FIGURES FROM THE ANNUAL SHOT REPORT 2019

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The risks of transfusion-transmitted infection are much lower than all other transfusion-related complications.
Figure 2.1: Status of reports submitted to SHOT in the calendar year 2019

- **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- **Withdrawn**: 679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

The graph shows the number of reports submitted to SHOT and the number of reports per 10,000 components issued from 2010 to 2019. The number of reports increased gradually from 3200 in 2010 to 4248 in 2019. The reports per 10,000 components also increased, starting from around 2 in 2010 and rising to 18 in 2019.
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 2.3: Flow of SHOT haemovigilance data

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

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

- **Total components issued:** 186,551
  - **Number of reports:** 395
  - **Reports per 10,000 components issued:** 21.2

- **Total components issued:** 1,957,857
  - **Number of reports:** 3,539
  - **Reports per 10,000 components issued:** 18.1

- **Total components issued:** 105,388
  - **Number of reports:** 165
  - **Reports per 10,000 components issued:** 15.7

- **Total components issued:** 57,187
  - **Number of reports:** 149
  - **Reports per 10,000 components issued:** 26.1
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
Figure 3.2: Deaths related to transfusion (with imputability) reported in 2019 n=17

Preventable deaths n=5/17 (29.4%)

TTI = transfusion-transmitted infections; TAD = transfusion-associated dyspnoea; PCC = prothrombin complex concentrate; UCT = uncommon complications of transfusion; TACO = transfusion-associated circulatory overload

TTI = transfusion-transmitted infections; TAD = transfusion-associated dyspnoea; PCC = prothrombin complex concentrate; UCT = uncommon complications of transfusion; TACO = transfusion-associated circulatory overload
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.
Figure 3.4: Summary data for 2019, all categories (includes RBRP and NM) n=3397
Figure 3.5: Cumulative data for SHOT categories 1996-2019 n=23341

- UCT: Uncommon complications of transfusion
- PTP: Post-transfusion purpura
- TTI: 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

*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) (1530/2857 = 53.6%)
- Medium number of incidents (1323/2857 = 46.3%)
- Small number of deaths (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 knowledge and understanding of transfusion principles and processes
- 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 investigations when things go wrong and right actions to be taken
- Right amount to be transfused at the right rate
- Right blood component for transfusion
- Right time for the transfusion
- Right to refuse blood transfusion and actions needed
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

Access coverage

Quality safety
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
Figure 6.3: Summary of serious donor adverse events in the UK in 2019

SUMMARY OF SERIOUS DONOR ADVERSE EVENTS IN THE UK IN 2019

DONATION IS GENERALLY SAFE!

ONLY 42 SERIOUS EVENTS WERE REPORTED IN UK IN 2019 AND A TOTAL OF 1,841,400 DONATIONS COLLECTED IN THE CALENDAR YEAR. GIVING A LOW RATE OF SAE = 0.23 PER 10,000 DONATIONS

BREAKDOWN OF 42 SERIOUS ADVERSE EVENTS (SAED) IN 2019

- 50% DEATH
- 24% INHIBITION
- 15% HOSPITALIZATION
- 43% FRACTURE
- 57% NERVE INJURY

Three of these SAEs were reported in component donors.

Some SAEs were related to persistent problems with donor post donation.

Some SAEs were related to a direct result of venepuncture reaction.

Some SAEs were related to fainting. Only SAEs were related to belittled fainting.

All SAEs were female and relate to whole blood donors.

80% of donors who suffered a SAE were withdrawn from future donations.

10% SAEs were related to fainting. These are not related to donors who were found to have high blood pressure prior to donation.

Donor death reported within a year of donation. However, this was not related to blood donation as the donor was found to have a pre-existing cancerous condition.

Transmission problems related to needle insertion persisting for more than a year, and year-end events resulting in donors, hospitalization or injury continue to be the most frequently reported SAEs.

Improving donor experience with awareness to reduce risk of complications related to blood donation along with prompt recognition and management of complications is vital.

