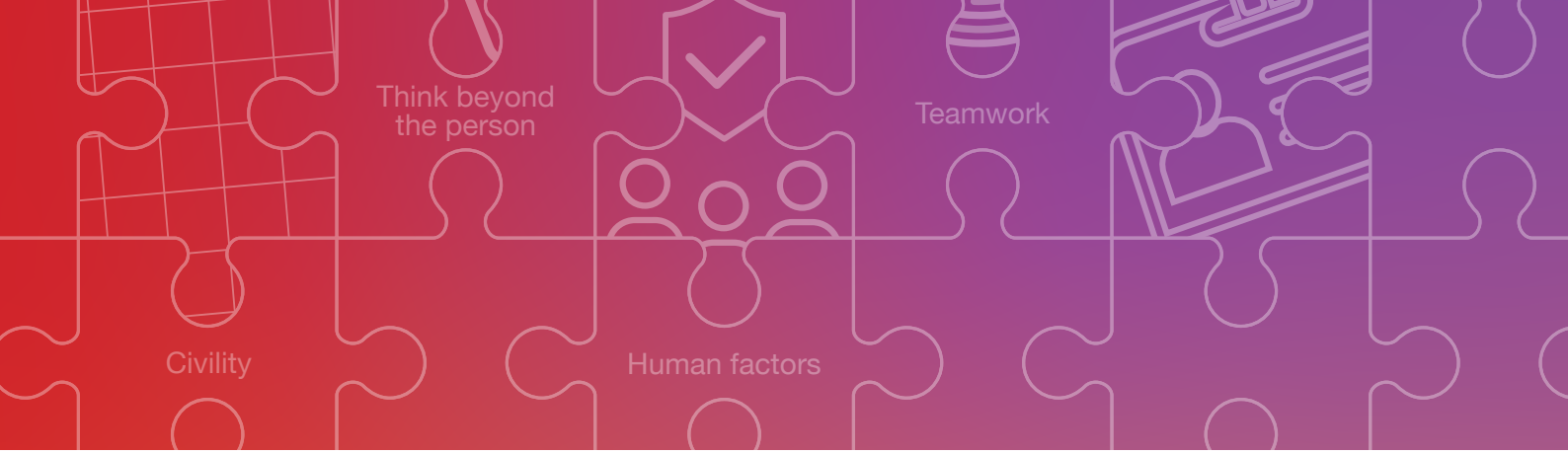

ANNUAL SHOT REPORT 2024

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SHOT
Serious Hazards of Transfusion

Serious Hazards of Transfusion (SHOT)

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Chair: Professor Mark Bellamy and Dr Megan Rowley

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Mr Graham Donald	Lay member
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Dr James Reid	Royal College of Physicians
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Prof David Roberts	British Blood Transfusion Society
Dr Susan Robinson	British Society for Haematology
Ms Emma Rose	Royal College of Midwives
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Dr Hannah Cohen	Founder Member and former Steering Group Chair
Dr Sue Knowles	Former Interim Medical Director of SHOT
Dr Elizabeth Love	Former National Medical Coordinator of SHOT
Prof John Lumley	Founder Member
Dr Brian McClelland	Founder Member

Dr Derek Norfolk	Founder Member
Dr Dorothy Stainsby	Former National Medical Coordinator of SHOT
Dr Clare Taylor	Former SHOT Medical Director
Dr Dafydd Thomas	Former Steering Group Chair
Dr Lorna Williamson	Founder Member

NB. All members of the WEG are members of the Steering Group in their own right.

Note: Those who have contributed to various chapters in this Annual SHOT Report but are not members of the SHOT WEG have been included as authors in the respective chapters. We are grateful for their valuable contributions.

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Disclaimers:

Case studies: The information in Annual SHOT Report case studies is provided to SHOT by reporters. All reports are anonymised and SHOT relies on reporters submitting correct and accurate information. SHOT does not accept responsibility for any inaccuracies which may arise from incorrect information being submitted.
Data interpretation: There are many factors that can influence the number of reports submitted to SHOT, including awareness of what to report, and staffing levels within organisations. Combined with a lack of accurate real time denominator data about transfusions across the UK, this makes interpretation of the fluctuations in number of reports very difficult. The comparisons made to reporting numbers from previous years are based on actual numbers submitted only and should be interpreted with caution.

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Foreword

1

I have been part of the SHOT Steering Group and Working Expert Group since 2012, so it is a great honour for me to continue to support SHOT as the Steering Group Chair and to introduce the 2024 Annual SHOT Report.

There have been many significant changes since the first Annual SHOT Report (ASR) in 1996 and much progress in transfusion safety from the period covered by the Infected Blood Inquiry (IBI) Report published in May 2024 (IBI, 2024). And yet, new challenges have emerged which require different thinking as well as resilience in our practice. At a time when we feel less secure in our personal lives and are experiencing huge pressure on resources in healthcare across the UK, we must continue to learn lessons from haemovigilance and aspire to the high standards that our patients reasonably expect.

We must be proud that SHOT-reportable events are recognised, investigated, and reported so diligently by our hospital transfusion teams and healthcare colleagues involved in the transfusion of patients. Expertise in the application of human factors is increasing and, as a result, the quality of the reports is improving and the potential for realistic improvements in transfusion practice is being identified at a local level and, through this ASR, shared with others.

SHOT promotes patient safety and supports healthcare workers in delivering safe clinical transfusion practice. To disseminate haemovigilance messages as widely as possible, SHOT has diversified its resources, and these are all available on the new upgraded SHOT website with access to the current and all previous ASR, including figures and cases for shared learning, and ASR summaries for distribution at a local level. The 'Meet the Experts' webinars throughout the year provide an opportunity for the SHOT chapter authors from the Working Expert Group to discuss the various sections of the report in detail and answer questions. These webinars are recorded and are free to access at any time. The SHOT Bites topic summaries are regularly updated and expanded as issues are identified. Short, animated videos cover key transfusion safety subjects including learning from the IBI. Sadly, these resources are probably under-used and many people who would benefit from their content are unaware they exist. I would encourage you to explore the new SHOT website and spread the word to your colleagues.

There are several concerns highlighted in this year's ASR. Firstly, the number of deaths where transfusion events are possibly or probably implicated has increased significantly. As in previous years, the two reporting categories where most deaths have occurred are transfusion delays and pulmonary complications, particularly transfusion-associated circulatory overload. Both were the subject of Patient Safety Alerts in 2022 and 2024 respectively with the purpose of raising awareness and systematically reviewing processes to reduce the risks (SHOT, 2022; MHRA and SHOT, 2024). Whilst it could be argued that increased awareness leads to increased reporting, the intended reduction in risk has not led to a reduction in deaths. This raises the wider issue of how to move from evidence into practice, or for haemovigilance reporting to translate into improved outcomes.

The human factor analysis of haemovigilance reports demonstrates some of the potential barriers which need to be addressed and overcome. These include appropriate clinical and laboratory staffing levels, sufficient up to date knowledge, competencies relevant to role for all skilled healthcare staff and a supportive culture where adverse events are treated as opportunities to learn and improve. In this reporting year there have been difficulties in healthcare recruitment in many areas leading to understaffing, strikes leading to increased pressure on critical services and reduction in time and budgets for training and continuing professional development. All of these, as well as other issues, have been referenced in the reports to SHOT.

One of the main opportunities to improve processes has been the use of technology, particularly information technology (IT), to guide and support safe and efficient processes in clinical and laboratory transfusion (BBC, 2024a). SHOT has encouraged this, at the same time reiterating the importance of

maintaining the knowledge and understanding of the correct processes that underpin the systems we use and having robust downtime procedures. SHOT has been pleased to observe an increased uptake of clinical transfusion IT systems, as well as implementation and upgrading of laboratory IT systems. These have increasingly been configured to work across networked hospitals and laboratories and to integrate with clinical systems. But we have also seen the catastrophic consequences of the failure of these systems when subject to malicious attack resulting in a forced return to manual systems. These cyber-attacks have been widely reported (NHSE, 2024b) and you can see the specific transfusion-related adverse events in this ASR. This is not to discourage the use of technology but to highlight the critical importance of resilience and business continuity.

The IBI recommendations (2024) have rightly guided us and focused our attention over the past year and should continue to do so. In response to the IBI, SHOT has been involved with the planning and delivery of haemovigilance workshops across the UK. Recognising the difficulty some hospitals have in responding in a consistent and lasting way to the many and varied SHOT recommendations over the years, a different approach has been taken. This includes standardising the presentation of the haemovigilance data in the ASR to make it easier to access and to disseminate. It also includes translating the recommendations into a series of structured standards for transfusion safety which apply to all hospitals where patients are transfused. These have been the subject of a wide stakeholder consultation before being launched at the Annual SHOT Symposium in July 2025.

Finally, I would like to thank all of those who report to SHOT for your continued dedication to improving patient safety. Thank you also to the members of the SHOT Steering Group and the Working Expert Group for your time, expertise, and guidance. I particularly thank the patient representatives who provide such valuable insight.

I hope you all find time to read this ASR and share it with others. There is so much still to be done to honour the principles and recommendations in the IBI report and those that have been affected by the adverse effects of transfusion.

Dr Megan Rowley
Chair SHOT Steering Group.

SHOT
Serious Hazards of Transfusion

Participation in United Kingdom (UK) Haemovigilance

2

Author: Debbi Poles

Introduction

Following a substantial rise in the number of reports received in 2023, the level of reporting appears to have evened out. The total number of reports submitted to SHOT in 2024 was 5033, similar to the number of reports submitted in 2023 (n=4972).

Figure 2.1: Haemovigilance reports submitted by year with reports per 1,000 blood components issued 2010-2024

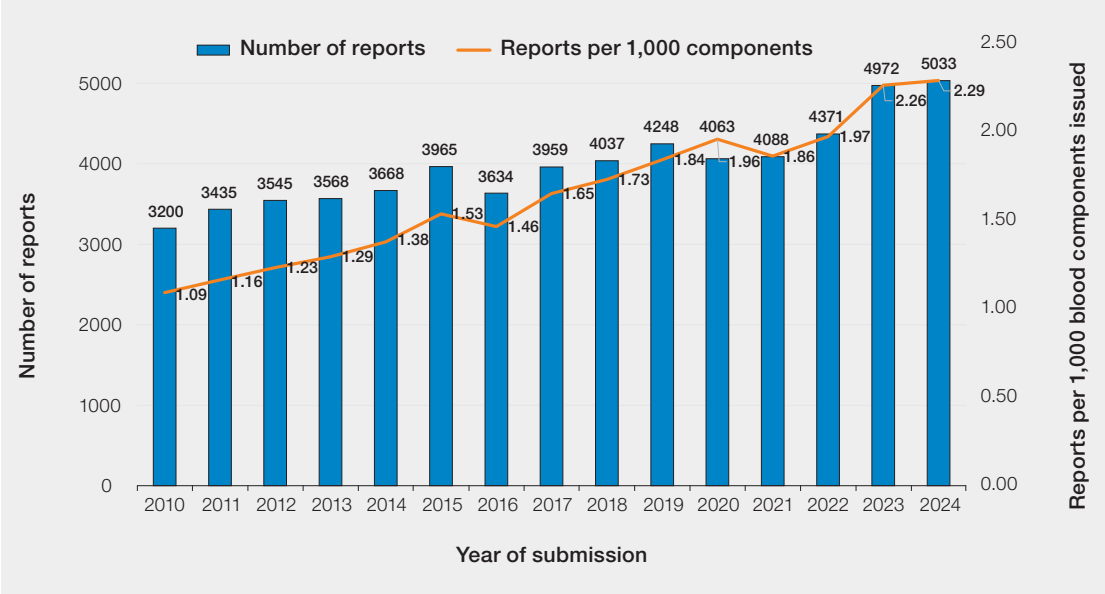
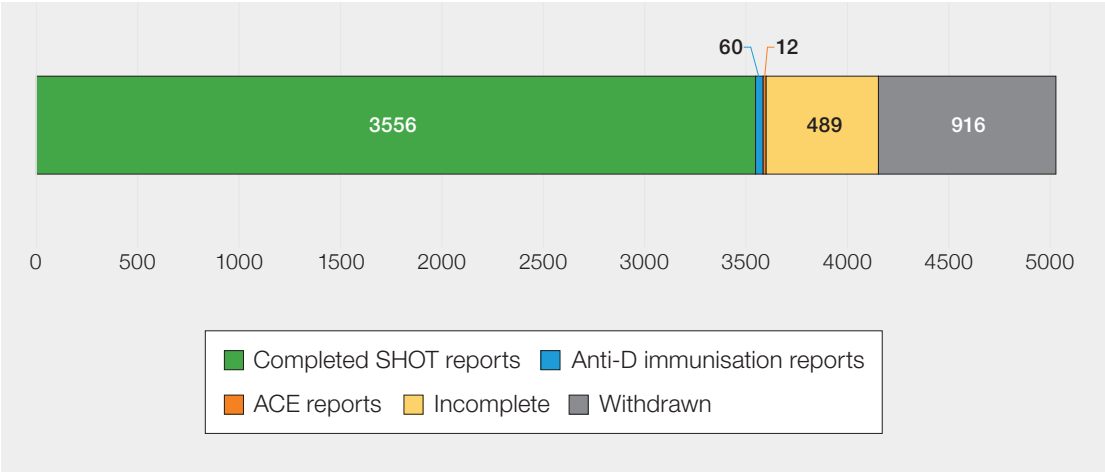


Figure 2.2 shows that 3628/5033 (72.1%) were completed by the reporter and have been included in the Annual SHOT Report. This total includes 3556 SHOT reports, 60 anti-D immunisation reports, and 12 acknowledging continuing excellence (ACE) reports. There were 916 withdrawn reports (main reasons for withdrawal were Medicines and Healthcare products Regulatory Agency (MHRA)-reportable only, mild reactions, or reactions determined to be unrelated to transfusion, and not fitting SHOT definitions), and 489 that were incomplete at the cut-off date for inclusion in this year's Annual SHOT Report.

Figure 2.2: The status of reports submitted to SHOT in 2024 (n=5033)



ACE=acknowledging continuing excellence

Note: One case submitted and completed in 2024 was a possible transfusion-transmitted infection (TTI) from 2023. This has not been included in this year's Annual SHOT Report numbers, but was discussed in the 2023 Annual SHOT Report (Narayan, et al., 2024)

Cases included in the 2024 Annual SHOT Report n=3998

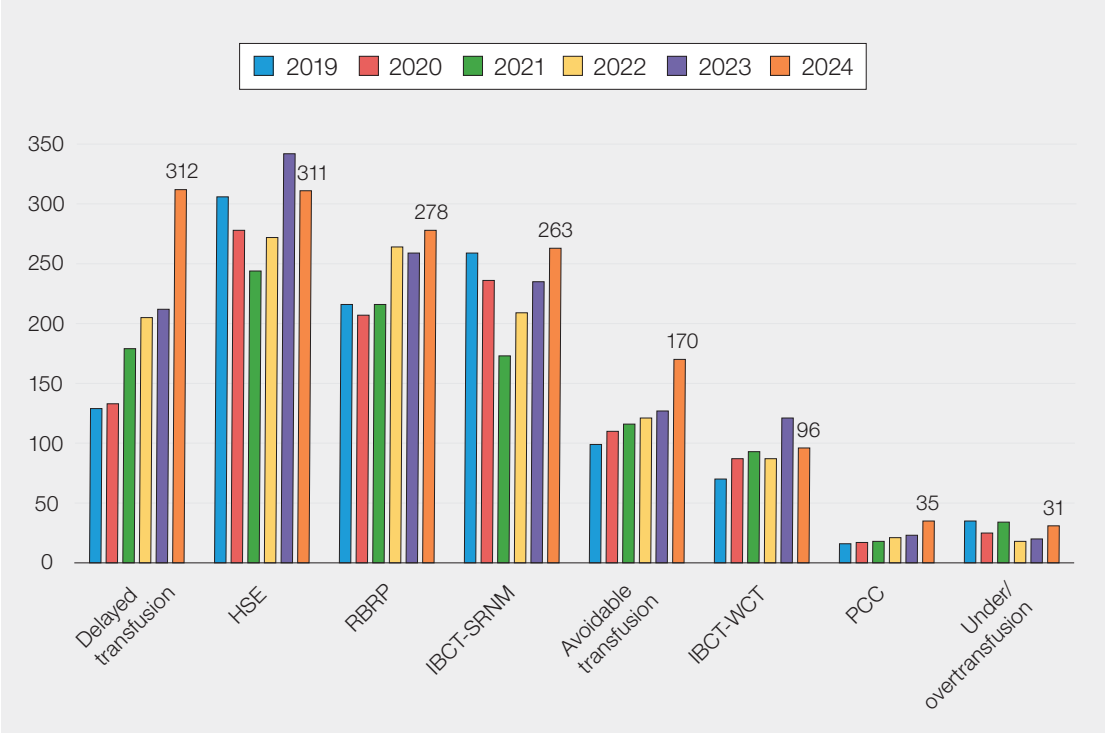
The total number of reports analysed and included in the 2024 Annual SHOT Report was 3998. This total comprises 3555 reports submitted and completed in 2024 (see Figure 2.2), plus 443 that were submitted in earlier years, but not finalised until 2024. This is a small increase of 165 from the 3833 reports included in the 2023 Annual SHOT Report (Narayan, et al., 2024).

In addition to these 3998 reports, there were 68 reports of immunisation against the D-antigen. These are counted separately as part of a stand-alone study. There were also 12 reports included in the ACE category, as examples of good practice. These included 5 cases of excellent practice and 7 cases where there was good learning from everyday events.

The number of reports with potential for patient harm (excluding 'near miss' and 'right blood right patient') was 2312, an increase of 158 from 2023 (n=2154).

Most reporting categories contained comparable numbers to previous years, but there were a couple of notable exceptions. Delayed and avoidable transfusions have both seen a steady increase year-on-year, followed by a striking increase in 2024. Figure 2.3 shows reports by year in each of the error categories where a component was transfused from 2019 to 2024. Delays increased by 47.2%, from 212 in 2023 to 312 in 2024, and avoidable transfusions increased by 33.9%, from 127 in 2023 to 170 in 2024.

Figure 2.3: Number of reports by SHOT error category, 2019 to 2024



HSE=handling and storage errors; RBRP=right blood right patient; IBCT-SRNM=incorrect blood component transfused-specific requirements not met; IBCT-WCT=IBCT-wrong component transfused; PCC=prothrombin complex concentrates

Blood component issue data 2024

Table 2.1 lists the total number of blood components issued from the UK Blood Services in 2024, and the number of solvent detergent-treated fresh frozen plasma (SD-FFP) (Octaplas®) units issued in each country.

Table 2.1: Blood components and SD-FFP issue data for the calendar year 2024 in the UK

	Red cells	Platelets	FFP	SD-FFP	Cryoprecipitate	Totals
NHS Blood and Transplant	1,348,369	252,784	171,535	55,715	42,078	**1,870,481**
Northern Ireland Blood Transfusion Service	41,823	8,547	4,078	2,136	761	**57,345**
Scottish National Blood Transfusion Service	137,614	23,184	13,284	2,109	2,578	**178,769**
Welsh Blood Service	73,677	9,540	7,573	1,595	422	**92,807**
Totals	**1,601,483**	**294,055**	**196,470**	**61,555**	**45,839**	**2,199,402**

SD=solvent-detergent; FFP=fresh frozen plasma

Cryoprecipitate numbers are expressed as pools and single donations as issued; all other components are adult equivalent doses

SD-FFP data is supplied by Octapharma for England and Scotland; in England, hospitals order directly from Octapharma and in other countries, the process is via the Blood Services

SHOT reporting by UK country

Full tables containing the breakdown of data from 2024 by UK country and previous years can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Reporting organisations in 2024

To calculate participation data by reporting organisations, SHOT combines data from individual hospitals into their parent National Health Service (NHS) Trust or Health Board. This is because there are varying reporting arrangements between different organisations. Some NHS Trusts/Health Boards submit from only one reporting account, whereas others may have one reporting account per hospital.

