td>
<td>1</td>
<td>7</td>
<td>2</td>
<td>33</td>
<td>4</td>
</tr>
<tr>
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<td>10</td>
<td>2</td>
<td>9</td>
<td>11</td>
<td>19</td>
<td>1</td>
</tr>
<tr>
<td>IBCI</td>
<td>58</td>
<td>17</td>
<td>6</td>
<td>9</td>
<td>14</td>
<td>14</td>
<td>22</td>
</tr>
</tbody>
</table>

See Figure 26.5 for key to category abbreviations
### Figure 26.8: Blood establishment SAE event category by specification

<table>
<thead>
<tr>
<th>Category</th>
<th>Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood collection</td>
<td>1</td>
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<tr>
<td>Apheresis collection</td>
<td>1</td>
</tr>
<tr>
<td>Testing of donations</td>
<td>1 2 1</td>
</tr>
<tr>
<td>Storage/HSE</td>
<td>1 2 1</td>
</tr>
<tr>
<td>Processing</td>
<td>1 3 4</td>
</tr>
<tr>
<td>Distribution/HSE</td>
<td>2 3 1</td>
</tr>
<tr>
<td>Other</td>
<td>1 3 4 7 3 1</td>
</tr>
<tr>
<td>Donor selection</td>
<td>32 25 12 3 3 1</td>
</tr>
</tbody>
</table>

- **Human error - procedural steps omitted/wrong procedure performed**
- **Human error - procedure performed incorrectly**
- **Human error - ineffective training**
- **Human error - inadequate process**
- **Human error - inadequate training**
- **Human error - incorrect procedure**
- **Human error - inadequate QMS – staffing and workload**
- **Human error - lapsed/no training**
- **Other - unknown**
- **Product defect**
Figure 26.9: BE reports in ‘other’ category

<table>
<thead>
<tr>
<th>Category</th>
<th>Inadequate process</th>
<th>Inadequate QMS – staffing and workload</th>
<th>Inadequate training</th>
<th>Ineffective training</th>
<th>Procedural steps omitted/wrong procedure performed</th>
<th>Procedure performed incorrectly</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLE</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DEE</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FR</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<td>PTTE</td>
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<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

See Figure 26.5 for key to category abbreviations
Figure 26.10: SAR reports, by imputability, reported to SABRE in 2019

<table>
<thead>
<tr>
<th>Imputability level</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
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</thead>
<tbody>
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<td>Not assessable</td>
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<td></td>
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<tr>
<td>0</td>
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<td>245</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td>58</td>
</tr>
</tbody>
</table>
1. General principles
2. Personnel and organisation
3. Premises
4. Equipment and materials
5. Documentation
6. Blood collection, testing and processing
7. Storage and distribution
8. Non-conformance and recall
9. Self-inspection, audits and improvements
10. Quality monitoring and control

Figure 26.11: Good practice section referenced in major deficiencies 2019
Figure 26.12: Good practice section referenced in other deficiencies 2019

1. General principles: 24
2. Personnel and organisation: 27
3. Premises: 18
4. Equipment and materials: 56
5. Documentation: 36
6. Blood collection, testing and processing: 6
7. Storage and distribution: 3
8. Outsourced activities management: 1
9. Non-conformance and recall: 36
10. Self-inspection, audits and improvements: 4
11. Quality monitoring and control: 2
Figure 26.13: Good practice section 4: equipment and materials

- **4.1 Equipment and materials general requirements**: 2 major deficiencies, 26 other deficiencies
- **4.2 Data processing systems**: 14 major deficiencies, 9 other deficiencies
- **4.3 Qualification and validation**: 13 major deficiencies, 12 other deficiencies
- **4.4 Process validation**
- **4.5 Validation of test methods**
- **4.6 Change control**: 14 major deficiencies, 8 other deficiencies
- **4.7 Control of equipment and materials**: 1 major deficiency, 1 other deficiency

Legend:
- Red: Major deficiencies
- Blue: Other deficiencies
Figure 26.14: Good practice section 9: non-conformance and recall

9.1 Deviations

- Major deficiencies: 14
- Other deficiencies: 9

9.2 Complaints

- Other deficiencies: 1

9.3 Recall

- Other deficiencies: 19

9.4 Deviation management and corrective and preventative actions

- Major deficiencies: 13
- Other deficiencies: 7
5.1 Documentation general principles
5.2 Required good practice documentation
5.3 Generation and control of documentation
5.4 Good documentation practices
5.6 Specifications
5.7 Preparation instructions
5.8 Labelling
5.9 Procedures and records
5.11 Documentation other

Figure 26.15: Good practice section 5: documentation