Donor safety is of paramount importance and is ensured as far as possible. It can be by donor selection guidelines, standard operating procedures, adequately trained staff and appropriate facilities.
Figure 7.1: Factors identified for one change likely to reduce recurrence of the incident (970 responses)

Factors identified in question responses:

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

- 4 factors: 18.0% (513)
- 3 factors: 15.6% (446)
- 2 factors: 21.2% (607)
- 1 factor: 34.1% (973)
- No score given: 11.1% (318)
Figure 7.3: Evaluation of uptake of self-learning opportunity and comparative percentages of scores for human and organisational factors

Percentage of scores given

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<th>Not watched HF video</th>
<th>Read learning package</th>
<th>Not read learning package</th>
<th>Watched HF video (77.5%)</th>
<th>Not watched HF video (22.5%)</th>
<th>Read learning package (74.5%)</th>
<th>Not read learning package (25.5%)</th>
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<td>62.6%</td>
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<td>18.9%</td>
<td>62.6%</td>
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Reporter use of learning material
To improve patient safety, a combined approach using both Safety-I and Safety-II principles is essential.

- Respond when something happens or is categorised as an unacceptable risk
- As few things as possible go wrong
- Humans seen as liability or hazard
- Investigation purpose: identify causes and contributory factors

- Continuously trying to anticipate developments and events
- As many things as possible go right
- Humans seen as resource for system flexibility and resilience
- Investigation purpose: understand how things usually go right to explain how things occasionally go wrong
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

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

- Not known:
  - Hospital (n=369): 63
  - Community (n=44): 0

- Routine:
  - Hospital (n=369): 286
  - Community (n=44): 44

- Out-of-hours:
  - Hospital (n=369): 20
  - Community (n=44): 0
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 OR 500IU at 28 weeks and 34 weeks

#### Opportunity for error
- Dose incorrectly omitted after PSE
- Results incorrectly transcribed into the hand-held record
- Blood results in hand-held record used to inform treatment decisions
- Pre-planning for clinics not done — anti-D Ig ordered after clinic

#### Corrective and preventative action
- Avoid transcription errors by printing results and placing those in the hand-held record
- Never use handwritten results to inform treatment decisions
- Pre-plan for clinics and pre order anti-D Ig

### 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
- Anti-D Ig not requested in time for discharge

#### Corrective and preventative action
- Review discharge protocols and arrange for anti-D Ig prophylaxis on day 2 when required for D-negative blood groups
- Review protocols in conjunction with the laboratory for notifying of sample issues, and timely supply of anti-D Ig

### 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
- Do not wait for Kleihauer results before requesting dose of anti-D Ig

#### Corrective and preventative action
- Ensure those with D-negative blood groups are aware of the risks associated with PSE
- 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

### Corrective and preventative action
- Print results and place them in the hand-held record
- Never use handwritten results to inform treatment decisions
- Pre-plan for clinics and pre order anti-D Ig

### Serious Hazards of Transfusion
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
- 29 (41.4%)
- 41 (58.6%)

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

- **Request**: 83
  - SRNM: 3
  - WCT: 5
- **Sample taking**: 10
  - SRNM: 3
  - WCT: 7
- **Collection**: 11
  - SRNM: 3
  - WCT: 8
- **Prescription**: 26
  - SRNM: 4
  - WCT: 22
- **Administration**: 2
  - SRNM: 3
  - WCT: 8
- **Sample receipt and registration**: 30
  - SRNM: 26
  - WCT: 4
- **Testing**: 42
  - SRNM: 7
  - WCT: 35
- **Component selection**: 2
  - SRNM: 2
  - WCT: 0
- **Component labelling, availability and HSE**: 9
  - SRNM: 2
  - WCT: 7

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
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

**Number of ABO-incompatible red cell transfusions**

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DH=Department of Health; CAS=central alerting system
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: Collection
  - 1: Miscellaneous

- WBIT
  - 4: Sample

- D-mismatch
  - 1: Request
  - 2: Collection

- Wrong component
  - 3: Collection
  - 2: Administration

- Wrong patient
  - 1: Request
  - 3: Collection
  - 5: Administration

HSCT=haemopoietic stem cell transplant; WBIT=wrong blood in tube
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: 1
Blood warmer: 3
Incorrect phenotype: 3, 2
HLA-matched: 1
CMV-screened: 7
Irradiated: 73, 2, 9, 1

Request
Collection
Prescription
Administration
Miscellaneous

SD-FFP=solvent detergent fresh frozen plasma; HLA=human leucocyte antigen; CMV=cytomegalovirus
Figure 9.7: Laboratory errors resulting in WCT n=41