In 2024, there was only 1 NHS organisation that did not submit any report. This was a very low blood user (issued with less than 500 components).

There were 27 non-NHS organisations that submitted 56 reports in 2024 which is a slight decrease from 2023 (65 reports from 26 non-NHS organisations). This includes healthcare organisations situated in the Channel Islands who are not considered to be a part of the UK and therefore are not regulated by the MHRA.

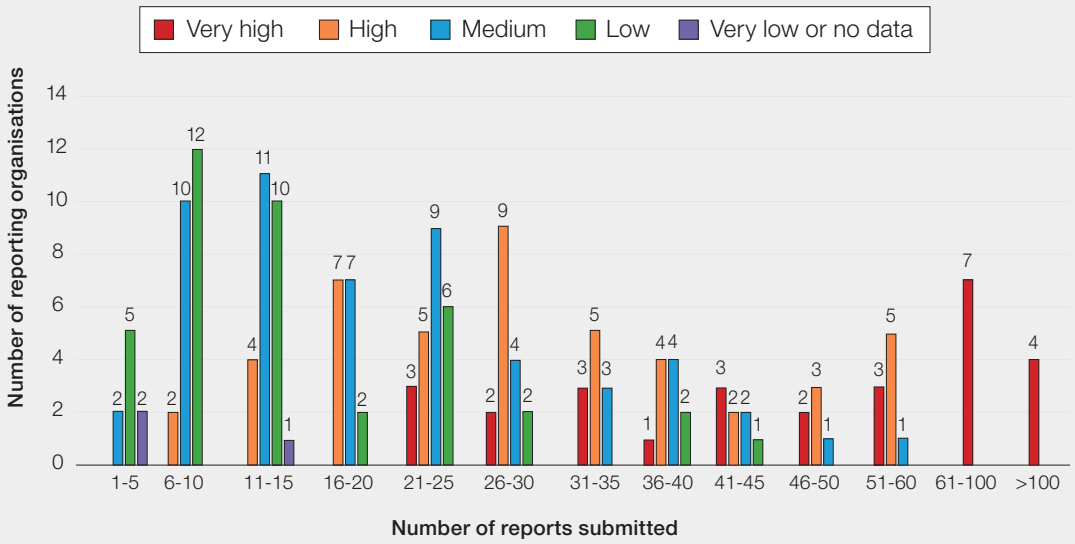
In 2022, analysis was carried out on reporting levels between different sized organisations, based on blood component issue data (Narayan, et al., 2023). The same analysis has been performed for 2024, and this has seen a marginal shift in the number of reports submitted by very large blood users. In 2022, there were 4 very large users with less than 20 reports, while in 2024, the lowest number of reports in the very large user category was 21. This suggests a move towards more balanced reporting proportionate to blood usage. However, Figure 2.4 still demonstrates variation in reporting levels, with many low and medium users submitting more reports than high or very high users. While there isn't a single 'optimal' incident reporting level for every organisation, high-performing, safe healthcare systems typically have high levels of reporting with the majority of incidents being no-harm to low-harm events. This aligns with a strong safety culture where staff feel confident reporting incidents, including near misses, to learn from them and prevent future harm. If severe harm incidents dominate, it may suggest poor early intervention and learning. Too few incidents reported including no-harm or near miss reports may indicate under-reporting and the safety culture would need to be addressed.

The characteristics of an organisation with optimal reporting should ideally include:

- High volume reporting of minor incidents and near misses signalling a strong reporting culture
- Proportionally fewer severe harm incidents suggesting effective risk mitigation
- Actionable learning from reports; reporting should lead to changes, not just data collection
- Feedback to staff encouraging continued engagement and learning
- Integration with excellence reporting, balancing learning from failures and successes

For haemovigilance reporting, it would be logical to expect that the number of reports submitted would correlate to the amount of blood components used in an organisation. Other factors influencing reporting levels include staffing levels, experience and knowledge, safety culture and local practices. A higher level of reporting indicates a willingness to participate and learn from transfusion events to improve patient safety.

Figure 2.4: Number of reports by NHS reporting organisation and component usage level in 2024

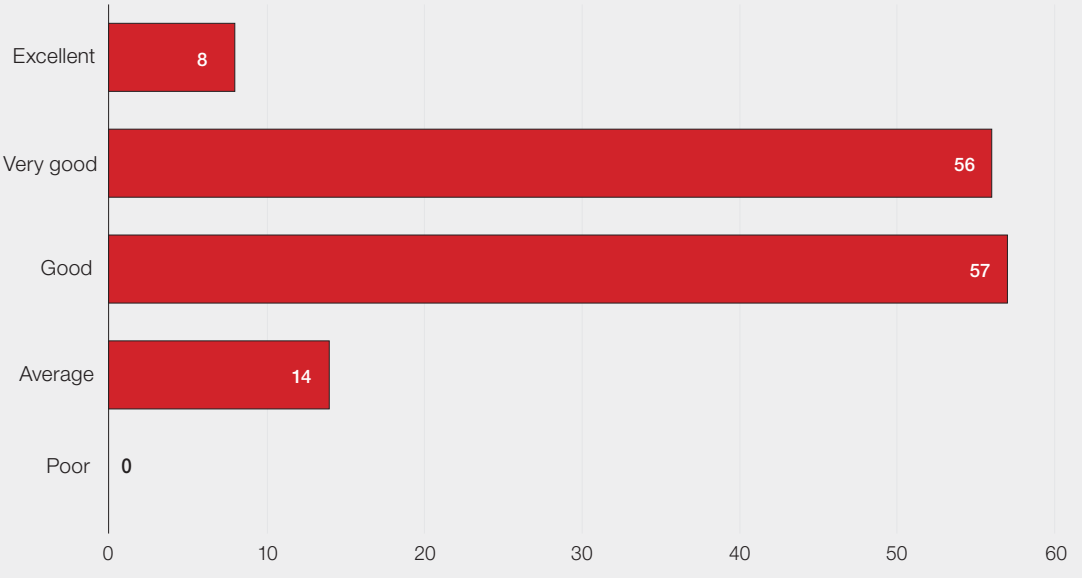


SHOT reporting database developments (Dendrite)

The SHOT database was given an upgrade in January 2024, which brought the look of the database more in line with SHOT branding and colours. It was also intended to be more easily readable, with a larger font size and user-friendly. The other main changes were to introduce colour coding for questions: red for an unanswered question, and green for answered. There was also a change to the mechanism for changing the questionnaire type if the report had been submitted inadvertently in an incorrect category.

A survey was sent to all SHOT reporters in July 2024 to ask for their feedback on the new changes, which had been in effect for more than 6 months. In total, 135 responses were received from reporters who had used the revised database. Most users, 121/135 (89.6%) rated the ease of use to be good, very good or excellent.

Figure 2.5: Survey responses for ease of use of the new SHOT database user interface in July 2024



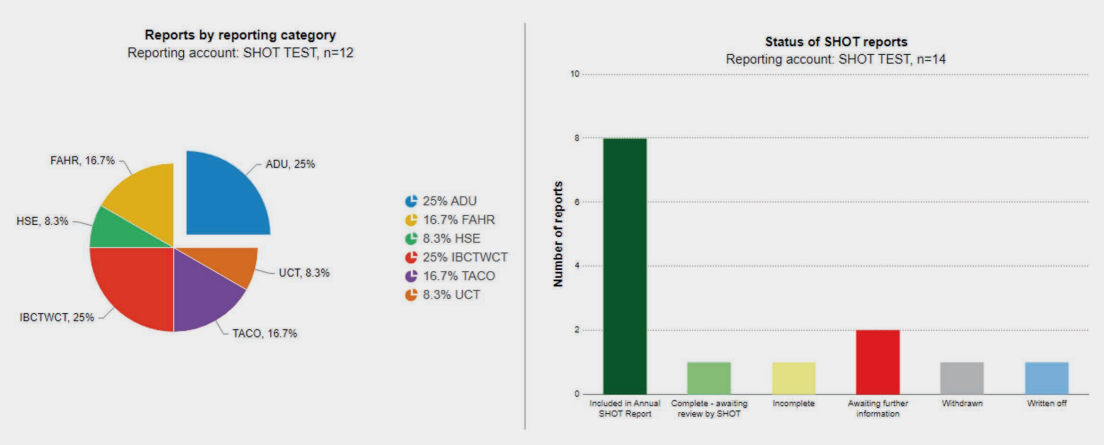
SHOT database dashboards

SHOT has developed a dashboard with a series of graphs displaying useful real-time data for reporters. This was implemented in July 2025 and includes the following data:

1. Number of reports submitted
2. Reports by reporting category
3. Status of SHOT reports
4. Average time taken to complete submitted reports
5. Incomplete reports
6. Reports by age and gender
7. Reports by location

These graphs and tables are interactive and are configurable by localisation, i.e., reporting account, NHS organisation, region/devolved country, and for the whole UK. They can also be filtered by SHOT reporting category.

Figure 2.6: Example graphs from the SHOT dashboard



More information about the new dashboards can be found at https://www.shotuk.org/reporting/incident/user-guides/.

Blood Services reporting to SHOT

A project has been underway since late 2023 to extend SHOT reporting for Blood Service errors that have an impact on patients. Previously, SHOT reports have only been submitted from hospitals. This will initially cover three new categories: incorrect blood component issued for wrong components, specific requirements not met, and errors related to incorrect issue of anti-D immunoglobulin (Ig). ACE reporting has been extended to include reports from Blood Services.

This will be implemented later in 2025 and will be discussed in more detail in the 2025 Annual SHOT Report next year.

SHOT participation benchmarking data and the 'Model Hospital'

SHOT continues to publish both monthly and annual participation data on the SHOT website. A collaborative project is being planned to incorporate the annual data into the 'Model Hospital', which is part of NHS England's Model Health System. This workstream is part of the wider implementation action plan for the Infected Blood Inquiry report recommendations.

The Model Hospital is a data-driven improvement tool that contains a wide range of benchmarking metrics that NHS providers can use to assess their performance against their peers. At present, this is only available to NHS Trusts in England (NHSE, 2025b).

Conclusion

Haemovigilance would not be possible without the valuable contribution made by our dedicated hospital reporters, and SHOT is extremely grateful for their continued engagement. This is evidenced by the continuing high levels of participation being maintained, despite the ongoing challenges faced across the healthcare sector. Ensuring timely haemovigilance reporting and effective benchmarking for transfusion incident reporting enables continuous improvement and helps enhance transfusion safety.

Every report matters. Taking the time to report an event, whether it's an error, a near miss, a reaction or an example of excellence shows a commitment to learning and improving care. SHOT acknowledges and deeply values each report as a vital contribution to safety, transparency, and better outcomes for patients and staff.

Recommended resources

Definitions of current SHOT reporting categories & what to report
https://www.shotuk.org/reporting/incident/

SHOT Participation Benchmarking Data
https://www.shotuk.org/reporting/participation-benchmarking/

SHOT Monthly Participation Data
https://www.shotuk.org/reporting/participation-data/

SHOT
Serious Hazards of Transfusion

Headline Data: Deaths, Major Morbidity and ABO-Incompatible Transfusions

3

Authors: Shruthi Narayan and Debbi Poles

Key SHOT messages

- Errors continue to account for the majority of reports. In 2024, 3322/3998 (83.1%) of all reports (including near miss (NM) and right blood right patient (RBRP)), and 70.8% of incidents excluding NM and RBRP were due to errors
- There were no confirmed or probable transfusion-transmitted infections reported in 2024
- The risk of death related to transfusion in the United Kingdom (UK) is 1 in approximately 37,000 components issued, and the risk of serious harm is approximately 1 in 11,500 components issued (includes solvent detergent-treated fresh frozen plasma (SD-FFP) data) based on the reports submitted to SHOT
- Transfusion-related deaths reported to SHOT have almost doubled in 2024
- There were no deaths which were definitely related (imputability 3) to transfusion in 2024
- Pulmonary complications and transfusion delays were the main causes of reported transfusion-related deaths in 2024
- There has been a steep rise in deaths due to transfusion-associated circulatory overload (TACO)
- Near miss events continue to account for a large proportion, 1408/3998 (35.2%) of the incidents reported to SHOT
- Inadequate staffing, lack of appropriate training, suboptimal supervision and poor safety culture continue to be identified as contributory factors to numerous incidents reported to SHOT
- Trends in pathological transfusion reactions, like the febrile, allergic, hypotensive, and haemolytic reactions are similar to previous years
- It is encouraging to see a reduction in the ABO-incompatible (ABOi) red cell transfusions reported. However, ABOi plasma component transfusions continue to be reported: these were mainly due to component selection errors in the laboratory

Introduction

The SHOT haemovigilance data from 2024 indicate worsening trends, both in the numbers reported and the severity of cases. These are elaborated on further in this chapter and throughout the 2024 Annual SHOT Report.

The risk of death related to transfusion in the UK is 1 in approximately 37,000 components issued, and the risk of serious harm is approximately 1 in 11,500 components issued based on the reports submitted to SHOT. This includes the risks of harm from errors in the transfusion process. The risk of death has worsened in 2024 due to an increase in the number of transfusion-related deaths reported, mainly in TACO cases but also an increase in delayed transfusions.

Avoidable errors consistently account for most of the reports 3322/3998 (83.1%) (Figure 3.1), and this percentage has been unchanged for the last 3 years. This figure includes errors with no harm to patients but had the potential to do so, such as near misses and right blood right patient errors.

Figure 3.1: Errors account for most reports in 2024 (n=3322/3998)

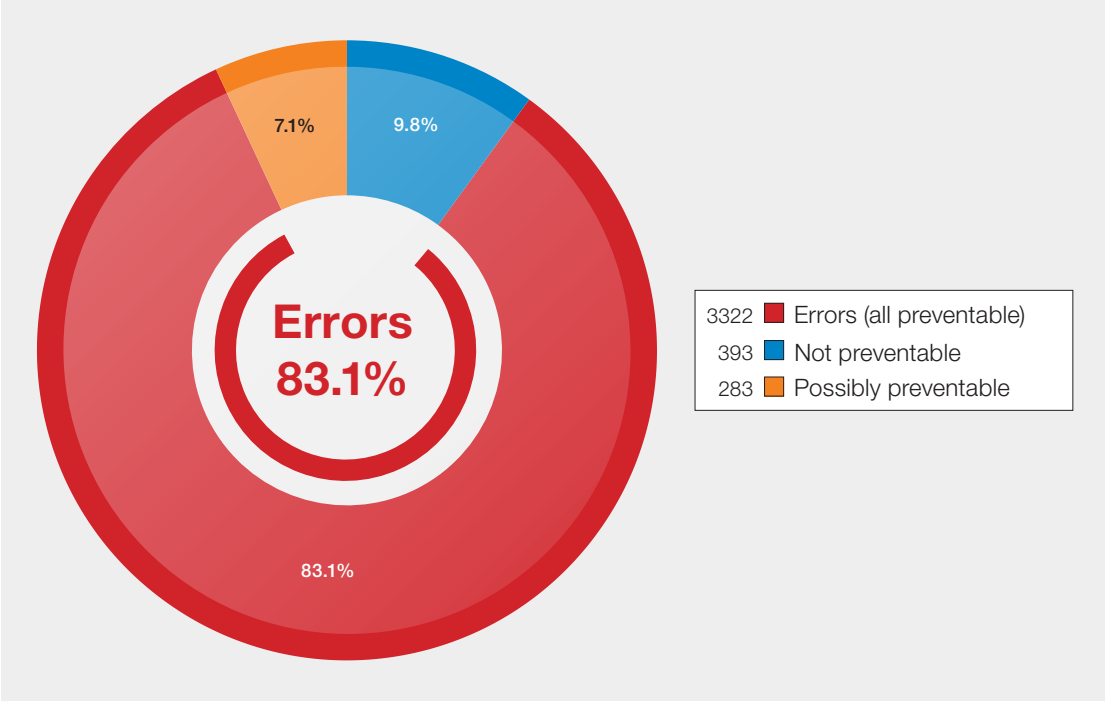
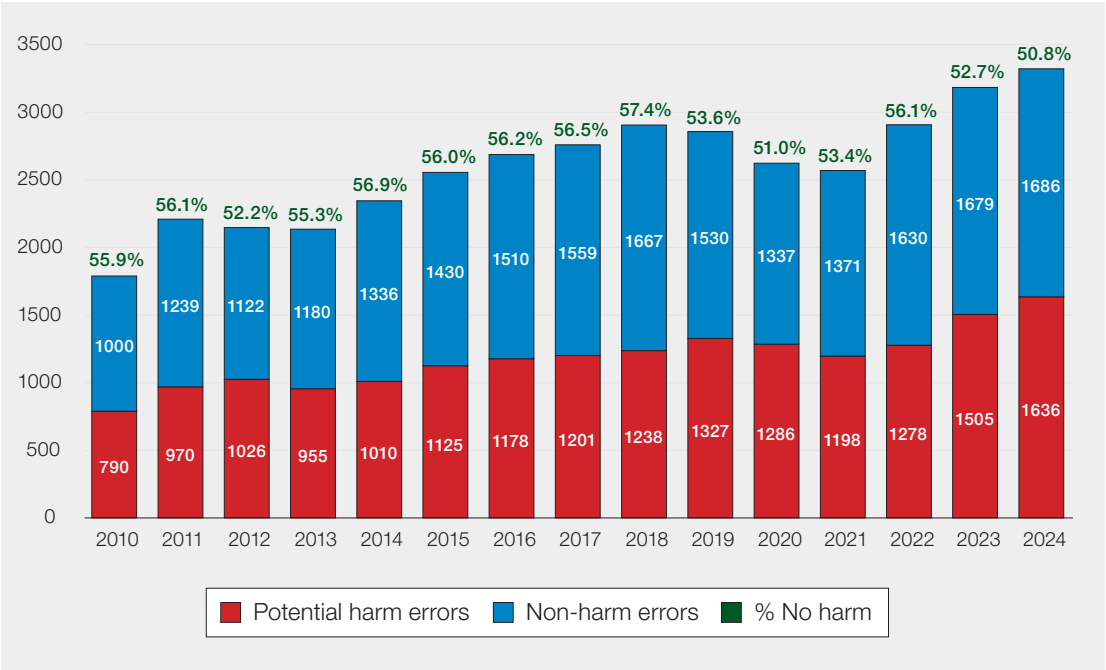


Figure 3.2 shows the percentage of no harm incidents in the errors reported to SHOT since 2010. The dip in the percentage of no-harm incidents noted in 2023 has increased further in 2024, and is now almost at 50%, which is less than 2020 when it was at its lowest since 2010. This highlights the urgent need for actions to improve transfusion safety.

Figure 3.2: No patient-harm and potential patient-harm incidents 2010-2024



Potential harm incidents include incorrect blood component transfused (IBCT) errors, delayed transfusion, avoidable transfusion, under or overtransfusion, incidents related to prothrombin complex concentrates, handling and storage errors (HSE) and errors related to anti-D immunoglobulin administration
Non-harm incidents include near miss (NM) and right blood right patient (RBRP) errors

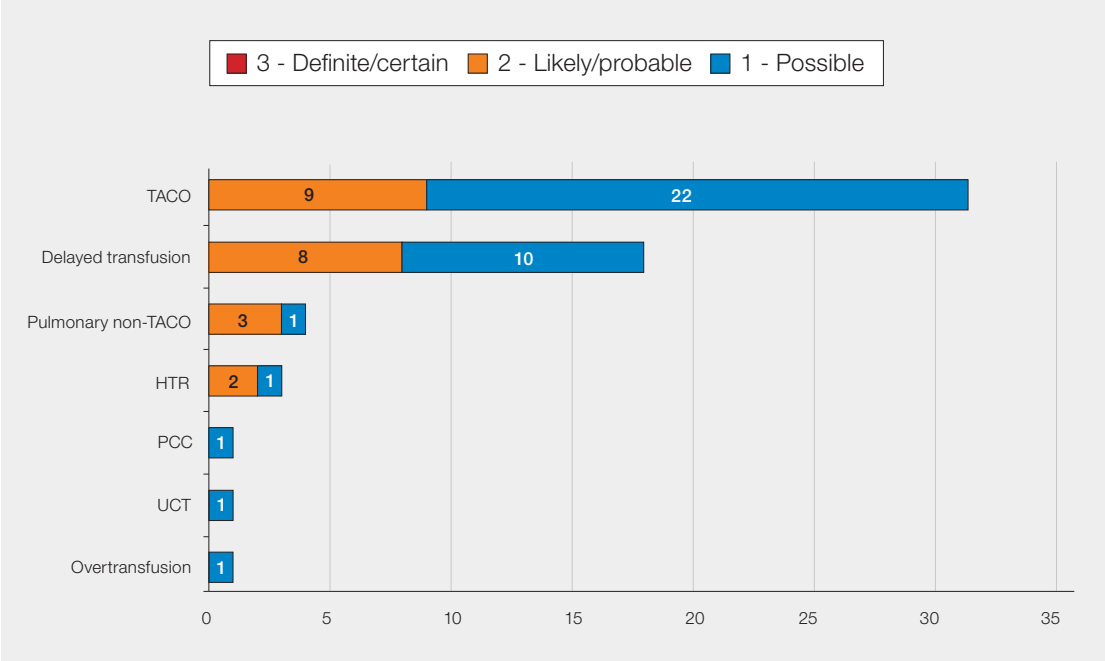
Deaths related to transfusion n=59

All serious reactions reported to SHOT are assessed for imputability i.e., the relationship of the blood transfusion to the reaction. The imputability criteria can be found in the SHOT definitions document (https://www.shotuk.org/reporting/incident/definitions/).

The number of reported deaths assessed as being related to the transfusion increased dramatically to 59 in 2024, from 38 in 2023. Pulmonary complications and transfusion delays were still the most common causes of transfusion-related deaths reported to SHOT in 2024, accounting for 53/59 (89.8%) of total deaths. In 2024, TACO (n=31) was responsible for the highest number of deaths in a single category reported to SHOT, followed by delays (n=18). The number of deaths in both these categories has doubled since 2023. The slight decrease in the number of deaths due to transfusion delays seen in 2023 was hoped to have been a result of the impact of the Medicines and Healthcare products Regulatory Agency (MHRA)/SHOT central alerting system (CAS) alert (SHOT, 2022), however this has not been sustained in the 2024 data.

Key factors identified in transfusion-related deaths are discussed in the relevant chapters of this Annual SHOT Report. Figure 3.3 shows the distribution of deaths related to transfusion reported in 2024 and respective imputability. There were no deaths in 2024 that were considered to be directly and solely the result of the transfusion.

Figure 3.3: Deaths related to transfusion with imputability reported in 2024 (n=59)



HTR=haemolytic transfusion reactions; PCC=prothrombin complex concentrates; TACO=transfusion-associated circulatory overload; UCT=uncommon complications of transfusion

Figure 3.4 shows the deaths reported to SHOT 2010-2024 reflecting the degree of imputability assigned. While the number of deaths definitely related to the transfusion episode have remained low, the rising trend in the overall number of deaths is concerning. While longstanding issues remain unresolved, additional challenges have become evident with patients accessing healthcare having more complex needs and often affected by multiple co-morbidities. These are further compounded by financial constraints limiting expenditure on resources that are crucial for patient safety, such as staffing levels, staff training, IT equipment and investment in appropriate facilities. Without decisive actions to address these gaps, the situation is likely to worsen with missed opportunities to rectify preventable factors and optimise safety.

Figure 3.4: Deaths related to transfusion with imputability reported 2010-2024 (n=379)

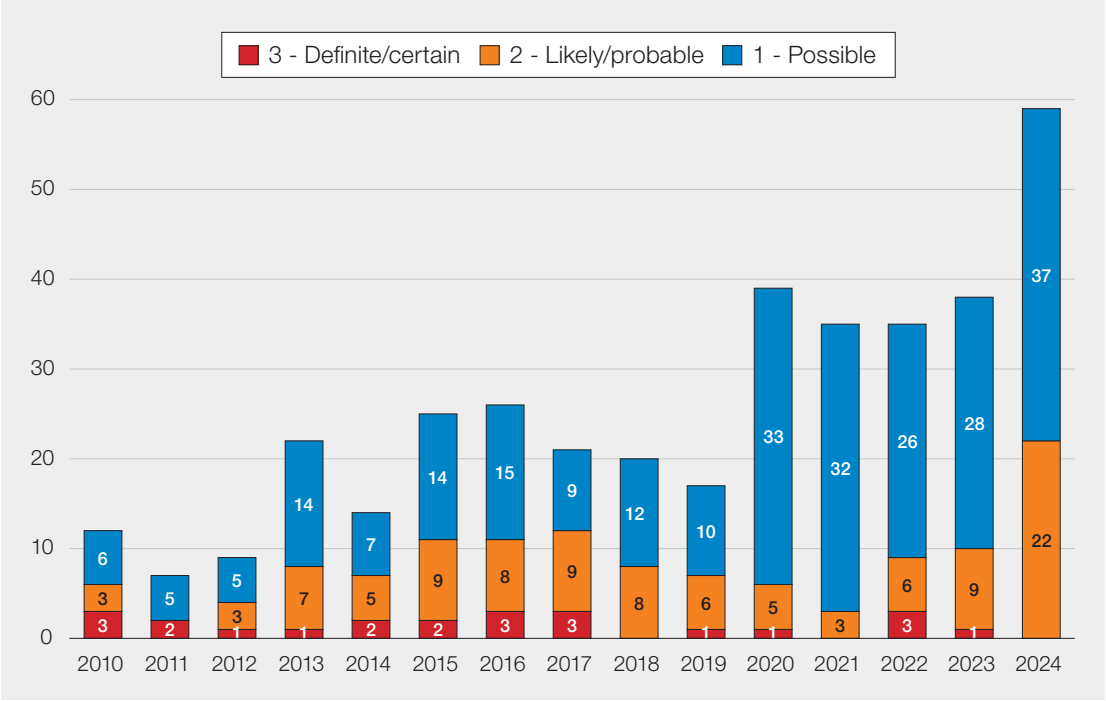
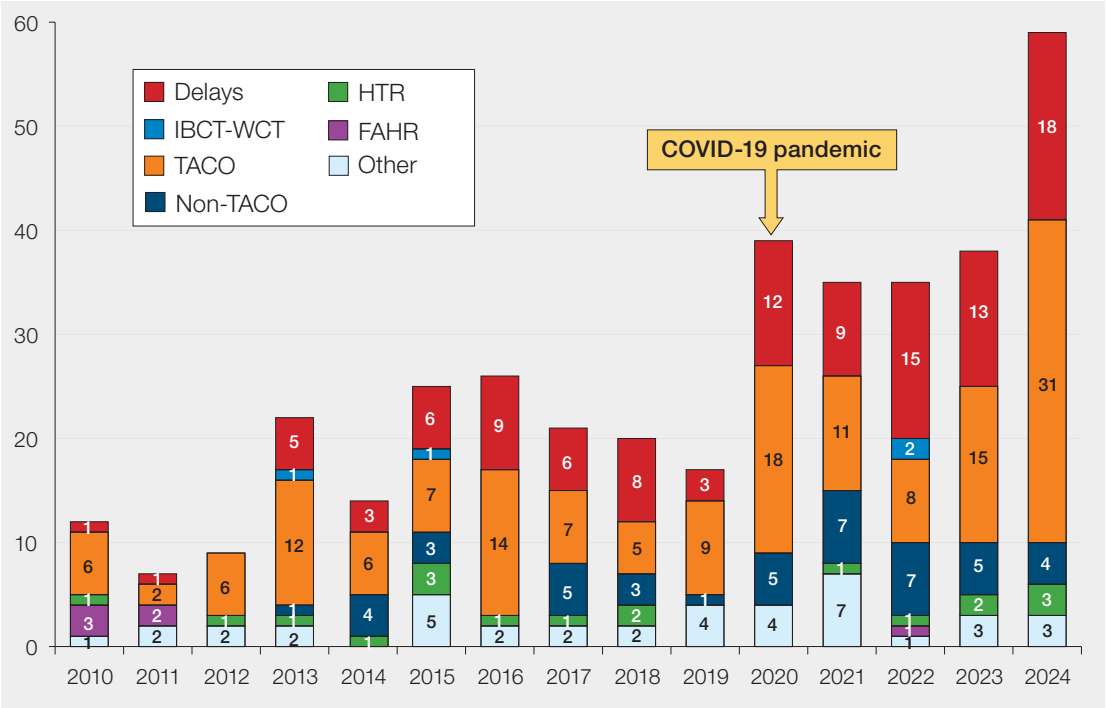


Figure 3.5 shows the trend in the transfusion-related deaths reported to SHOT since 2010 by category. It is alarming to note an increasing trend in the deaths reported especially related to transfusion delays and pulmonary complications, with a further steep rise in 2024 due to TACO deaths. While this could potentially be due to improved awareness and reporting following the national patient safety alert for TACO released in April 2024 (MHRA and SHOT, 2024), this could also be a true increase reflecting the worsening challenges faced in healthcare as described earlier. This worrying trend continues despite the release of UK-wide national patient safety alerts addressing preventable transfusion delays and TACO in recent years. This is most likely reflecting the ongoing systemic issues including inadequate staffing levels and suboptimal IT that are yet to be resolved.

Figure 3.5: Transfusion-related deaths by SHOT category, 2010 to 2024 (n=379)



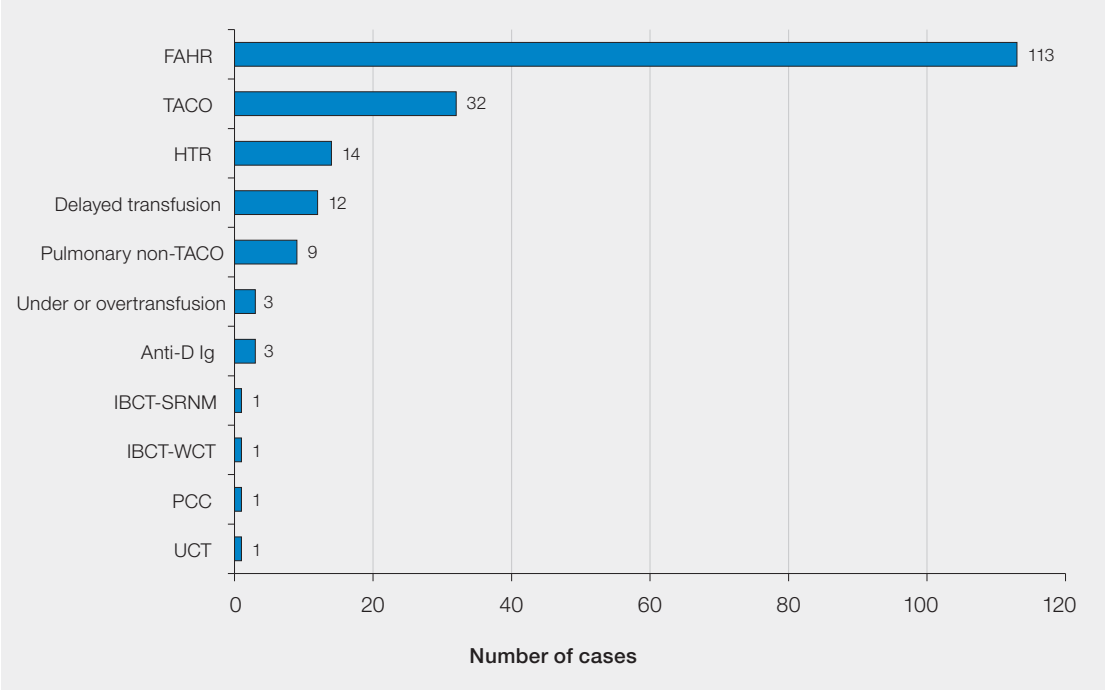
FAHR=febrile, allergic, and hypotensive reactions; HTR=haemolytic transfusion reaction; IBCT-WCT=incorrect blood component transfused-wrong component transfused; TACO=transfusion-associated circulatory overload;

Delays include 1 delay related to PCC in 2019, 2 in 2022 and 4 in 2023; 'Other' includes 1 each for post-transfusion purpura, transfusion-associated graft-versus-host disease (2012) and anti-D Ig related; there were 11 in the avoidable, over or undertransfusion category, 3 transfusion-transmitted infections, and 23 deaths related to other unclassified reactions

Major morbidity n=190

Febrile, allergic, and hypotensive transfusion reactions continue to account for most of the cases with major morbidity, 113/190 (59.5%) followed by TACO, 32/190 (16.8%). These are detailed further in the respective chapters in this Annual SHOT Report. Major morbidity criteria are outlined in the SHOT definitions document which is reviewed and updated annually.

Figure 3.6: Ranking of categories to show number of serious reactions in 2024 (n=190)



FAHR=febrile, allergic, and hypotensive reactions; HTR=haemolytic transfusion reactions; IBCT-SRNM=incorrect blood component transfused-specific requirements not met; IBCT-WCT=IBCT-wrong component transfused; Ig=immunoglobulin; PCC=prothrombin complex concentrates; TACO=transfusion-associated circulatory overload; UCT=uncommon complications of transfusion

Summary data and risks associated with transfusion

Data collected in 2024 are shown in Figure 3.7. Near miss reports continue to be the largest category, 1408/3998 (35.2%), however, this percentage is steadily reducing from 37.0% in 2023 and 39.0% in 2022. Cumulative haemovigilance data from SHOT between 1996-2024 are shown in Figure 3.8.

Figure 3.7: Summary data for 2024, all categories (includes RBRP and NM) (n=3998)

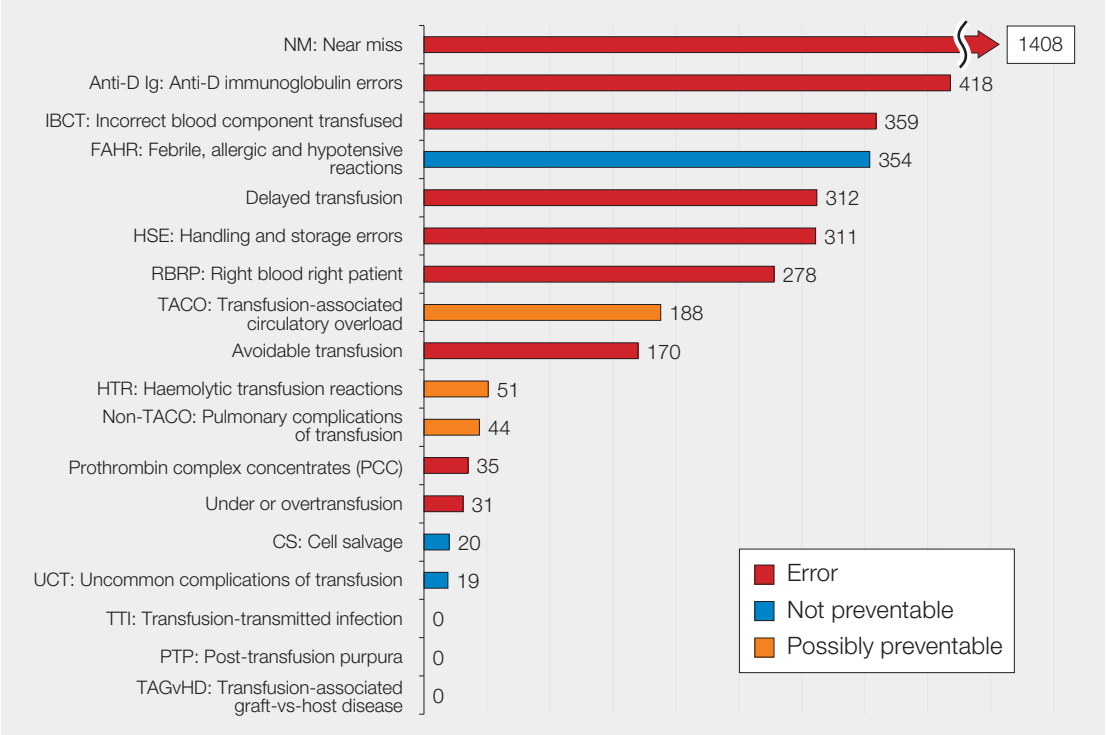
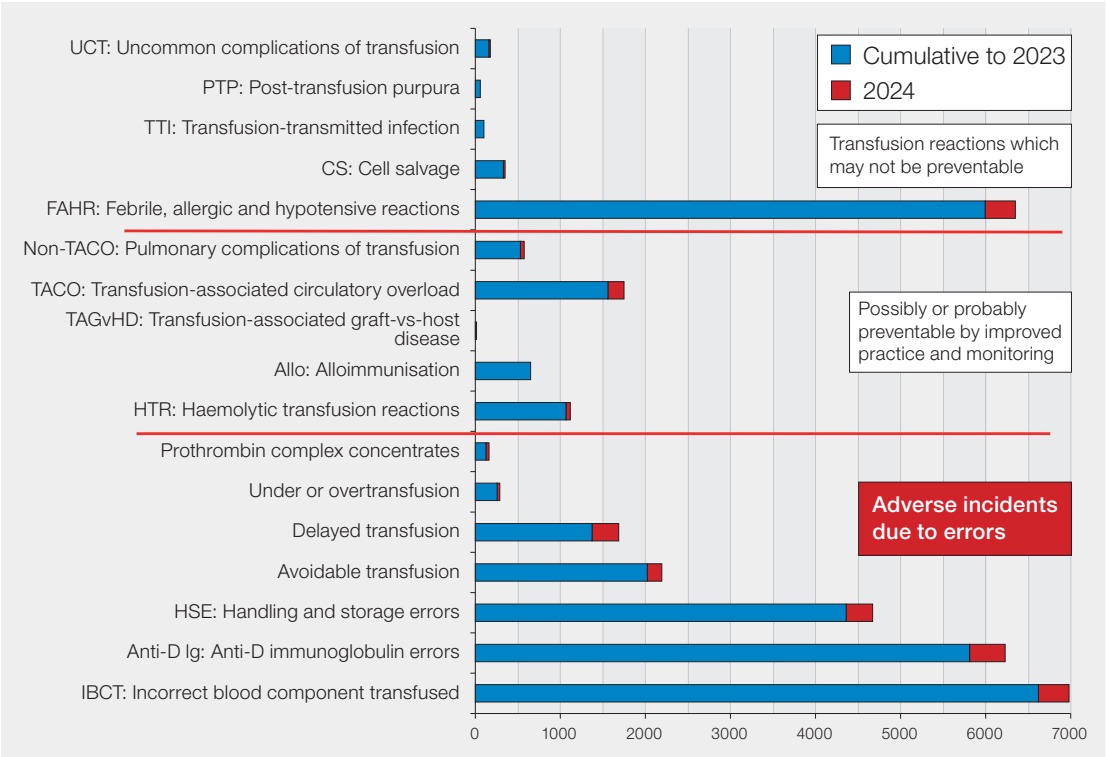