- **Miscellaneous**: 1
- **ABO-incompatible**: 3
- **D-mismatch**: 2, 10
- **Wrong ABO/D to transplant patient**: 2, 2, 10
- **Wrong patient**: 1, 1
- **Wrong component**: 1, 2, 6

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

- **Inappropriate EI**: 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**: 11

El=electronic issue; HLA=human leucocyte antigen; CMV=cytomegalovirus
Figure 10.1: Breakdown of 2019 handling and storage error (HSE) reports n=306

Handling and storage errors n=306

Clinical: 199
Laboratory: 107

Cold chain errors n=103
- Clinical: 20
- Laboratory: 83

Excessive time to transfuse n=80
- Clinical: 78
- Laboratory: 2

Expired unit transfused n=19
- Clinical: 12
- Laboratory: 7

Technical administration error n=89
- Clinical: 89
- Laboratory: 0

Reservation period exceeded n=15
- Clinical: 0
- Laboratory: 15
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.

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

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<th>Activated partial thromboplastin time</th>
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<td>Normal</td>
<td>Factor VII deficiency</td>
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<tr>
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<td>Abnormal</td>
<td>Normal</td>
<td>Deficiency of FXII, XI, IX, VIII (single or multiple)</td>
</tr>
<tr>
<td>Abnormal</td>
<td>Abnormal</td>
<td>Normal</td>
<td>Deficiency in the common pathway, isolated V or X deficiency. Multiple factors e.g. liver disease, warfarin therapy</td>
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**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)

### Results

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<td>pCO₂</td>
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<tr>
<td>pO₂</td>
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<td>K⁺</td>
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<tr>
<td>Cl⁻</td>
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<tr>
<td>Ca²⁺</td>
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<tr>
<td>Hct</td>
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<td>Lac</td>
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<tr>
<td>CO-Oximetry</td>
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<td>tHb</td>
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<td>O₂Hb</td>
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<td></td>
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<tr>
<td>COHb</td>
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<td></td>
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<tr>
<td>MetHb</td>
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<td>BE(B)</td>
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<td>HCO₃⁻ std</td>
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</table>

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>tHb ↓ 110 g/L [70 117 174 200]</td>
<td>O₂Hb 92.5 % [-- 90.0 95.0 --]</td>
</tr>
<tr>
<td>COHb 1.3 % [-- 0.0 3.0 10.0]</td>
<td>MetHb 0.8 % [-- 0.0 1.5 --]</td>
</tr>
<tr>
<td>HHb ↑ 5.4 % [-- 1.0 5.0 --]</td>
<td>sO₂ 94.5 % [-- 94.0 98.0 --]</td>
</tr>
<tr>
<td>BE(B) ↑ 3.1 mmol/L [-- -2.0 3.0 --]</td>
<td>HCO₃⁻ std 27.3 mmol/L [10.0 21.0 28.0 40.0]</td>
</tr>
</tbody>
</table>

↑↓ Outside Reference Range
Figure 12a.1: Reports of WBIT 2010 to 2019

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of WBIT</th>
<th>% of near misses</th>
<th>% of total error incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>386</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>469</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>505</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>643</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>686</td>
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<td></td>
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<tr>
<td>2015</td>
<td>780</td>
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<td>2016</td>
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<td>2017</td>
<td>789</td>
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<td></td>
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<tr>
<td>2018</td>
<td>792</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2019</td>
<td>728</td>
<td></td>
<td></td>
</tr>
</tbody>
</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)

<table>
<thead>
<tr>
<th>Staff Group</th>
<th>% Near miss SHOT</th>
<th>% Collections (Oxford)</th>
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</thead>
<tbody>
<tr>
<td>Other/unknown</td>
<td>18.4</td>
<td></td>
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<tr>
<td>Phlebotomist</td>
<td>5.2</td>
<td>9.6</td>
</tr>
<tr>
<td>Healthcare assistant</td>
<td>9.1</td>
<td>26.1</td>
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<tr>
<td>Nurse</td>
<td>20.3</td>
<td>51.0</td>
</tr>
<tr>
<td>Midwife</td>
<td>7.0</td>
<td>26.2</td>
</tr>
<tr>
<td>Doctor</td>
<td>6.3</td>
<td>20.7</td>
</tr>
</tbody>
</table>
Figure 12a.3: Primary sampling errors