Figure 3.8: Cumulative data for SHOT categories 1996-2024 (n=33343)



Data on alloimmunisation has not been collected by SHOT since 2015

ABO-incompatible (ABOi) transfusions n=4

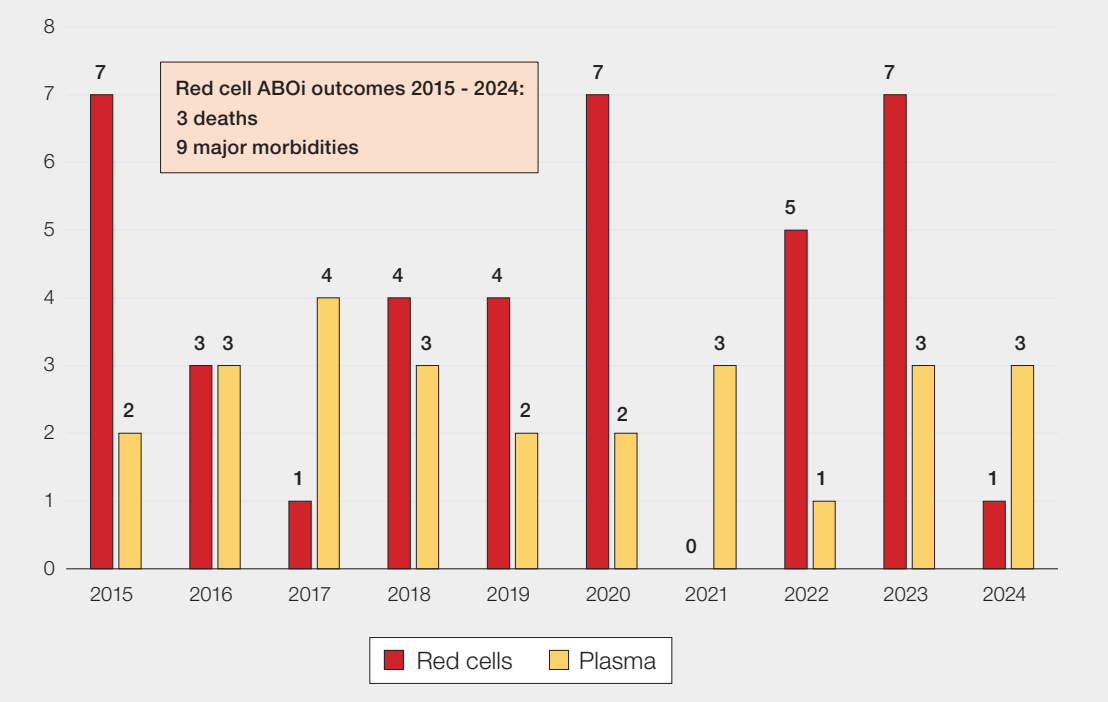
In 2024, there was 1 ABOi red cell transfusion reported and 3 ABOi plasma transfusions. Fortuitously, there were no adverse outcomes in any of the cases reported this year. In the ABOi red cell case, the transfusion was not started, however, as the transfusion was connected to the patient, this fulfils the criteria for a 'transfused' incident and has been included as such.

Of the ABOi plasma transfusions, all 3 were due to component selection errors in the transfusion laboratory, 2 involved FFP, and the 3rd related to SD-FFP.

These cases are explored in more detail in Chapter 9, Incorrect Blood Component Transfused (IBCT) and Chapter 17, Laboratory Errors.

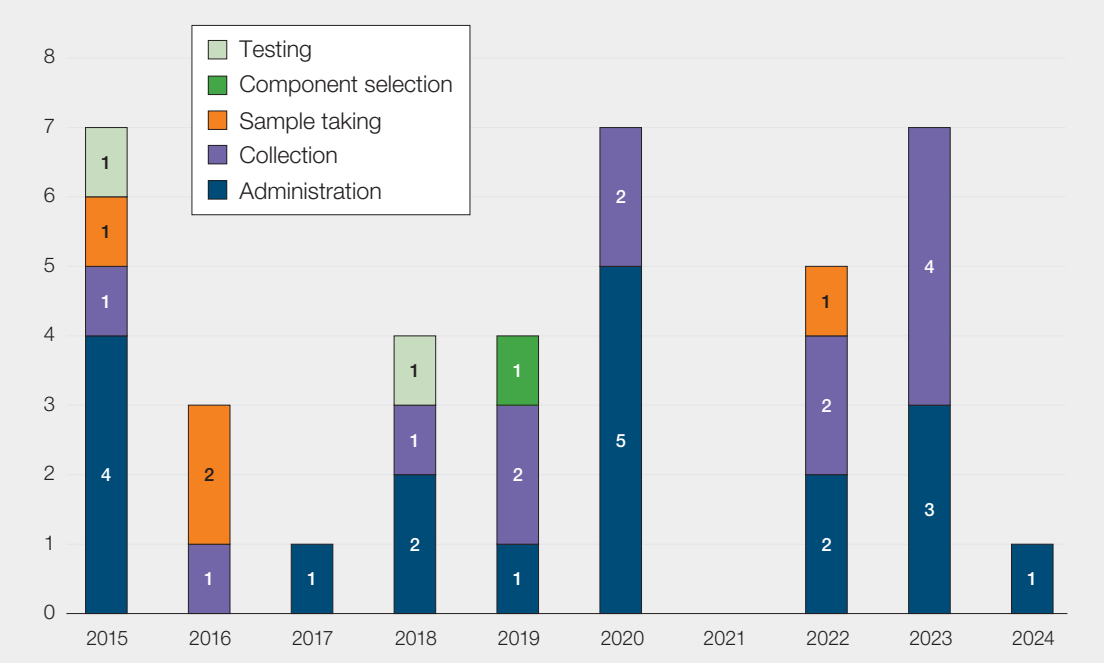
Figure 3.9 shows the number of ABOi red cell and plasma transfusions reported to SHOT in the last decade.

Figure 3.9: Number of ABO-incompatible (ABOi) transfusions 2015-2024



A review of ABOi red cell transfusions over the last 10 years shows that most were due to clinical errors, 36/39 (92.3%). In these, the primary error was mostly during either collection of the component (n=13) or administration of the component (n=19) due to the correct checks not being performed at these critical steps.

Figure 3.10: ABO-incompatible red cell transfusions by step in the transfusion process 2015-2024 (n=39)



Safety measures in place to prevent ABOi from happening currently include a combination of information technology (IT) and people dependant controls. Several factors contribute to continuing preventable errors including staffing issues, high workload mismatched to staff capacity, poor IT, suboptimal staff training, under-resourced systems and ineffective learning from incidents. A pre-administration safety check is the last step before transfusion when errors can potentially be picked up. There is therefore a requirement for a comprehensive safety check at this step. Checks are ineffective and can fail when carried out inappropriately.

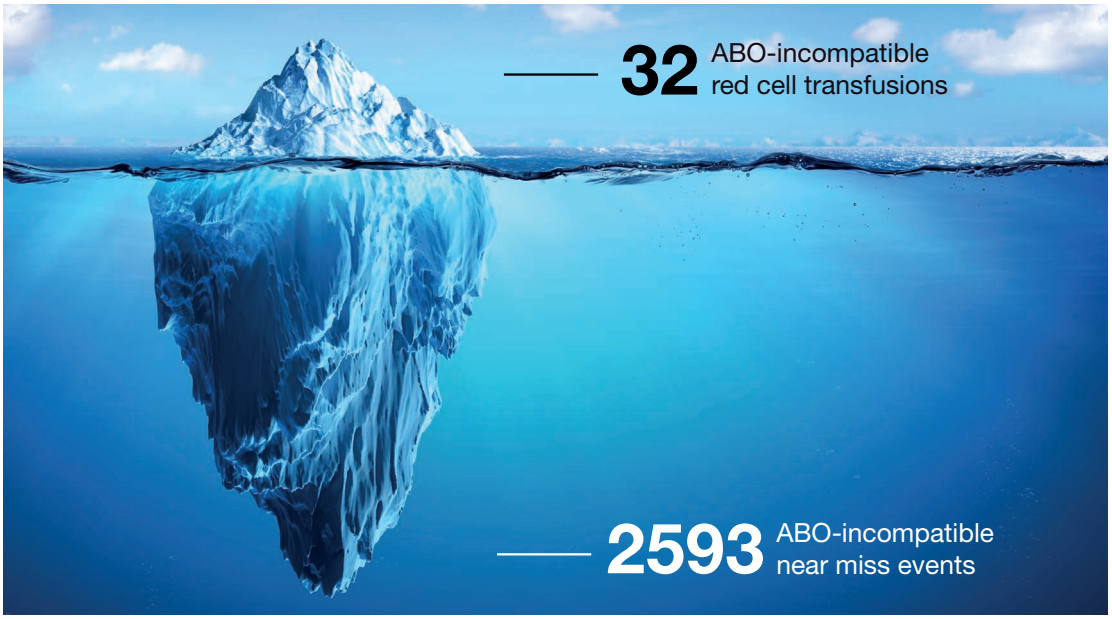
Inadvertent ABOi transfusions are categorised as Never Events in England (NHSE, 2021). The outcome from the NHS England consultation for the Never Events list and framework is still awaited. The main aim was to clarify whether the current framework is an effective mechanism to drive patient safety improvement. Further details can be found at this link: https://www.england.nhs.uk/long-read/never-events-framework-consultation/. SHOT provided input during this consultation supporting review of the framework with continuing inclusion of ABOi events and facilitating appropriate systemic improvements to prevent these.

Despite existing protocols and safety checks, current measures to prevent ABOi transfusions are not fully effective in eliminating this preventable and potentially fatal event. Similar average ABOi frequencies have been observed in France (0.19 [SD:0.09]/100 000 issued red cell units) and in the UK (0.28 [SD:0.17]/100 000) which have different safety measures. A higher frequency (0.71 [SD:0.23]/100 000) was observed in Germany which has similar bedside safety measures to France (Mirrione-Savin, et al., 2025). There is an urgent need to strengthen the safety measures to prevent ABOi transfusions.

Transfusion decisions in haemopoietic stem cell transplant settings, especially with blood group mismatch, are particularly complex due to several factors. Challenges related to ABO and D compatibility exist at multiple phases of the transplant process and the patient's blood group may convert to the donor's blood type over time. Effective management requires close coordination between transplant and transfusion services, both clinical and laboratory, with tailored strategies for different transplant decisions in various phases. These are discussed further in Chapter 28, Transfusion Errors in Transplant Cases.

Data from 2016-2024 show that although there were 32 ABOi red cell transfusions, there were 2593 near misses which could have resulted in an ABOi transfusion. Most of these were WBIT incidents which constitute the largest subset of near miss cases reported to SHOT in 2024, 899/1408 (63.8%), and these are discussed in Chapter 15a, Near Miss – Wrong Blood in Tube (WBIT). It is important to note that these may not be detected routinely unless there is a historical record in the transfusion laboratory and demonstrate the importance of the group-check policy (Milkins, et al., 2013). Such errors could result in patient deaths and highlight the risk of not undertaking positive patient identification at the time of collecting and labelling pre-transfusion samples. As is evident from the iceberg representation below (Figure 3.11), these occur much more frequently and offer more opportunities to learn than the rarer serious adverse events. When WBIT are not identified or investigated, they represent missed opportunities that can contribute to future risks of potentially lethal ABOi. Analysing these incidents helps refine transfusion safety practices, such as patient identification protocols, labelling accuracy and verification processes.

Figure 3.11: ABO-incompatible red cell transfusions 2016-2024: few events (n=32) but many near misses (n=2593)



Conclusion

Haemovigilance data from 2024 indicates a troubling increase in transfusion-related errors and deaths, signalling deeper systemic issues within healthcare. Transfusion errors are not isolated incidents, they are warning signs of broader challenges in healthcare safety, including communication failures, flawed workflow designs, procedural inconsistencies, poor safety culture and governance gaps.

There is no room for complacency. Immediate steps must be taken to strengthen the workforce, standardise and promote best practices, leverage technology, improve learning, enhance training and accountability.

The continuing trend of a high percentage of preventable errors is a canary in the coalmine; a warning that demands urgent response. Transfusion incidents indicate vulnerabilities in the healthcare system that can impact all aspects of patient care. Leadership at every level must prioritise patient safety and deliver improvement initiatives. Addressing transfusion safety can serve as a gateway to improving overall patient safety.

Recommended resources

SHOT videos: Learning from transfusion related deaths
https://www.shotuk.org/resources/learning-from-transfusion-related-deaths/

Cumulative SHOT Data by Category
https://www.shotuk.org/resources/cumulative-shot-data-by-category/

SHOT Webinar: Every Minute Counts
https://www.shotuk.org/resources/every-minute-counts-webinar-2021/

SHOT Transfusion Safety Standards
https://www.shotuk.org/transfusion-safety-standards/

4 Key Messages and Recommendations

Authors: Shruthi Narayan with input from members of the SHOT team

Key SHOT messages

- **Making safe transfusion decisions and ensuring patients are well informed:** Transfusions are safe and effective when used appropriately. All staff involved in blood transfusions need to have relevant knowledge of the blood components appropriate to their role, indications for use, alternate options available, risks and benefits and possible reactions and their management. Unnecessary transfusions must be avoided, and patients or their carers must be informed about the risks, benefits, and alternatives to transfusions
- **Addressing transfusion errors:** Errors continue to be the source of most SHOT reports (83.1%). While transfusions are largely safe, errors can result in patient harm. Communication issues, assumptions and distraction compounded by staffing issues, ineffective and misuse of information technology (IT) and poor safety culture contribute to errors. Errors must be investigated using human factors principles-based incident investigations and appropriate improvement measures implemented
- **Ensuring clinical and laboratory transfusion teams are well resourced:** Adequate numbers of appropriately trained staff must be available to ensure safe transfusions; there should be contingency planning for staffing levels below a minimum level and for times of high workload. Safe staffing levels matched to the workload with well-resourced systems are vital for ensuring high quality care for patients and safety
- **Addressing knowledge gaps, cognitive biases, and holistic training:** Transfusion training with a thorough and relevant knowledge base in transfusion to all clinical and laboratory staff along with training in patient safety principles, understanding human factors and quality improvement approaches are essential. It is important that staff understand how cognitive biases and assumptions contribute to poor decision-making so that they can be mitigated appropriately
- **Policies and processes:** Policies, guidelines/decision-making aids and standard operating procedures need to be simple, clear, easy to follow and explain the rationale for each step. These should be up to date, accessible and reflect current national guidelines and recommendations. This will then ensure staff are engaged and more likely to follow and avoid any workarounds or deviations
- **Safety culture:** Fostering a strong and effective safety culture that is 'just, restorative and learning' is vital to ensure reduction in transfusion incidents and errors, thus directly improving patient safety. Staff should be able to confidently raise concerns, discuss issues and promote innovative ideas for improvement. Regular monitoring of the safety culture and impact on patient safety and staff wellbeing is strongly recommended to ensure timely improvement actions are implemented
- **Learning from near misses:** Reporting and investigating near misses helps identify and control risks before actual harm results, thus providing valuable opportunities to improve transfusion safety. The appropriate response to a near-miss with potential for high-risk transfusion event includes: (1) reporting to haemovigilance agencies as required, (2) investigate near miss, (3) develop and implement a corrective and preventive action plan and (4) monitor effectiveness of interventions
- **Shared care:** Clear, timely and comprehensive communication between all teams and hospitals involved in the patient pathway care is vital in ensuring patient safety. Robust and transparent processes must be in place for safe and effective transfer of information at all points in the patient care pathway
- **Investigating incidents and focussing on improvements:** Investigations must be systematic and thorough, using human factors principles and systems thinking, identifying systems-based corrective and preventive actions. Systemic and organisational problems should be fully investigated, as focusing on individual staff actions is unlikely to address the underlying systemic issues or lead to lasting improvements. Learning from the incidents should be shared widely

- **Safety checks before transfusions:** The pre-transfusion patient-side safety check provides a final opportunity for staff to identify errors ensuring the right component with the right specification is transfused to the right patient; the transfusion-associated circulatory overload (TACO) risk assessment facilitates appropriate mitigating measures in vulnerable patients at high risk of TACO. These checks serve as safety pauses to ensure staff safeguard patient well-being and prevent potentially life-threatening complications, these are not tick-box exercises
- **Patients as safety-partners**: Staff must ensure that they involve, engage, and listen to patients as 'partners' in their own care, including transfusion support. Engaging patients, their families, and carers as 'safety partners' helps co-create safer systems, identify, and rectify preventable adverse events

Transfusion safety is a critical aspect of modern healthcare and warrants a systematic approach to minimise risks and optimise patient outcomes. Signals from haemovigilance reports do more than highlight transfusion-specific issues; they mirror the broader challenges facing patient care across the entire healthcare system. These insights reveal systemic weaknesses, lapses in communication, strains on workforce capacity that affect safety and quality at every level. They are not isolated concerns, but symptoms of deeper, widespread pressures that demand urgent actions.

This Annual SHOT Report highlights continuing error trends with 83.1% reports related to preventable errors. Worsening trends in reported transfusion delays, laboratory errors and TACO are concerning. Analysis of reported cases continue to highlight gaps in our systems. It is time for urgent, co-ordinated, system-level action to embed a culture of safety, addressing identified issues and ensuring every transfusion is as safe as possible. It is imperative that healthcare leaders, policy makers, and frontline teams unite in transforming transfusion practice, because patients and staff deserve nothing less.

Roadmap to enhance patient safety

The Patient Safety Commissioner in England published the Patient Safety Principles in October 2024. These were developed as one of the Commissioner's statutory duties following a public consultation which received over 800 responses. They provide a framework for decision-making, planning and collaborative working with patients as partners in a just and learning culture and are for everyone working in the healthcare system (Patient Safety Commissioner, 2024).

Figure 4.1: Patient Safety Principles set out by the Patient Safety Commissioner, England

The key safety messages and recommendations from SHOT over the years align with the principles advocated by the Patient Safety Commissioner. We put patients first by listening, learning, and acting; every voice matters, every incident teaches and every action counts for safer care.

Worsening healthcare challenges in the United Kingdom (UK) and the National Health Service (NHS) in crisis also provides an opportunity for innovation and act as a catalyst for change. This requires adaptive leadership with healthcare leaders being able to:

- Anticipate likely future needs, trends and options
- Articulate these needs to build collective understanding and support for action
- Adapt so that there is continuous learning and adjustment of responses as necessary and
- Accountable, including maximum transparency in decision-making processes and openness to challenges and feedback (Sott & Bender, 2025; Ramalingam, et al., 2020)

The UK government recently announced that it planned to abolish NHS England and move many of its functions back into the Department of Health and Social Care. While streamlining processes, reducing duplication, increasing savings, and improving productivity have been identified as key drivers for this restructuring, the prioritisation of patient and staff safety must remain paramount (Wise, 2025). Transformations in structure, governance or service delivery should be designed and implemented in ways that protect and strengthen safety. Changes may be necessary, but safety should be paramount. Clinical leadership is critical during change; it keeps patient care at the centre, bridges the gap between strategy and reality and ensures safety, quality and compassion aren't lost in the process. As has been repeatedly highlighted, changes and decisions in healthcare should be clinically led with evidence-based decision-making.