42.6% Patient identification errors

- Patient not identified correctly at phlebotomy n=310 (42.6%)
- Sample not labelled at the bedside n=205 (28.2%)
- Sample not labelled by the person taking the blood n=41 (5.6%)
- Pre-labelled sample tube used n=5 (0.7%)
- Other n=122 (16.8%)
- Unknown n=45 (6.2%)
Figure 13.1: Breakdown of 2019 RBRP reports n=216

- **Clinical**: 153 (21 errors, 62 errors, 1 error)
- **Laboratory**: 62
- **Other**: 1

- **Patient identification errors n=140**: 118 (21 errors, 1 error)
- **Prescription errors n=20**: 20
- **Labelling errors n=44**: 39 (5 errors, 2 errors)
- **Miscellaneous n=5**: 3 (3 errors, 2 errors)
- **No bedside check performed n=7**
Figure 14.1: Laboratory component labelling and exit check

**Component check**

1. ✓ Type of component
   - ✓ ABO- and D-compatible with patient’s blood group
   - ✓ Donation number matches component issued on LIMS and on compatibility label
   - ✓ Patient demographics on compatibility label identical to request form/LIMS

   ✓ Within expiry period (up to anticipated time of transfusion end)
   - ✓ Patient specific requirements met (if applicable)
   - ✓ Required phenotype met (if applicable)
   - ✓ Component quality (e.g. no leaks, tears or clots)

**Storage check**

2. ✓ Storage requirements met
   - ✓ 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

- WCT: 41/43
- SRNM: 157
- HSE: 66/107
- RBRP: 62/87
- Delay: 45
- Avoidable: 9/2
- Delay: 1
- Overtransfusion: 1
- PCC: 1
- Anti-D Ig: 73/23

Legend:
- Red: Laboratory errors
- Blue: Laboratory near miss
Figure 14.3: SHOT laboratory data showing at which stage in the transfusion process the primary error occurred n=495

- **Sample receipt and registration**: WCT=4, SRNM=26, HSE=8, RBRP=11, Miscellaneous=5
- **Testing**: WCT=7, SRNM=80, HSE=5, RBRP=8, Miscellaneous=24
- **Component selection**: WCT=30, SRNM=42
- **Component labelling, availability and HSE**: WCT=105, SRNM=51, RBRP=26, Miscellaneous=44
- **Miscellaneous**: WCT=7

**Legend**: WCT=wrong component transfused; SRNM=specific requirements not met; HSE=handling and storage errors; RBRP=right blood right patient; Ig=immunoglobulin

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

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
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
If ‘yes’ to any of these questions

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?
3. 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

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.
Figure 17b.2: Number of surveillance criteria versus number of accepted TACO cases

Number of TACO criteria met

- Two: 2
- Three: 56
- Four: 80
- Five: 1

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

Withdrawn - other causes thought to be mainly contributing to patient’s clinical features n=5
- Recategorised as TRALI type II based on recent consensus redefinition n=3
- Transferred to TACO n=3
- Transferred to FAHR n=2

Figure 17c.1: Summary of transfers and categorisation of cases included under TAD
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

Acute HTR n=15

Delayed HTR n=30

Hyperhaemolysis n=4

Typical clinical features reported including fever, dyspnoea, rigors, tachycardia, reports of pain and haemoglobinuria

No clinical symptoms of transfusion reaction reported in 12/30 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

Figure 18.1: Overview of HTR cases n=49
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. 19/25 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

- Jk<sup>a</sup>: 8
- Fy<sup>a</sup>: 6
- C: 4
- E: 2
- M: 1
- IH: 1
- Fy<sup>b</sup>: 1
- Co<sup>a</sup>: 1
- C: 1
- Jk<sup>b</sup>: 1
- D: 1
Figure 20.1: Outcome of UK reports of suspected TTI made to the NHSBT/PHE Epidemiology Unit in 2019

152 Reports for investigation

139 Suspected bacterial incidents investigated

- 130 Post-transfusion reactions with no evidence of bacteria on investigation
- 9 Not TTI (1 HBV, 4 HCV, 2 HEV, 2 HIV, 2 CMV)

13 Suspected viral incidents reported and investigated

- 11 Not TTI
  - 11 Not TTI (1 HBV, 4 HCV, 2 HEV, 2 HIV, 2 CMV)

- 1 Probable TTI
  - 1 Probable TTI (1 HBV)

- 1 Confirmed TTI
  - 1 Confirmed TTI (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

- **Adverse event**
- **Adverse reaction**
Figure 22.1: Percentages of paediatric and total reports in each category

TII=transfusion-transmitted infection; CS=cell salvage; UCT=uncommon complications of transfusion; TRALI=transfusion-related acute lung injury; TAD=transfusion-associated dyspnoea; TACO=transfusion-associated circulatory overload; HTR=haemolytic transfusion reactions; FAHR=febrile, allergic and hypotensive reactions; HSE=handling and storage errors; IBCT-SRNM=incorrect blood component transfused-specific requirements not met; IBCT-WCT=IBCT-wrong component transfused

Percentage of reports

- TII: 0.2%
- CS: 1%
- UCT: 3%
- TRALI: 3%
- TAD: 0.1%
- TACO: 4%
- FAHR: 49%
- Anti-D: 4%
- HSE: 35%
- Under or overtransfusion: 11%
- Delayed: 129%
- Avoidable: 99%
- IBCT-SRNM: 259%
- IBCT-WCT: 70%

% of total reports (1867)
% of paediatric reports (132)
Figure 22.2: Summary of paediatric cases by category and age 2019

<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>
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</thead>
<tbody>
<tr>
<td>Incorrect blood component transfused (IBCT)</td>
<td>15</td>
<td>7</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>Under or overtransfusion</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Delayed</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Febrile, allergic and hypotensive reactions (FAHR)</td>
<td>3</td>
<td>30</td>
<td>5</td>
<td>38</td>
</tr>
<tr>
<td>Anti-D immunoglobulin errors (Anti-D Ig)</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Handling and storage errors (HSE)</td>
<td>1</td>
<td>7</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>Transfusion-associated circulatory overload (TACO)</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Haemolytic transfusion reactions (HTR)</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cell salvage (CS)</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Uncommon complications of transfusion (UCT)</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[Chart showing the number of cases in different categories by age group]
Figure 22.3: Trends in paediatric cases from 2009-2019
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
Figure 22.4: Breakdown of incorrect blood component transfused reports

IBCT-WCT Totals

- Laboratory: 3 ≤28 days, 2 >28 days to <1 year, 1 1 to <16 years, 1 16 to <18 years
- Clinical: 4 ≤28 days, 1 >28 days to <1 year, 1 1 to <16 years

IBCT-SRNM Totals

- Irradiated: 3 ≤28 days, 1 >28 days to <1 year, 1 16 to <18 years
- MB- or SD-plasma: 2 ≤28 days, 2 >28 days to <1 year

Others

- 5 ≤28 days, 5 >28 days to <1 year, 5 1 to <16 years, 1 16 to <18 years

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

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

**a. Sickle cell disease n=260**
- HTR & SRNM: 72.7%
- SRNM: 98
- HTR: 91
- FAHR: 34
- ADU: 24
- IBCT: 9
- TACO: 2
- TAD: 1
- TTI: 1

**b. Thalassaemia n=58**
- FAHR: 41.4%
- FAHR: 24
- SRNM: 14
- HTR: 10
- IBCT: 5
- TACO: 4
- ADU: 1
- TTI: 1

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

- **Previous pregnancy**
- **No previous pregnancy**
17 NPP

RAADP
12 received RAADP
3 no RAADP received
2 did not provide information

PSE
4/12 PSE
3 x fall
1 x APH

Outcome of pregnancy
12 live births
8 no treatment
4 treatment for HDFN

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=intraterine death
Figure 24.3: Summary of 2019 PP data n=37

37 PP

When anti-D detected

RAADP

RAADP in preceding pregnancy

PSE

PSE in preceding pregnancy

Outcome of index pregnancy

6 live births
1 stillbirth, 1 miscarriage
2 unknown
5 treatment for HDFN
4 no treatment
1 unknown

10 in first trimester

6 received RAADP
2 TOP or miscarriage
2 unknown

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

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

20 later in pregnancy

RAADP in index pregnancy

PSE in index pregnancy

2 x PV bleeding
1 x fall

7 at delivery

18 received RAADP
9 did not receive RAADP

6/27 PSE, 3 x APH

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
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).