A recent white paper on patient safety from the International Society for Quality in Health Care (ISQua) provides a practical, evidence-informed, structured roadmap for healthcare organisations to enhance patient safety and embed continuous improvement into daily operations (ISQua, 2025). The framework is aligned with the World Health Organisation Global Patient Safety Action Plan (GPSAP) 2021–2030 (WHO, 2021). The white paper outlines four foundational pillars for improving patient safety in healthcare organisations:

1. Advocacy and leadership – prioritising patient safety in hospital policies and governance.
2. Health worker education and safety – empowering healthcare professionals through training and well-being initiatives.
3. Patient, family, and carer engagement – encouraging collaboration between healthcare providers and patients.
4. Improvement in clinical processes – implementing evidence-based practices to reduce preventable harm.

This framework aims to create practical, scalable solutions that can be applied across diverse healthcare settings, ultimately improving patient outcomes and staff satisfaction.

Recommendations from the Infected Blood Inquiry (IBI) Report and SHOT

The IBI highlighted several failures in ensuring safe transfusion practices, which led to thousands of infections with human immunodeficiency virus (HIV) and hepatitis C (IBI, 2024). The contaminated blood crisis serves as a stark reminder of the importance of safety in transfusion. Implementing the wide-ranging recommendations from the IBI report can safeguard healthcare systems and prevent similar tragedies. It is incumbent upon all of us not to squander this opportunity to turn the hard lessons of the IBI into action, embed its recommendations and strengthen transfusion safety. Safety isn't just a policy; it is a shared responsibility and a commitment to protect patients and providers. SHOT has been working with various stakeholders across the UK, seeking practical solutions to implement the recommendations from IBI and addressing longstanding issues (such as staffing, laboratory safety, IT) that pose risks to safety, fostering a culture of continuous improvement and shared responsibility.

One of the key IBI recommendations under 7. Patient Safety: Blood Transfusions was related to the implementation of SHOT recommendations. The recommendation states:

(e) That all NHS organisations across the UK have a mechanism in place for implementing recommendations of SHOT reports, which should be professionally mandated, and for monitoring such implementation.

SHOT Transfusion Safety Standards

In view of similar recurring themes in the recommendations in serial Annual SHOT Reports, SHOT Transfusion Safety Standards have been produced and are being released in 2025 following feedback from key stakeholders. These standards cover fundamental principles to ensure safe and effective transfusions by identifying risks, as well as implementing strategies that create a safer environment for everyone involved. These are intended to contribute to better patient outcomes, staff wellbeing and overall system safety. The transfusion safety standards cover all aspects of the SHOT 10 steps for blood component handling and use (SHOT, 2024). It is important to recognise that local improvement plans must be identified and implemented to address any non-compliance with any of these standards to optimise transfusion safety. It is expected that compliance against each of these standards can be recorded locally as either fully compliant/partially compliant or non-compliant with an action plan to address gaps when not fully compliant. This would also facilitate benchmarking between organisations.

The transfusion safety standards are aligned with the fundamental pillars for improving patient safety that have been highlighted in the ISQua white paper (ISQua, 2025). Having transfusion safety standards and ensuring compliance are key to improving safety. Standards provide the 'what' and the 'how' and compliance ensures they are actually used in practice. They are intended to help:

- Create a clear baseline for safety: standards define what 'safe' looks like, providing staff with a consistent reference point for best practice
- Reduce variability and prevent errors: when staff follow the same protocols, there is less room for mistakes caused by inconsistent procedures
- Enable early detection of risks: compliance checks and audits can uncover unsafe practices or system weaknesses before they lead to harm
- Promote a culture of accountability and learning: knowing that standards are in place and monitored encourages teams to take responsibility and continuously improve
- Improve trust and transparency: patients and families may feel safer when they know care teams are following recognised safety standards

Implementing these safety standards and ensuring compliance transforms transfusion safety from a reactive process into a proactive system. Regulatory bodies such as the Care Quality Commission or equivalent play a critical role by monitoring and inspecting healthcare providers, enforcing accountability, driving transparency and public trust.

Further information and the standards can be accessed on the SHOT website (https://www.shotuk.org/transfusion-safety-standards/).

Recommendation

- All healthcare organisations should systematically identify gaps in transfusion safety by benchmarking practices against the SHOT Transfusion Safety Standards, implement targeted corrective measures and actively monitor compliance through structured audits and performance indicators

These SHOT Transfusion Safety Standards do not replace but complement other regulatory or best practice recommendations for safe transfusions (Department of Health, 2005; BSH, 2025; SHOT, 2025a; NICE, 2016). These standards provide a framework for peer review/self-assessment, compliance check by regulatory organisations and/or national oversight. Where inspection against the SHOT safety standards show deficiencies, organisations may be requested to demonstrate compliance with these other transfusion requirements. Additional drivers for developing these safety standards include Lord Darzi's report and the Health Services Safety Investigations Body (HSSIB) report released in 2024

(Department of Health and Social Care, 2024; HSSIB, 2024). Transfusion safety standards will help drive improvement actions to minimise risks, maintain reliability, ensure effectiveness of transfusions, and optimise safety for all.

Transfusion governance within hospitals

Following discussions as part of the IBI recommendations implementation, a framework for effective transfusion governance within hospitals in the UK addressing existing gaps has been drafted and is being reviewed by a wide range of stakeholders. This framework will ensure adequate support for transfusion staff, provide an effector mechanism to ensure compliance with the transfusion safety standards, support integration with existing patient safety governance framework and facilitate adequate oversight. Insights from infection prevention and control as well as maternity safety governance systems helped inform this transfusion governance framework which will be released later this year. Effective governance frameworks are the backbone of safe, high-performing systems and drive accountability, enable benchmarking and ensure safety standards and regulatory requirements aren't just met, but meaningfully upheld.

Patient consent and shared decision-making

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) consent guidance has been reviewed, and an updated guidance is expected to be released shortly (SaBTO, 2020). The 2024 National Comparative Audit of NICE Quality Standard QS 138 results highlight ongoing issues with patient consent and shared decision-making (NHSBT, 2025a). Poor consent practices including poor documentation of the discussions with patients and families result in patients not being fully aware or informed of the risks, benefits or available alternatives, particularly in non-emergency settings. There is an urgent need to strengthen communication, embed shared decision-making into practice and ensure that consent is a meaningful, ongoing dialogue with appropriate use of transfusions. SHOT, working with patient representatives and other key transfusion stakeholders, has been also leading on the development of a MyTransfusion mobile application which will provide generic information about transfusions in adult recipients. The content of the app is based on national guidelines and reflects the UK-wide transfusion patient information leaflets which will help patients and families to review and assimilate information in their own time. The app and a browser version are now available. A driver diagram has also been developed to support the identification of local issues related to consent and shared decision-making; this can be used to map out tangible improvement actions to address gaps and enhance safety (see 'Recommended resources').

Laboratory safety

The IBI report also highlighted the importance of optimising laboratory safety to support safe transfusions. Laboratory safety in transfusion practice is a cornerstone of patient care, yet it is often overlooked. Concerning signals in this Annual SHOT Report have highlighted a steep increase in laboratory errors leading to unsafe transfusions emphasising the critical need to improve laboratory safety. These incidents continue to occur due to systemic issues such as understaffing, high workloads, inadequate training, and poor leadership/safety culture. Serial UK Transfusion Laboratory Collaborative (UKTLC) surveys have highlighted these issues (SHOT, 2025b). A safe, supported laboratory team is essential to ensure every blood component is tested, stored, and issued appropriately contributing to saving lives without compromise. The urgency to address these challenges cannot be overstated. Strengthening laboratory safety requires a culture of vigilance, robust training, optimal staffing, and a commitment to continuous improvement. For more information about laboratory cases, see Chapter 17, Laboratory Errors.

Cyber incidents and impact of blood stock issues on transfusion safety

A total of 43 reports included in this Annual SHOT Report were related to a cyber-attack incident in London during 2024. The majority of these, 36/43 (83.7%) occurred in laboratory areas, mostly related to component labelling, 22/36 (61.1%). Errors resulting from this cyber incident affected all steps in the transfusion pathway and incidents occurred in several SHOT reporting categories. Near misses

accounted for the highest number of reports, 19/43 (44.2%) but errors were reported resulting in transfusion delays (5), incorrect blood components transfused (7), anti-D Ig errors (4) and right blood right patient reports (8). These have been covered in the respective chapters in this Annual SHOT Report. It is important to note that such cyber-attacks on healthcare systems are not just IT failures, they are critical patient safety incidents. When hospital networks are compromised, the consequences are immediate and severe. Delayed surgeries and appointments with disruptions to patient care including transfusion support (NHSE, 2024; BBC, 2024). These attacks expose the vulnerabilities in our digital infrastructure and highlight a broader issue of lack of preparedness. This is a wake-up call and there is an urgent need to invest in secure, modern IT systems, implementing robust cybersecurity protocols, training staff, and developing clear, tested reliable incident response plans. Patient safety depends on effective cybersecurity, a core component of safe, high-quality healthcare.

The blood stock shortages in the last few years are a stark reminder of fragility and finiteness of the blood supply (NHSBT, 2024; NHSBT, 2025; Chowdhury, et al., 2024). Multiple factors have been identified as being contributory including seasonal donation dips, increased demand, and impact of the cyber-attack that disrupted pathology services. This highlights the need to strengthen the donor base with a more resilient and diverse donor pool and using blood wisely. UK Blood Services have been addressing this issue and are proactively engaging the public and under-represented donor populations, evaluating methods to improve donor retention, and addressing barriers to donation. Shortages underscore the importance of appropriate transfusion practices, using evidence-based guidelines, adhering to restrictive transfusion thresholds where safe, and promoting alternatives to transfusion where possible. Avoiding unnecessary transfusions will help conserve stock and improve patient outcomes. Preventing blood wastage will also help conserve limited stock, ensuring availability for patients when it's most needed.

Optimising staff wellbeing and safety

Staff wellbeing and safety are the foundation of a safe, high-performing healthcare system. When staff feel supported and valued, they are better able to focus, make sound decisions and provide compassionate care. Burnout, stress, and unsafe working conditions undermine both morale and patient safety. By urgently prioritising wellbeing and safety of our healthcare workforce, both clinical and laboratory, we strengthen the very heart of patient care and create an environment where excellence can thrive.

The annual NHS staff survey, one of the largest workforce surveys in the world, asks NHS staff in England about their experiences of working for their respective NHS organisations. The 2024 survey provides valuable insights into the experiences of over 700,000 people working in the NHS in autumn 2024 and highlights key trends in staff wellbeing, fatigue, and safety, showing both progress and ongoing challenges (NHSE, 2025).

A few key aspects from the 2024 NHS staff survey related to staff wellbeing, fatigue, safety and support are included here:

- Staff wellbeing: while overall wellbeing scores remained stable compared to 2023, 41% of staff reported work-related stress, a figure that remains high despite improvements since 2021
- Fatigue and presenteeism: nearly 56% of staff reported coming to work despite feeling unwell, indicating ongoing concerns about burnout and workplace pressures
- Safety and support: the health and safety climate indicator showed that 71.5% of staff felt supported by their line managers, a slight improvement from previous years (NHS Employers, 2025)

Insights from such staff surveys provide valuable data that can be used to enhance workplace wellbeing, address fatigue-related risks, and improve patient safety by shaping policies that support staff resilience and sustainable working conditions. It is vital to recognise that such staff surveys are more than feedback tools. Listening is just the start; real value comes from translating insights into visible, meaningful improvements that shows staff their voices matter.

Staff fatigue

A recent report from the Health Services Safety Investigations Body in England highlighted the adverse impact of staff fatigue on patient safety (HSSIB, 2025). Staff fatigue is not routinely captured as part of

patient safety event reporting or routinely considered as part of patient safety event learning, or other governance processes. The report also highlighted that there is limited regulatory and national oversight of the risks posed to patient safety by staff fatigue in healthcare. One of the key safety recommendations from this report is that NHS England/Department of Health and Social Care identifies and reviews any current processes that may capture staff fatigue related data. The staff fatigue data will help inform the development of any future strategy and action to address this risk and its impact on patient safety. Caring for staff is caring for patients; safety and wellbeing must start with the people who deliver care.

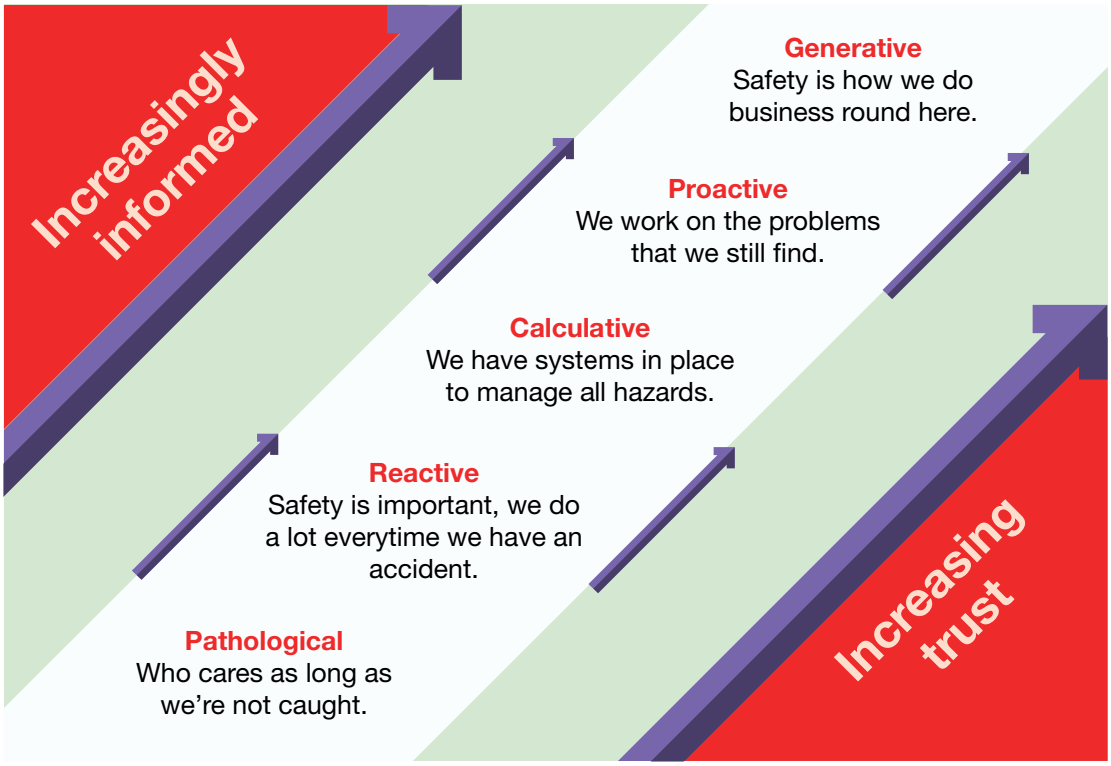
A white paper on 'Fatigue risk management for health and social care' from the Chartered Institute of Ergonomics and Human Factors highlights a chronically fatigued workforce due to several factors including staffing issues and high workload. It provides a foundation for national health and social care bodies to recognise the risk that staff fatigue poses to safe and efficient healthcare services and advocates a systemic approach to managing these risks (CIEHF, 2024).

The SHOT Human Factors Investigation Tool explores staff fatigue as one of the contributory factors for transfusion incidents. Collecting these data will help understand the issue better and identify measures to address this effectively.

Safety culture

Fostering a strong and effective safety culture is vital to reducing transfusion incidents and errors, thereby directly improving patient safety. This has been one of the key recommendations from SHOT (Narayan, et al., 2022). A just, restorative, learning safety culture is critical with good communication between healthcare leaders, managers, and staff. Professor Patrick Hudson aptly says, 'What costs money is not safety but bad safety management' (Hudson, 2001). Organisations can be distinguished along a line from pathological to generative safety culture as shown in Figure 4.2.

Figure 4.2: The evolution of a safety culture



Adapted from Hudson, P., 2001. Safety culture: The ultimate goal. Flight Safety Australia, pp. 29-31.

Any change to safety culture within organisations takes time and effort. But it is imperative that all healthcare leaders promote a just, learning safety culture with a collective, inclusive, and compassionate leadership. Effective leaders must ensure staff access to adequate training, mentorship, and support.

All staff in clinical and laboratory areas have a responsibility to speak up in case of any concerns and help embed the safety culture in teams.

Conclusions

The SHOT Transfusion Safety Standards provide a structured and consistent approach to maintaining safety. These will help create lasting changes by embedding safe practices into daily operations, making them part of organisational culture. Standards will help establish clear benchmarks, support regulatory checks, facilitate tangible improvements, and foster accountability among healthcare providers. The standards help address known risks systematically and support organisations to allocate resources effectively by prioritising essential safety measures. Robust and reliable transfusion governance within hospitals is fundamental to ensure compliance with these standards.

Worrying signals in this Annual SHOT Report stand as a stark reminder and a clear warning: the current state of our healthcare systems is not just unsustainable, it is unsafe. Without urgent, decisive actions to improve systems and practices, we continue to place both patients and staff at unacceptable risk. The warning signals are flashing red, and the time for complacency has long passed. We must act now to restore safety, rebuild trust, and reform our systems that are failing those they are meant to protect. Patient safety must remain a non-negotiable priority.

Recommended resources

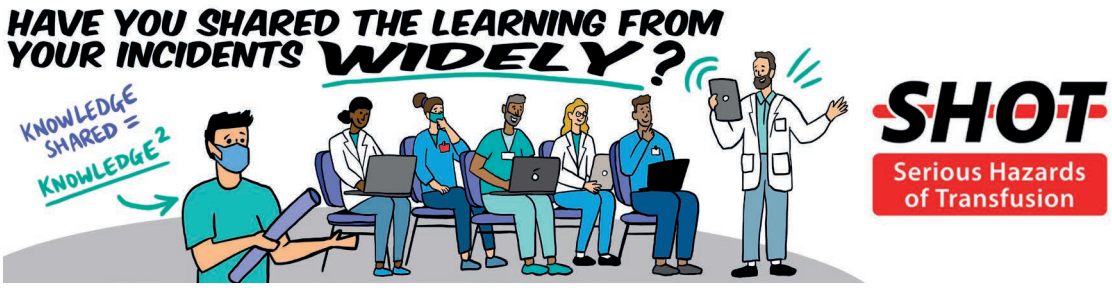
SHOT Transfusion Safety Standards
https://www.shotuk.org/transfusion-safety-standards/

Patient information page with relevant resources from the SHOT website
https://www.shotuk.org/patients/

Transfusion information for patients on the JPAC website
https://www.transfusionguidelines.org/transfusion-practice/consent-for-blood-transfusion/consent-information-for-patients

UKTLC surveys
https://www.shotuk.org/resources/uktlc-surveys/

National Comparative Audit: 2024 Audit of NICE Quality Standard QS138
https://hospital.blood.co.uk/audits/national-comparative-audit/reports-grouped-by-year/2024-national-comparative-audit-of-nice-quality-standard-qs138/



5 Acknowledging Continuing Excellence in Transfusion (ACE) n=5

Authors: Shruthi Narayan and Victoria Tuckley with input from the SHOT Team and Working Expert Group members

Definition:

Exceptional transfusion practice by a team or department, that was above and beyond routine practice and has widespread learning opportunities.

Introduction

The cases submitted to SHOT under ACE are still low in numbers highlighting the need to improve awareness and engagement including ease of reporting. While the name of the category SHOT ACE suggests that it tends to identify extremely good (i.e., excellent) examples of work/practices, submitted reports are capturing everyday excellence. This includes examples of good communication, collaboration, and innovation to address patient-care issues or a human approach resulting in a positive outcome. These often occur in difficult circumstances amidst staff shortages, high workload, and suboptimal IT. The SHOT team would like to acknowledge the hard work, dedication, and teamwork that transfusion staff in both clinical and laboratory areas demonstrate whilst caring for patients despite all the current challenges. This chapter is a celebration of these efforts.