“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.
Figure 25.3: Source of the HSCT-related error $n=324^*$

- **ABO/D clinical**: 33 errors, 10 near misses
- **SRNM clinical**: 86 errors, 29 near misses
- **ABO/D laboratory**: 76 errors, 41 near misses
- **SRNM laboratory**: 24 errors, 25 near misses

*Excludes 1 case of wrong component transfused to a neonate
SRNM=specific requirements not met
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
- Other: 2

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

- 52.4% detected at the bedside
- Bedside check: 55
- Component selection: 6
- Testing: 11
- Component collection: 4
- Other or unknown: 29
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.**
Figure 25.7: Important steps in ensuring safe transfusion practice in HSCT

1. Inform transfusion laboratory of transplant details
2. Laboratory to update LIMS
3. Confirmation of updated LIMS
4. Local hospital informed
5. Everyone involved in patient care (other local hospitals and primary care) also informed of patient’s transfusion requirements
6. Patient and family informed and educated about new transfusion requirements

Transfusions in HSCT

HSCT=haemopoietic stem cell transplant; LIMS=laboratory information management system.
Figure 26.1: Submitted confirmation reports 2010-2019
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
Figure 26.3: Human error sub-categories of the two most increased storage errors

- Lapsed/no training: 2
- Ineffective training: 1
- Incorrect procedure: 2
- Inadequate training: 1
- Inadequate QMS – staffing and workload: 4
- Procedure performed incorrectly: 8 (Component expiry: 7, Return to stock error: 1)
- Procedural steps omitted/wrong procedure performed: 14 (Component expiry: 6, Return to stock error: 8)
- Inadequate process: 40 (Component expiry: 33, Return to stock error: 7)

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

- Incorrect procedure: 2
- Procedure performed incorrectly: 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
Figure 26.6: Human error sub-category

- 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

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

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

HSE=handling and storage errors; QMS=quality management system
<table>
<thead>
<tr>
<th>Category</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
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<th>F</th>
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<td>1</td>
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</tbody>
</table>

- Red: Inadequate process
- Blue: Inadequate QMS – staffing and workload
- Orange: Inadequate training
- Green: Ineffective training
- Purple: Procedural steps omitted/wrong procedure performed
- Yellow: Procedure performed incorrectly

See Figure 26.5 for key to category abbreviations.
Figure 26.10: SAR reports, by imputability, reported to SABRE in 2019
Figure 26.11: Good practice section referenced in major deficiencies 2019

1. General principles: 30
2. Personnel and organisation: 11
3. Premises: 1
4. Equipment and materials: 44
5. Documentation: 5
6. Blood collection, testing and processing: 4
7. Storage and distribution: 0
8. Non-conformance and recall: 27
9. Self-inspection, audits and improvements: 3
10. Quality monitoring and control: 1
### Figure 26.12: Good practice section referenced in other deficiencies 2019

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<td>2. Personnel and organisation</td>
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<tr>
<td>3. Premises</td>
<td>18</td>
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<tr>
<td>4. Equipment and materials</td>
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<td>5. Documentation</td>
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<tr>
<td>6. Blood collection, testing and processing</td>
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<td>7. Storage and distribution</td>
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<td>8. Outsourced activities management</td>
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<td>9. Non-conformance and recall</td>
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<tr>
<td>10. Self-inspection, audits and improvements</td>
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<tr>
<td>11. Quality monitoring and control</td>
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4.1 Equipment and materials general requirements
4.2 Data processing systems
4.3 Qualification and validation
4.4 Process validation
4.5 Validation of test methods
4.6 Change control
4.7 Control of equipment and materials

Figure 26.13: Good practice section 4: equipment and materials
Figure 26.14: Good practice section 9: non-conformance and recall

- **9.1 Deviations**
  - Major deficiencies: 14
  - Other deficiencies: 9

- **9.2 Complaints**
  - Major deficiencies: 1

- **9.3 Recall**
  - Major deficiencies: 19

- **9.4 Deviation management and corrective and preventative actions**
  - Major deficiencies: 13
  - Other deficiencies: 7
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<td>5.11 Documentation other</td>
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