A total of 12 cases were submitted, 5 met the criteria for SHOT ACE and 7 were learning from everyday events and are summarised in the supplementary information on the SHOT website. (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

ACE cases 2024

Table 5.1 summarises 5 ACE cases from 2024, all demonstrating key safety aspects such as communication, patient-centred approach, collaboration and team-working.

Supporting and encouraging excellence reporting within organisations

It is encouraging to see the steady number of reports of excellence being submitted. Learning from excellence still needs to be embedded in day-to-day practice widely. The following aspects need to be considered to facilitate improved reporting of excellence within organisations:

- Making reporting simple and accessible – ensuring reporting is quick and easy, using digital forms and easy to use templates minimising the need for lengthy narratives
- Using real-time recognition with immediate appreciation of staff involved and monthly excellence shout-outs
- Demonstrating the value of reporting excellence – sharing meaningful outcomes from reports to encourage future reporting; using team briefings or newsletters to show how reports led to improved processes, recognition of outstanding staff and patient safety enhancements
- Incentivising and normalising reporting with active participation from leaders; include a 'What went well today?' at the end of shift huddles
- Creating campaigns to improve staff awareness for example, a 'What's working well' campaign that would help promote positive event reporting including potential impact and testimonials from staff who have received positive feedback through excellence reporting

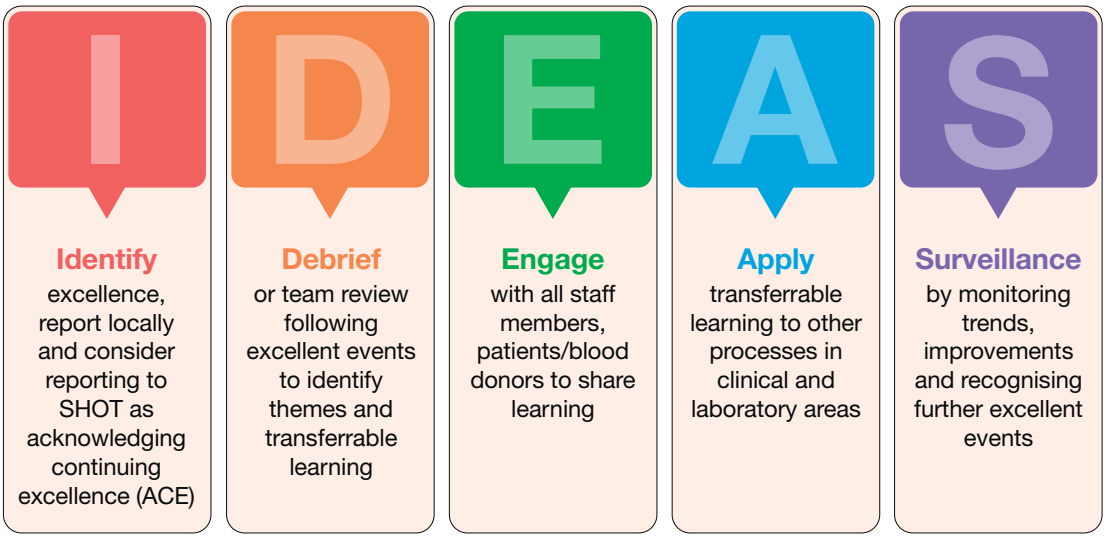
Table 5.1: Acknowledging continuing excellence (ACE) case summaries 2024

Case number	Summary	ACE themes
	Transfusion practice - clinical	
5.1	A staff nurse queried an inappropriate authorisation of two units of red cells and rapid rate, in a patient who had not had their haemoglobin checked for 3 weeks. They escalated concerns to the transfusion practitioners who discussed the patient with the haematology registrar. This facilitated identification of iron and folate deficiencies, and appropriate treatment was initiated. **Reporters' key learning point: 'If not sure, escalate'**	Patient focus Communication
	Teamwork and collaboration	
5.2	Good collaboration between the transfusion laboratory, surgical team, clinical haematology, and reference laboratory to provide blood components for a patient with a complex transfusion history. The laboratory team joined the surgical and anaesthetic teams to complete the pre-procedure World Health Organisation (WHO) surgical checklist. This helped timely provision of transfusion support and reassurance to the treating teams. **Reporters' key learning point: 'The communication with the entire theatre team via the WHO meeting was invaluable'**	Communication Collaboration Patient focus
5.3	Neonatal sample labels were redesigned to reduce the rejection rate. The new design allowed all core identifiers to be captured. A re-audit found the rejection rate had reduced to zero. This has prevented unnecessary re-bleeds for neonatal patients. **Reporters' key learning point: 'Work collaboratively with clinical areas and a systems-based solution will appear.'**	Collaboration Patient focus
5.4	Excellent teamwork and collaboration facilitated provision of 49 blood components over a 6-hour period for a patient with major obstetric haemorrhage, requiring emergency caesarean section. This occurred in a hospital which does not routinely deal with this clinical situation. **Reporters' key learning point: '… Our patient blood management (PBM) lead/transfusion practitioner was on-site and helping at the bedside which was invaluable… I think we are lucky to have a PBM team so involved as I don't believe this is the case in all organisations.'**	Communication Collaboration Patient focus
5.5	Outstanding care ensured good outcomes for mother and baby, both requiring resuscitations following an urgent caesarean section. The mother went into cardiac arrest due to a suspected amniotic embolism and required subsequent exploratory surgery for massive blood loss. Furthermore, the baby required transfer to neonatal intensive care after being born unresponsive. Multiple specialties collaborated on the care of these patients ensuring both survived. A significant number of blood components (n=20) were transfused in addition to salvaged red cells, fibrinogen, and tranexamic acid. This complex and hyperdynamic situation was managed with timely provision of transfusion support and surgical intervention. The case required input from multiple specialities (obstetrician, haematologist, surgeon, laboratory staff, cardiologist). This emergency occurred out-of-hours, overnight, where a limited number of staff and services would be routinely available. Staff were called in from home or from another site to assist and without question, contributed to the positive outcome for this patient. Clear communication and collaboration facilitated appropriate management for mother and baby. **Reporters' key learning point: 'Working together in effective teams to achieve common goals was vital…every member of staff involved stepped up to achieve the positive outcome for mother and baby.'**	Communication Collaboration Patient focus

Full case descriptions of the other ACE cases can be found in the supplementary information on the SHOT website.

Creating a sustainable learning culture by starting small, promoting useful tools that best fit with team's workflow, celebrating and learning from progress made, keeping it simple ensuring feedback loops in place and involving patients to reinforce learning is vital. An example framework for embedding learning from excellence into everyday practice is provided in Figure 5.1.

Figure 5.1: Framework to transfer IDEAS of excellence into practice

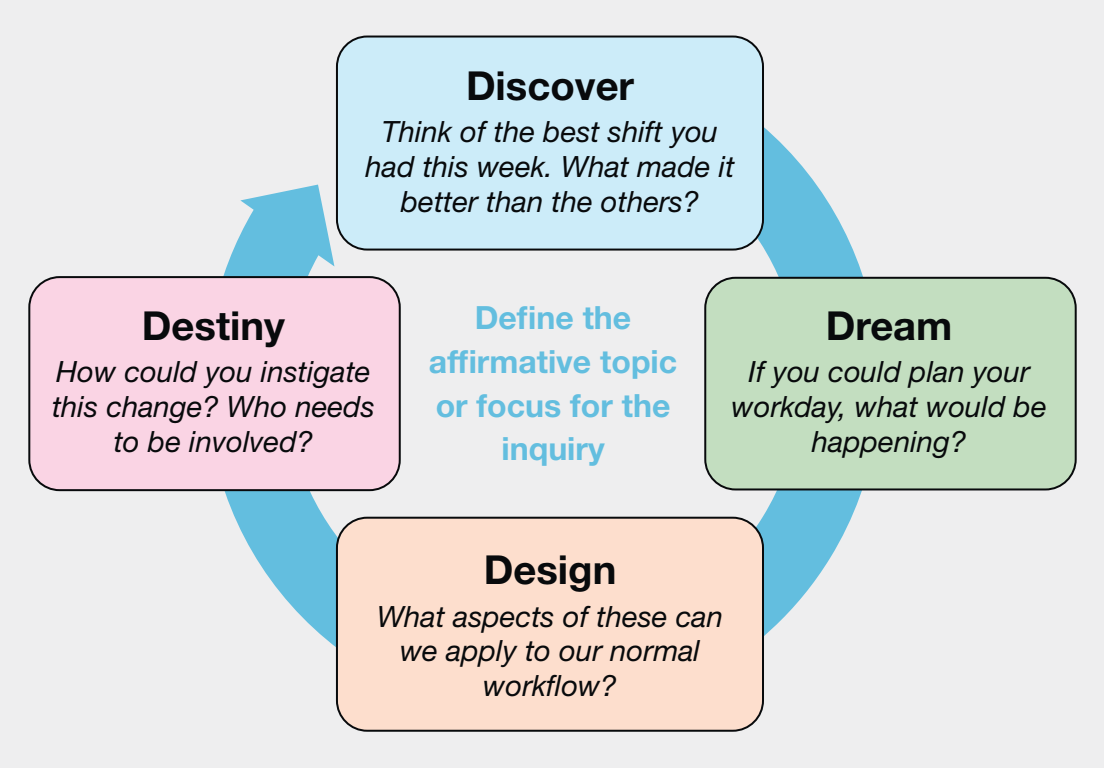


Tools to promote learning from excellence and everyday events

There are several tools and frameworks available to promote learning from excellence and everyday events, a few of which have been covered in previous Annual SHOT Reports.

Appreciative Inquiry is a strengths-based change approach used to bring about positive change in the system. It asks people to explore strengths and successes that already exist to facilitate change. This leads to extraordinary performance by reinforcing relationships and culture, creating common vision and direction, promoting learning and innovation, and energising collective action. Methods focus on the entire system, ensuring leaders, managers, employees, customers, and stakeholders all feel heard and acknowledged. The result is happier, more engaged employees with lower turnover, higher-performing employees, more collaboration, more creativity, and stronger teams and organisation (Cooperrider & Whitney, 2005). Appreciative Inquiry is essentially a set of core principles that can potentially change existing patterns of conversation and ways of relating and give voice to new and diverse perspectives to expand what can be possible (Ludema & Fry, 2008). It can be used in team debriefs, meetings or feedback sessions. Figure 5.2 shows an example of the Appreciative Inquiry process and some example questions. NHS Health Education England provide further example questions in their module 'Start with what's working - An introduction to appreciative inquiry' (Russo, 2022).

Figure 5.2: Appreciative Inquiry process with example questions



This figure shows the '4D cycle' for appreciative inquiry on a mutually agreed affirmative topic (Cooperrider & Whitney, 2005) with questions from the NHS England introductory module on appreciative inquiry (Russo, 2022)

There are several ways in which learning from day-to-day events can be optimised. Event debriefs should include discussions about what went well and what can be improved. Additionally, team safety huddles; daily or shift-based quick meetings (5-10 minutes) facilitating structured approach, brainstorming solutions, and quality walkarounds offer opportunities to recognise and learn from excellence. A multidisciplinary, proactive approach ensures input from all staff groups to identify strengths, weaknesses, and measures to address them to optimise safety.

Neutral language matters for safety

Using a neutral taxonomy is essential for promoting objectivity, fairness, and learning. It reduces bias and blame, helps ensure clear communication and fosters a more constructive, just safety culture promoting staff engagement. This promotes a culture of learning and improvement.

The following changes are needed to adopt neutral language in safety matters:

- Review and standardise existing terminology: identify and remove emotionally charged, punitive or biased language; replace terms such as 'failure' with process-based descriptors 'unintended deviation'
- Ensure consistency in event categorisation across departments

- Train staff on the use of neutral language with focus on learning; provide examples of neutral versus biased terminology to promote consistency
- Update reporting systems to use neutral system-focused language
- Align policies and communications to reflect neutral, non-judgemental language avoiding implied blame

The language and terms used currently in healthcare focus on shortcomings or problems which can unintentionally reinforce negative stereotypes or low expectations, thus missing opportunities to learn from strengths or successes. Steven Shorrock (2023) has further elaborated on how such language can become weapons that can harm people and organisations, albeit to improve safety. Moving to a strengths-based approach will help identify what is working and build on those positives.

Some examples of language shift in safety taxonomy are listed below:

Traditional (blame-oriented)	Neutral (system-focused)
Nurse failed to verify identity	Identity verification process incomplete
Human error caused the event	Contributing human factors identified
Doctor's prescribing error	Medication order discrepancy

This is explored further in Chapter 7, Human Factors and Ergonomics in SHOT error incidents.

Neutral language helps avoid unwarranted and harmful blaming language, bias, and counterfactual reasoning to encourage learning and healing following events (Shorrock, 2023).

Compassionate governance

Compassionate governance is vital to enhance safety, and it ensures that policies, leadership, and safety practices prioritise patient care and wellbeing of healthcare workers. This integrates empathy, ethics and accountability into leadership and decision-making.

The following are key aspects of compassionate governance:

- Psychological safety: fostering an environment where staff feel safe to speak up about concerns, mistakes, and improvements without fear of punishment
- Just restorative culture: balancing accountability with learning ensuring fair responses to events, focusing on repair, reconciliation, and rebuilding trust rather than punitive measures
- Empathetic leadership where leaders actively listen, engage with staff, make decisions that reflect both operational needs and human impact. Compassionate leadership involves four behaviours attending, understanding, empathising, and helping (Atkins & Parker, 2012)
- Strengthening patient-centred care: involving patients and families in care decisions, policy developments and addressing health disparities through equitable access to care
- System accountability: recognising that most incidents are system-based failures rather than individual-based and addressing these factors to improve safety
- Transparent communication: encouraging open, honest, timely discussions about safety issues while avoiding blame-focused language
- Focus on wellbeing: prioritising the mental, emotional, and physical wellbeing of individuals within the system, recognising that stress and burnout impact safety and performance
- Ethical decision-making: ensuring policies and actions align with core ethical principles such as fairness, integrity, and respect for dignity
- Inclusivity and equity: actively considering diverse perspectives and ensuring governance structures support fairness and equal opportunities for all

- Continuous learning and improvement: creating mechanisms to learn from all events, fostering a culture of growth and innovation

Compassionate governance leads to safer systems, better patient outcomes and healthier, more engaged staff (West & Dawson, 2012; West, 2021).

Conclusion

By balancing error-focused learning with excellence-focused learning, transfusion teams can enhance safety, patient outcomes, staff morale and wellbeing. Implementing learning from excellence and day-to-day events requires practical tools and frameworks that encourage a positive safety culture, continuous learning, and system-wide improvements.

There are several instances in transfusion events submitted to SHOT where staff have demonstrated excellence in communication and collaboration to ensure safe transfusions. Reporting of all these instances where staff have taken proactive measures to improve communication, reduce delays, mitigate risks, and ensure safe pre-administration checks is encouraged. If your team or organisation has made an extraordinary response in the face of adversity, please share this via an ACE submission. If you have implemented an improvement action or identified a further measure for safety in a risk assessment, that has worked well, is sustainable and transferrable to other organisations this should be reported.

Learning from excellence has a valuable role to play in haemovigilance schemes and SHOT strongly encourages submissions to ACE. Learning from excellence and sharing good practice acts as a proactive safety measure in the absence of patient harm. Sharing learning from these cases nationally can help promote safety across a multitude of other organisations.

Civility and psychological safety in workplaces foster a great safety culture within teams, providing a safe environment for staff to raise concerns, challenge norms, report incidents and near miss events, thus optimising learning and building safer systems. Clinical and laboratory transfusion staff are encouraged to use resources available to promote learning from excellence and embed civility in day-to-day practices (see 'Recommended resources' from SHOT at the end of this chapter and other sources such as https://learningfromexcellence.com/ and https://www.civilitysaveslives.com/).

While the term 'investigation' remains in use throughout this Annual SHOT Report, we are beginning a thoughtful shift toward more neutral safety language—such as 'learning review'—to better reflect our commitment to psychological safety and continuous improvement. This transition, designed to be compassionate and meaningful, will be phased in over the coming years. It signals a broader cultural change in how we approach safety, responsibility, and shared learning across the system. Alongside this, we continue to promote constructive attitudes and a learning-focused mindset to enhance safety practices.

Recommended resources

ACE reporting – SHOT Definitions and ACE Examples
https://www.shotuk.org/reporting/acknowledging-continuing-excellence/

SHOT video: Learning from excellence in transfusion
https://www.shotuk.org/resources/learning-from-excellence-in-transfusion/

SHOT video: Learning from day-to-day events
https://www.shotuk.org/resources/learning-from-day-to-day-events/

SHOT
Serious Hazards of Transfusion

6 Donor Haemovigilance

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Acknowledgements: Jessica Ryan, Senior Nurse Practitioner, Clinical Support Team, NHSBT and Donna Cullen, Head of Nursing – Plasma, NHSBT

Definition:

Donor haemovigilance: the systematic monitoring of adverse reactions and incidents in the whole chain of blood donor care, with a view to improving quality and safety for blood donors.

Serious adverse reaction: An unintended response in a donor or in a patient associated with the collection or transfusion of blood or blood components that is fatal, life threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity (according to Article 3 (h) of Directive 2002/98/EC).

Recommendations

- Blood Services must ensure that donors are aware of the importance of reporting all adverse events of donation, especially those that occur after the donor has left the donation session
- All United Kingdom (UK) Blood Services should continue to work collaboratively to ensure best practice in the prevention and management of donor complications is developed and shared. Measures such as the development of standard questions for donor adverse event follow up and guidance documents will facilitate harmonisation of practices
- Previous recommendations relating to donor/staff education and benchmarking to inform improvements continue to be pertinent

Action: All staff involved in care and management of blood donors

Key messages

- Ensuring blood donor safety is of paramount importance and is assured, in as far as it can be, by donor selection guidelines, standard operating procedures, adequately trained staff and appropriate facilities. Despite these measures, various adverse events and reactions can and do occur during and after blood donation
- Implementation of the severity grading criteria for donor complications is in progress across the UK. The rate of serious adverse events of donation (SAED) and serious donor complications (SDC) in 2024 was 0.43 per 10,000 donations in the UK or 1 SAED/SDC per 23,479 donations approximately. This figure needs to be interpreted with caution due to the changes in recording donor complications
- Arm pain related to needle insertion and vasovagal events continue to be the most frequently reported serious donor complications
- Blood Services have a duty to take reasonable care to ensure that donors are aware of 'material risks' of blood donation

Introduction

This chapter presents data from the four UK Blood Services on SAED and SDC (grade 3 and higher as per the severity grading criteria), with illustrative cases and recommendations for donor care and safety. Reports from each Blood Service along with denominator data have been presented. Blood donation is usually an uneventful experience for most donors, but as with any clinical intervention, there are risks associated with blood donation. These are usually minor adverse events but, on occasion, may potentially have moderate to severe consequences for the donor. Good donor care involves implementation of measures to minimise the risks of blood donation to donors as well as timely recognition and appropriate management of any complication. Ensuring donor safety also requires informing donors of the material risks of blood donation.

Implementation of severity grading of all blood donor adverse events

All the UK Blood Services record donor complications as per the 'Standard Surveillance of Complications Relating to Blood Donations' (Goldman, et al., 2016). Staff overseeing donor care in each Blood Service record, monitor and investigate the donor adverse events reported appropriately. Until recently, all UK Blood Services were recording serious complications as SAED which are events that result in a significant disability/incapacity persisting for >1-year post donation, hospitalisation, interventions or rarely death. There have been 10 SAED reporting categories, and those reported in the UK in 2024 are listed in Table 6.3.

The UK Blood Services have been implementing severity grading of donor adverse events following the release of validated donor severity grading criteria. These were developed by the Association for the Advancement of Blood & Biotherapies (AABB) Donor Haemovigilance Working Group and endorsed by the International Society of Blood Transfusion (ISBT), International Haemovigilance Network (IHN) and European Blood Alliance (EBA) (Townsend, et al., 2020). This helps rate severity of donor adverse events by grades 1-5, with 1 through 5 being roughly associated with mild, moderate, severe, life-threatening and death as described in Table 6.1. Any event of grade 3 or above will be reported as an SDC. Once implemented by all UK Blood Services, the reporting of SDC will replace the previous SAED categories. It is anticipated that the new grading system will result in more SDC being reported than SAED in previous years.

The Welsh Blood Service (WBS) went live with incorporating severity grading of donor complications in January 2024 and National Health Service Blood and Transplant (NHSBT) went live in October 2024. Training and education of staff, regular review of practices and feedback loops were instrumental in ensuring smooth implementation. The Scottish National Blood Transfusion Service (SNBTS) and Northern Ireland Blood Transfusion Service (NIBTS) are in the process of implementing this soon. Due to the staggered implementation across the UK, a summary of the SAED/SDC reported by each Blood Service has been provided separately in this chapter.

Table 6.1: Validated severity grading criteria for donor adverse events

Severity grade	General factors to consider in assigning severity. Donor adverse event (DAE) severity tool	DAE examples
Grade 1	No outside medical care (OMC) ***AND*** Short duration ≤2 weeks ***AND*** No limitation on activities of daily living (ADL) ***AND*** Resolved with no or minimal intervention	Arterial puncture, pressure bandage applied, resolved without intervention or sequelae Vasovagal event that resolves with comfort care and/or oral hydration Citrate reaction resolved with oral calcium or reduction in infusion rate
Grade 2	OMC, no hospitalisation ***OR*** Duration >2 weeks- ≤ 6 months ***OR*** Limitations on ADL for ≤2 weeks	Superficial thrombophlebitis resolved with oral antibiotics, no sequelae Vasovagal event that requires transport to ED for IV hydration Lacerations requiring sutures
Grade 3	Not life-threatening ***AND any of the following*** Hospitalisation ***OR*** Duration >6 months ***OR*** Limitations on ADL >2 weeks ***OR*** Require surgery ***OR*** Other serious complications (Category E)	Arteriovenous fistula requiring surgical repair Fracture, dental injury, or concussion Transient ischaemic attack and other cardiovascular events, which are not life-threatening
Grade 4*	Immediate medical intervention required to prevent death	Loss of consciousness with fall and intracranial bleed Anaphylaxis requiring intubation or tracheostomy
Grade 5*	Death	Death

*Grade 4 and Grade 5 are not shown in the severity grading tool of blood donor adverse events.

Based on the severity grading tool developed by the AABB Donor Haemovigilance Working Group (https://www.ihn-org.com/wp-content/uploads/2020/06/Tool_brochure_all_logos.pdf)

Imputability

Assigning imputability scoring (the strength of relation between donation and complication) is challenging, especially when information is incomplete or unavailable. History taking and donor assessment over the telephone varies between clinicians with often inconsistent information available to make a reasonable assessment. There are currently no uniformly agreed objective criteria to record levels of imputability and there is considerable variation in how this is recorded (Land, et al., 2018). There is an international working group currently working on developing a scoring matrix for imputability which would help ensure consistency and objectivity in determining this for significant events. Imputability for the SAED and SDC reported in 2024 have not been included in this chapter.

Data from 2024

UK donations

A total of 1,807,914 donations were collected by the four UK Blood Services in 2024 (Table 6.2). This includes whole blood and component donations, as well as plasma donations collected for the manufacture of medicinal products.

Table 6.2: Cumulative donation data from the four UK Blood Services in 2024

Donations from 2024		NHSBT	SNBTS	WBS	NIBTS
Whole blood donations	Donations from male donors	738,393	67,678	38,828	20,592
	Donations from female donors	689,259	77,358	41,086	20,754
	Donations from new donors	180,576	8,346	4,953	3,766
	Donations from repeat donors	1,247,076	136,690	74,961	37,580
Apheresis (includes plateletpheresis, plasmapheresis and PfM donations)	Donations from male donors	79,780	8,112	2,039	2,873
	Donations from female donors	19,434	942	400	386
	Donations from new donors	23,329	1	77	0
	Donations from repeat donors	75,885	9,053	2,362	0
Total number of donations in 2024		**1,526,866**	**154,090**	**82,353**	**44,605**

PfM=Plasma for Medicine

Table 6.3 summarises the number of SAED by category for Scotland and Northern Ireland for the period January 2024 to December 2024, and England until the end of September 2024. This table includes all cases reported in 2024 irrespective of the degree of imputability.

Table 6.3: SAED by category reported to SNBTS (Jan-Dec 2024), NIBTS (Jan-Dec 2024) and NHSBT (Jan-Sept 2024) (All SAED included here irrespective of imputability)

SAED category	NHSBT	SNBTS	NIBTS	Total number
01. Death within 7 days of donation	0	0	0	**0**
02. Hospital admission within 24 hours of donation	8	2	0	**10**
03. Injury resulting in a fracture within 24 hours of donation (including fractured teeth)	7	1*	0	**8**
04. Road traffic collision within 24 hours of donation	1	1*	0	**2**
05a. Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries)	20	3	0	**23**
05b. Problems relating to needle insertion requiring hospitalisation/ intervention (this mainly includes vascular complications)	0	0	0	**0**
06. Acute coronary syndrome diagnosed within 24 hours of donation	3	1	0	**4**
07. Anaphylaxis	0	0	0	**0**
08. Haemolysis	1	0	0	**1**
09. Air embolism	0	0	0	**0**
10. Other event	4	0	0	**4**
Total reported SAED in 2024	**44**	**8**	**0**	**52**

** SNBTS: Donation in 2023, reported to SNBTS in 2024*

Note: All events reported in 2024 to WBS were recorded under the new system incorporating severity grading, see SDC Table 6.4

There were no SAED reported to NIBTS in 2024.

SDC (grade 3 and above as per the severity grading criteria) reported to WBS (Jan-Dec 2024) and NHSBT (Oct-Dec 2024) are listed in Table 6.4.

Table 6.4: SDC (grade 3 or above) by category reported to WBS (Jan-Dec 2024) and NHSBT (Oct-Dec 2024)

SDC category	NHSBT	WBS	Total number
Blood outside vessel	0	1*	1
Arm pain	7	3**	10
Localised infection/inflammation of vein or soft tissue	1	0	1
Other major blood vessel injury	0	0	0
Vasovagal reactions	10***	0	10
Related to apheresis	0	0	0
Allergic reaction	0	0	0
Other serious complication	3****	0	3
Other	0	0	0
Total reported SDC in 2024	**21**	**4**	**25**

**WBS: 1 x haematoma leading to nerve irritation or inflammation*
***WBS: 1 x donation in 2022, captured as SDC in 2024*
****NHSBT: 1 x grade 4 following a delayed vasovagal reaction*
*****NHSBT: 1 x pulmonary embolism, 2 x myocardial infarction*

Table 6.5 summarises the total number of donations and SAED and SDC reported for each of the four UK Blood Services in 2024. The rate of SAED/SDC was 0.43 per 10,000 donations, irrespective of imputability. While this is higher than 0.3 per 10,000 donations reported previously, it must be interpreted with caution due to the changes in recording of donor complications. Trends in the subsequent years and the learning from incident investigations and operational insights will inform improvement actions. It is recognised that there is variation in the number/rate of SAED/SDC reported from each Blood Service. Factors contributing to this are being explored through a Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC)/SHOT working group and may include variable reporting thresholds and donor demographics among other factors. With regular collaboration and communication, the teams are working towards a better harmonisation across the UK Blood Services.

Table 6.5: Summary of total donations for the four UK Blood Services and total numbers of SAED/SDC for 2024

	NHSBT	SNBTS	WBS	NIBTS
Whole blood donations	1,427,652	145,036	79,914	41,346
Apheresis donations including PfM	99,214	9,054	2,439	3,259
Total donations	**1,526,866**	**154,090**	**82,353**	**44,605**
	Total donations in the UK: 1,807,914			
Total number of SAED/SDC in the calendar year 2024	**SAED:** 44 **SDC:** 21	**SAED:** 8	**SDC:** 4	0
Rate of total SAED/SDC per 10,000 donations in UK for 2024 (all submitted reports irrespective of imputability)	**0.43***			

**The new SDC is wider than the earlier 10 SAED categories, caution must be exercised when looking at trend over the years as this figure is not strictly comparable to the rate from previous years*

Illustrative cases

Case 6.1: Transient red urine in a post source plasmapheresis donation

A regular donor attended for a routine source plasma donation. The donor, who had been donating source plasma since 2021 had a history of successful donations without complications. During

the 7th cycle of the donation process, the haemoglobin (Hb) detector alarm was triggered on the plasmapheresis machine, indicating the presence of red blood cells in the plasma. Staff observed red discolouration in the tubing, (referred to as Hb in harness, which indicates a potential red cell spill or haemolysis: the breakdown of red blood cells). The donation was terminated without returning the remaining red cells to the donor.

The donor remained well and asymptomatic whilst in the care of the plasma centre but later reported observing blood in their urine. The donor declined the request to attend their general practitioner (GP) surgery as the symptoms had subsequently resolved and they were in good health. Due to the presentation of reported symptoms by the donor, it was believed the likely cause of red urine was haemoglobinuria (the clearance of haemolysis breakdown products through the kidneys). The donor was temporarily deferred but remains eligible to donate in the future.

Haemolysis can occur due to kinks in the lines of the apheresis disposable or other mechanical obstructions resulting in damage to the red blood cells (Vrielink, 2014).

If haemolysis is suspected (due to the presence of pink plasma or detection of Hb in the plasma collection line), the plasmapheresis procedure must be stopped without the return of any red cells remaining in the disposable harness. This is to avoid the risk of damaged cells being given back to the donors. Neyrink et al. (2018) suggest staff should inform the donor about the possibility of red colouring of the urine (haemoglobinuria) as part of their post donation advice.

Haemolysis is a known but rare complication of plasmapheresis donation. Whilst some data reports an occurrence rate of 0.14 per 100,000 apheresis procedures, Pink, et al. (2022) concur there is little evidence or literature reporting the frequency of haemolysis events or the outcome for affected plasmapheresis donors.

Case 6.2: Two donors with arm pain lasting more than 12 months since venepuncture

Two regular whole blood donors reported persisting arm pain for more than 12 months following their donation. The first case was a returning donor who reported the last donation was more painful than usual with accompanying slow flow. The donor could not recall whether they reported their symptoms to session staff at the time of donation and only reported it to the Blood Service 4 years later. At that time, a full donation was obtained, no needle adjustments or pain at session were recorded and it was noted to have been an uneventful donation. The donor reported developing a large haematoma with significant bruising and associated nerve symptoms (tingling and numbness) to their hand. The haematoma resolved without any further intervention and the donor was reviewed by their GP who did not recommend any further investigations or treatment.

The second donor was a regular donor who reported that a needle adjustment was performed soon after venepuncture due to slow flow; this caused them pain, but they did not report this to staff. The donor could not recall whether staff enquired regarding their wellbeing following the adjustment. A full donation was obtained. The donor reported that they continued to experience pain in the antecubital fossa with no other neurological symptoms. The donor received ultrasonic treatment to help alleviate symptoms.

Donating blood is generally considered to be safe (Veldhuizen, et al., 2012). There are however recognised complications of donation (Goldman, et al., 2016). These include well-defined venepuncture-related arm complications, e.g., bruising and nerve-related irritation/injury, which can affect donors to a varying degree, sometimes in the long-term.

From Case 6.2, it is observed that neither donor reported their initial symptoms of arm pain at donation when it became apparent. Various reasons may influence the donor to not report complications. This includes lack of awareness or unfamiliarity with complications, normalisation of symptoms, fear of being deferred, and other social or cultural factors.

Donor education therefore forms a vital part of the blood donation and consenting process. Donors should be made aware of what to expect and what to do in the event of any complication during or after donation. This is important, not only to ensure prompt management of the donor and ensuring their

safety, but also optimising the donor base by maximising return rate of donors (Wiersum-Osselton, et al., 2014). It is well recognised that donors who experience a venepuncture-related complication may either opt not to return or even be withdrawn from donation due to the complication.

Addressing gaps in staff knowledge and improving staff awareness about potential complications and management is equally important. This includes the observation of donors during the venepuncture and donation process, including noticing non-verbal cues, e.g., facial expression and restlessness, especially in the absence of any verbal reports by the donor.

When a donation rate is slow, a needle adjustment may occasionally be required. Staff should confirm with the donor regarding any discomfort before and after needle adjustments. They should also be vigilant for any signs of donor discomfort and act promptly to ensure donor safety. It is essential to stop a donation in the event of any symptoms, to help minimise risk of injury and possible long-term complications.

Conclusion

Staff should provide post-donation information to all donors. This should include the risk of delayed reactions, when to seek medical advice and guidance on prevention. Donors should be encouraged to make early contact with the Blood Service if they experience any complications. This will ensure appropriate clinical advice and management. Understanding these complications and predisposing risk factors will help lead to the development of appropriate interventions to reduce their likelihood, as well as better donor selection criteria to ensure donor safety.

Recommended resource

Post-donation management of blood donors with nerve injury related to donation
https://www.transfusionguidelines.org/document-library/documents/post-donation-management-of-blood-donors-with-nerve-injury-related-to-donation-v2-pdf

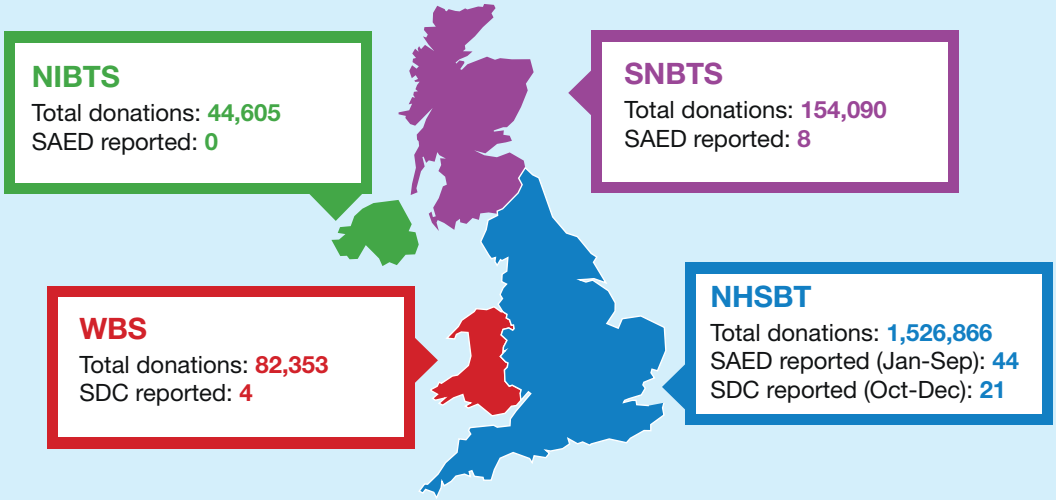
Serious adverse events following blood donation reported to the UK Blood Services in 2024

2024 has seen the gradual transition of the UK Blood Services away from serious adverse events of donation (SAED) which focused on grouping based on category to serious donor complications (SDC) which focuses on impact to the donor based on severity. The introduction of donor severity grading for adverse events also allows for a benchmarking via a uniform standard for all UK Blood Services and internationally.

SAED (Pre 2024)
- Serious adverse event of donation
- Focused on grouping by category

Transition (2024)
- SAED phased out
- SDC introduced

SDC (From 2024)
- Serious donor complications
- Focuses on impact to individual



NHSBT=National Health Service Blood and Transplant; NIBTS=Northern Ireland Blood Transfusion Service; SNBTS=Scottish National Blood Transfusion Service; WBS=Welsh Blood Service

Key messages:

1. The rate of serious donor complications in the UK is one SAED/SDC per 23,479 donations
2. Arm pain from needle insertion and vasovagal reactions remain the most common complications reported
3. Donor complications can occur despite best care, and some may have serious impact on donors
4. Improving donor experience with measures to reduce risk of complications related to blood donation along with prompt recognition and management of complications is vital
5. Blood Services must ensure that all donors are aware of the importance of reporting all adverse events of donation so the donor can be appropriately managed, and the adverse events can be recorded, monitored and appropriate actions taken to improve donor safety

ERROR REPORTS

7 Human Factors and Ergonomics (HFE) in SHOT Error Incidents n=3322

Authors: Emma Milser and Alison Watt

Key findings:

- An increase in cases investigated using HFE frameworks
- A more even spread of contributory factors shows broad consideration of the all the categories
- A decrease in attribution to situational factors, and a corresponding increase to organisational factors

Gaps identified:

- Organisational pressures played a role in the event in 16.8% of cases
- Gaps or issues with staff knowledge were reported in 28.4% of cases
- Mismatches between workload and staff provision occurred in 23.8% of cases
- Suboptimal system design resulted in unsafe workarounds

Good practice:

- HFE principles or frameworks/models to investigate events continue to be embedded
- Improved appreciation of system and organisational factors is evident due to a more even allocation of contributory factors
- Some cases included corrective and preventive action (CAPA) that showed organisational-wide learning

Next steps:

- Familiarisation with the updated Human Factors Investigation Tool (HFIT) questions for 2025
- Considering CAPA for action effectiveness utilising the hierarchy of intervention effectiveness
- Considering design HFE principles when implementing new systems

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

SHOT
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Definition:

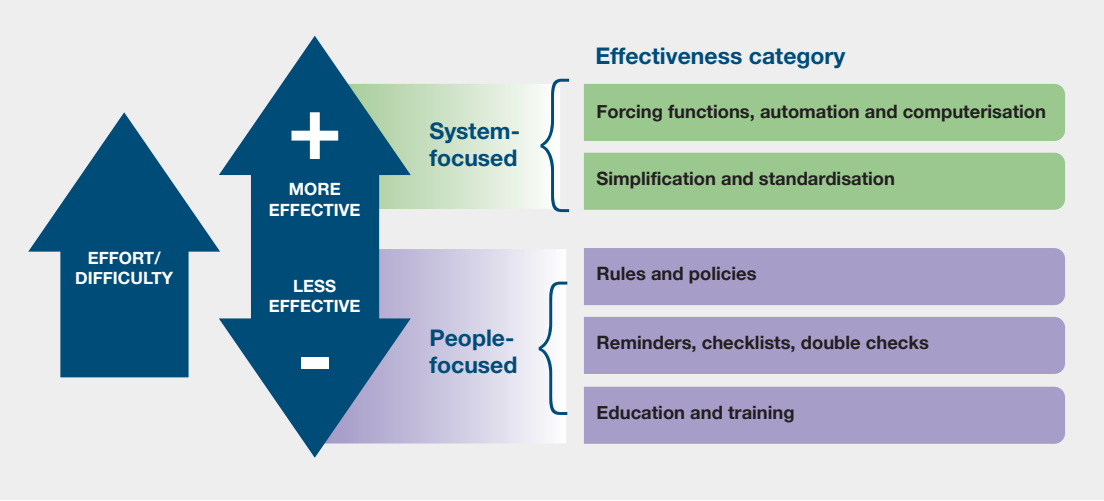
Human factors and ergonomics is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system.

Introduction

The fundamental principles of HFE are related to how the design of equipment, work and workplaces will influence the performance or outcomes of an organisation relative to safety, efficiency and wellbeing (Sujan, et al., 2021). Workarounds refer to methods that people may develop to overcome challenges or limitations in a system, process, or equipment in the workplace. Dekker's analysis of workarounds (Dekker, 2011) suggests that they are often the result of design flaws or wider organisational issues rather than individual negligence. Using HFE principles when investigating errors has been recommended by SHOT for several years and is becoming increasingly embedded. Potential workarounds in the workplace may be prevented if HFE factors are also recognised and implemented early on during the design stage, particularly when new equipment or systems are introduced.

In healthcare, when planning corrective and preventive actions following incidents, a hierarchy of interventions help prioritise actions based on effectiveness and sustainability. This was initially discussed in relation to haemovigilance reports in the 2022 Annual SHOT Report (Narayan, et al., 2023). This hierarchy emphasises designing safer systems rather than relying solely on individual vigilance or training. For 2025 an additional section has been added to the HFIT asking reporters to describe up to three main actions following investigation of a safety event and rank their effectiveness. This may assist those undertaking after-event reviews to identify effective systems-based preventive actions to help prevent occurrence or recurrence. SHOT resources are available to help, and the SHOT team can advise on categorisations. The HFIT tuition package on the SHOT website provides information and guidance to help understand the causal and contributory factors and effective actions related to transfusion events being reported.

Figure 7.1: HFIT questions for reporters to rank main actions against their effectiveness category



Neutral language

In their work on human factors, Shorrock & Williams (2016) allude to the 'language of blame' in the context of organisational culture and investigation of patient safety events. The impact of language on staff safety, described by Usrey (2024), likens the language used to that found in a criminal investigation. This can influence how individuals perceive safety, accountability, and organisational culture. This is because the term 'investigation' may evoke images of blame and punishment, rather than an opportunity for learning and improvement. The recommendation that healthcare organisations should introduce and promote a restorative just culture, with buy-in from leadership at all levels was made in this chapter in the 2023 Annual SHOT Report (Narayan, et al., 2024). Choice of language may also negatively affect patients' perceptions and experiences, potentially making them feel they are somehow to blame for poor outcomes (Cox & Fritz,

2022). For 2025, the language used in the updated HFIT questions has undergone subtle changes to reflect the shifting focus from a retributive to a restorative approach when examining contributory factors in patient safety events.

Table 7.1: Neutral language alternatives

Example	Alternative
Investigation	Learning review
The patient failed chemotherapy	Chemotherapy did not work for the patient
Pump user error by nurse	Pump allowed incorrect programming

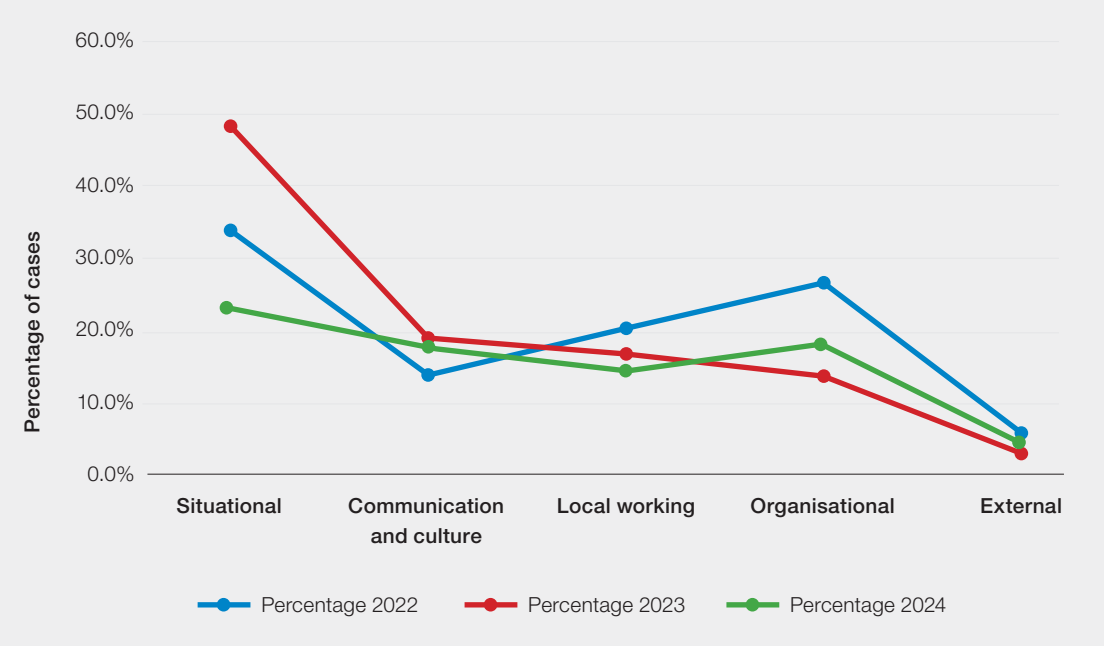
Staff fatigue

In promoting a restorative just culture, the detrimental effects of staff fatigue should be recognised as these can lead to errors and accidents, ill-health and injury, and reduced productivity (HSE, n.d) The challenge of addressing fatigue in healthcare is addressed in a new white paper 'Fatigue risk management for health and social care' from the Chartered Institute of Ergonomics and Human Factors (CIEHF, 2024). Staff fatigue can have potentially serious consequences and the paper sets out practical tips to approach the issue. Pertinent to this, the problem of ‘corridor care’ has gained media attention recently and a coalition letter from the Royal College of Nursing (RCN), British Medical Journal (BMJ) and multiple other organisations to the Health Secretary was published in January 2025 (RCN, 2025). The letter outlines concern for patient safety and staff wellbeing, highlighting that the issue causes moral distress and ultimately, moral injury. In the supplementary section for this chapter, some case studies where ‘corridor care’ was cited as being a contributory factor in errors are described.

Analysis of the SHOT HFIT

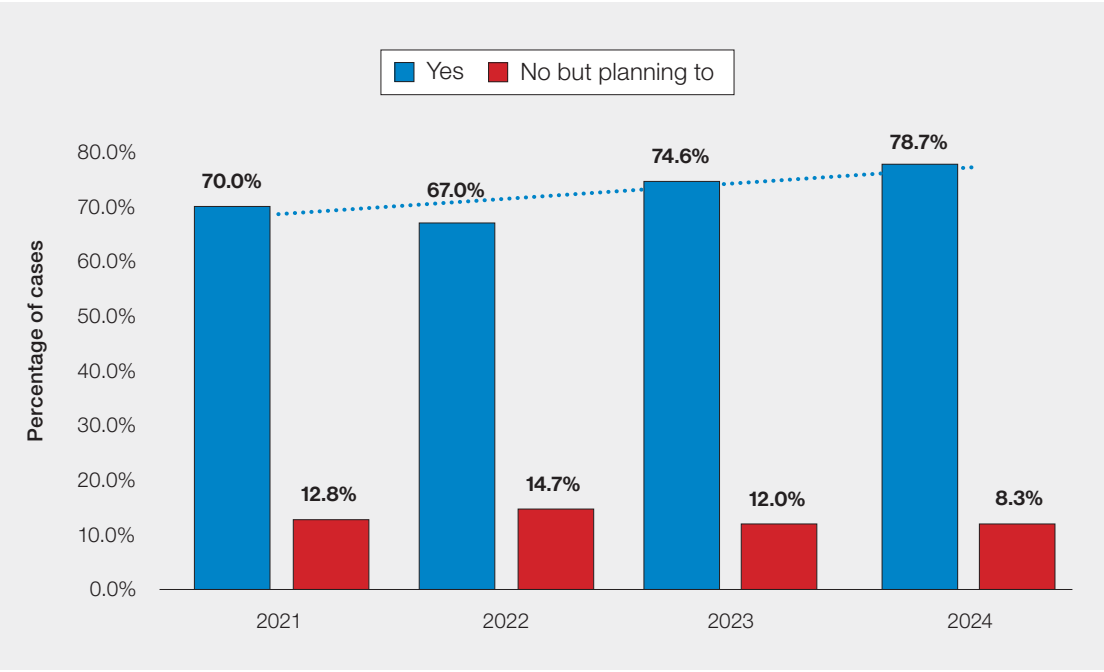
A total of 3322 error cases were included in 2024, representing an increase in the error cases reported in 2023 (n=3184). Throughout SHOT’s historical analysis of HFE, there has been evidence of an over-emphasis on blaming individuals, but analysis of the last 3 years’ data shows an improved appreciation of system and organisational factors. Figure 7.2 shows consideration across the breadth of factors, with a marked decrease of 24.6% attributed to situational factors and an increase of 3.2% attributed to organisational factors. Within the organisational factors category, where responses were provided, 558/3322 (16.8%) reported that organisational pressures played a role in the event, and 944/3322 (28.4%) shared that there were gaps or issues with staff knowledge. For local working conditions around the time of the event 792/3322 (23.8%) stated that there was a mismatch between workload and staff provision. In comparison to 2023 there was a more even allocation of contributory factors demonstrating consideration of the all the categories.

Figure 7.2: A comparison of HFIT categories assigned by SHOT reporters in 2022, 2023 and 2024



The 2021 Annual SHOT Report recommendation that 'a tried and tested human factors-based framework' should be applied to investigations remains pertinent (Narayan, et al., 2022). In 2024, 2615/3322 (78.7%) cases specified that HFE principles or a framework/model was used to investigate incidents and a further 276/3322 (8.3%) indicated they were planning to in the future. Figure 7.3 shows that this is an encouraging uptake compared to recent years and that more cases are being investigated using a formal framework to consider human factors.

Figure 7.3: Percentage of cases investigated using HFE principles or framework 2021-2024



Of those using a HFE framework, 2531/2615 (96.8%) provided data about the type that was used. The most common response 1039/2531 (41.1%) used the SHOT HFIT questions, which were adapted from the evidence-based Yorkshire Contributory Factors Framework (YCFF) (Improvement Academy, 2022) and 123/2531 (4.9%) used the YCCF framework, making it the sixth most commonly used. The Patient Safety Incident Response Framework (PSIRF) was introduced in England in 2022 to replace the

National Health Service England (NHSE) Serious Incident Framework. In 2023, 102/2227 (4.6%) used this framework and for 2024 this has risen to 457/2531 (18.1%). An increasing number of organisations in England have implemented the framework, now making PSIRF the second most commonly used investigation method. It remains important that SHOT-reportable events are fully investigated and in the case of Medicines and Healthcare products Regulatory Agency (MHRA)-reportable incidents, the Blood Safety and Quality Regulations (BSQR) require an investigation of factors leading to the incident and appropriate CAPA (Department of Health, 2005). The third and fourth most commonly used frameworks were in-house HFE and root cause analysis (RCA) tools. Organisations are discouraged from using RCA methods as they imply that a single root cause can be found and tend to favour a temporal narrative rather than a wider systems view (Peerally, et al., 2016).

Case 7.1: Workarounds by nursing staff during administration of platelets

A patient on the intensive care unit (ICU) received an adult therapeutic dose of platelets following a cardiac procedure. An incorrect identification (ID) band, not attached to the intended patient, and not at the patient's side, was scanned by the nurse administering the platelets. The electronic-tracking system alerted that an incorrect patient ID band had been scanned. When the error was realised, the correct patient received the transfusion.

The ICU had a very limited number of handheld scanning devices and so relied on additional scanners attached to workstations on wheels, which did not reach the ID bands attached to patients. As a workaround staff had begun printing spare ID bands which were not attached to patients, and it was common practice to have multiple ID bands at the computer desk.

The case demonstrates the workarounds that can arise when the design of equipment and processes do not consider HFE factors, meaning that staff cannot properly use a system which is intended to enhance patient safety. In the section of the HFIT that asks if one thing could be changed to make this incident less likely to happen again, the response was that adequate handheld scanning devices should be made available to all staff. The CAPA following the event included involvement of the hospital transfusion committee and nursing working group, and an organisational-wide review of hardware and infrastructure to support safe use of electronic systems. Therefore, from a single event much wider learning, and preventive action would take place beyond the department where the event originated. Once implemented the corrective actions identified represent higher ranked interventions on the hierarchy of intervention effectiveness (Figure 7.1), compared to potential human-based interventions. By ensuring adequate hardware and infrastructure, more effective 'automation and computerisation' and 'forcing function' interventions that are system-focused may prevent workarounds and optimise use of the electronic system.

Learning point

- Considering HFE factors during initial system design may help to avoid workarounds at a later stage. Workarounds have the potential to lead to unintended patient harm

Conclusion

From January 2025, SHOT has updated the HFIT to include an opportunity to record up to three main actions taken following the investigation of an event. Reporters can use this section to consider their CAPA for action effectiveness utilising the hierarchy of intervention effectiveness (Figure 7.1). Reporters are encouraged to become familiar with the updated HFIT questions and HFIT tuition package for 2025.

It is anticipated that reporting actions in the revised HFIT will provide useful data about problems known to occur with actions outside the immediate control of staff involved, e.g., the need for a new electronic system. These would usually be at the more effective level on the hierarchy (Figure 7.1) but can be difficult to implement. It can be important to record what may be seen as aspirational actions and if necessary, add to the organisation's risk register for long term monitoring. This year (2024) a mismatch between workload and staff provision was seen in almost a quarter of cases, which indicates that actions to improve staffing levels were needed. Such actions are often not included in the improvement plan

because they cannot be resolved locally and require very high-level input. However, patient harm events will continue if these issues remain unresolved.

SHOT is promoting a restorative just culture, so staff issues like fatigue, wellbeing and burnout all require consideration. The use of no blame and neutral language is encouraged, and SHOT is endeavouring to refer to reported cases as 'events' which has fewer negative connotations than the word 'incident'.

Finally, SHOT has been highlighting the importance of considering HFE in design principles when implementing new systems or purchasing equipment. Further information on this can be found in the SHOT Human Factors and Ergonomics (HFE) Meet the Experts Webinar.

Recommended resources

SHOT Human Factors Tuition Package
https://www.shotuk.org/resources/human-factors-investigation-tool-hfit/

SHOT Human Factors and Ergonomics (HFE) module
https://www.shotuk.org/resources/e-learning/

SHOT Human Factors and Ergonomics (HFE) Meet the Experts Webinar
https://www.shotuk.org/resources/human-factors-and-ergonomics-hfe-webinar/

SHOT
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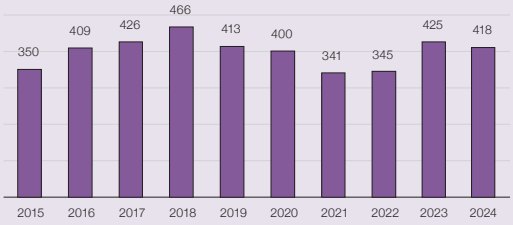
8 Adverse Events Related to Anti-D Immunoglobulin (Ig) n=418

Authors: Jennifer Davies, Clare Cook and Vera Rosa

Headline data 2024

Number of reports n=418
Deaths n=0
Major morbidity n=3

Anti-D Ig reports by year



Demographic data

Male n=0
Female n=418
Adults n=409
Paediatric n=8
Unknown n=1

Potential for major morbidity n=286

Late/omitted RAADP n=91
Late/omitted anti-D Ig following a PSE (including delivery) n=195

Key findings:

- Errors related to anti-D Ig continue to account for a large proportion of SHOT cases
- The majority of errors resulted in omission or late administration. These often occur as anti-D Ig is not administered prior to discharge
- The United Kingdom and Ireland Blood Transfusion Network (UKIBTN) information leaflet Anti-D Immunoglobulin During Pregnancy, provides information to support the decision-making process

Gaps identified:

- Under-reporting of discrepancies between D-type predicted from high-throughput non-invasive prenatal testing (NIPT) for fetal *RHD* genotype and cord sample testing
- Gaps in staff knowledge about appropriate administration of anti-D Ig
- Issues with communication among staff involved in the care pathway
- Information technology (IT) issues with lack of functionality, inappropriate algorithms to support safe practice and poor interoperability

Good practice:

- Effective investigation of events and consideration of human factors enable identification of effective improvement actions
- Investigation of discrepancies between D-type predicted from cell free fetal deoxyribonucleic acid (cffDNA) screening and cord sample testing can identify wrong blood in tube (WBIT) and ensure that anti-D Ig is administered where appropriate

Next steps:

- A national comparative audit is being scheduled to identify gaps in current practice and inform improvements
- Effective use of checklists to facilitate timely administration of anti-D Ig

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

Events relating to the requesting and/or administration of anti-D immunoglobulin (Ig) and routine antenatal anti-D Ig prophylaxis (RAADP) during pregnancy and after delivery.

Introduction

Anti-D Ig is an important aspect of management of D-negative pregnancies and in reducing the risk of developing immune anti-D in D-negative people with childbearing potential (including paediatric). This risk could also be following transfusion of D-positive blood components and D-mismatched solid organ transplants (Qureshi, et al., 2014). Guidelines for safe and appropriate administration of anti-D Ig following potentially sensitising events (PSE) and RAADP are available in the United Kingdom (UK) (Qureshi, et al., 2014; NICE, 2008; NICE, 2019; NICE, 2023). Organisations should ensure that the requirements for safe practice are reflected in local policies, systems, and processes. The SHOT aide memoire for anti-D Ig in pregnancy is based on available national guidance on the appropriate use of anti-D Ig and is freely accessible on the SHOT website.

High-throughput NIPT for fetal *RHD* genotype, i.e., cffDNA, is available across the UK for non-immunised D-negative pregnant women and birthing people, as recommended by the National Institute for Health and Care Excellence (NICE) (NICE, 2016). Prediction of the fetal D-type supports targeted administration of anti-D Ig. The screening assay has limitations, with sensitivity of 99.3% (95% confidence interval (CI) 0.982-0.997) and specificity of 98.4% (95% CI 0.964-0.993) (Mackie, et al., 2017). False-positive and false-negative results must be reported to SHOT and to the test provider. A cffDNA discrepancy investigation form is available on the SHOT website, enabling local investigation and appropriate provision of anti-D Ig.

SHOT data continue to demonstrate that errors in anti-D Ig and RAADP management occur in both clinical and laboratory settings. The management of anti-D Ig and RAADP is multifaceted; errors occur at all stages of the process, from the identification of the requirement, ordering, prescription, laboratory release, storage, and administration. In 2024, SHOT released an anti-D Ig safety notice. This provides a checklist that staff can use to measure local compliance, enabling identification of gaps and development of an action plan for improvement.

Major morbidity n=3

There were 3 cases that resulted in major morbidity (sensitisation to the D antigen). In 1 case a D-negative patient of childbearing potential received a D-positive renal transplant. Anti-D Ig was not given, and the patient developed immune anti-D.

Case 8.1: Omission of anti-D Ig administration in a D-mismatched renal transplant

A D-negative patient of childbearing potential received a D-mismatched renal transplant (D-positive donor). The renal registrar did not complete the requirement for anti-D Ig in the patient's admission booklet. Furthermore, this requirement was not identified by the renal or the surgical teams involved in the patient's care. During the incident investigation, it was stated that the transplant nurse identified the need for anti-D Ig and this was communicated to the ward staff verbally. There was no evidence of this communication in the patient's notes and no request was made to the blood transfusion laboratory. The omission of anti-D Ig was identified when anti-D was detected in the patient's plasma one-month post transplant.

The second case involved a delay in administration of anti-D Ig following an abdominal trauma at 17^{+5} weeks. No anti-D Ig was ordered initially but was given 9 days later. The woman developed immune anti-C+D which were detected at birth.

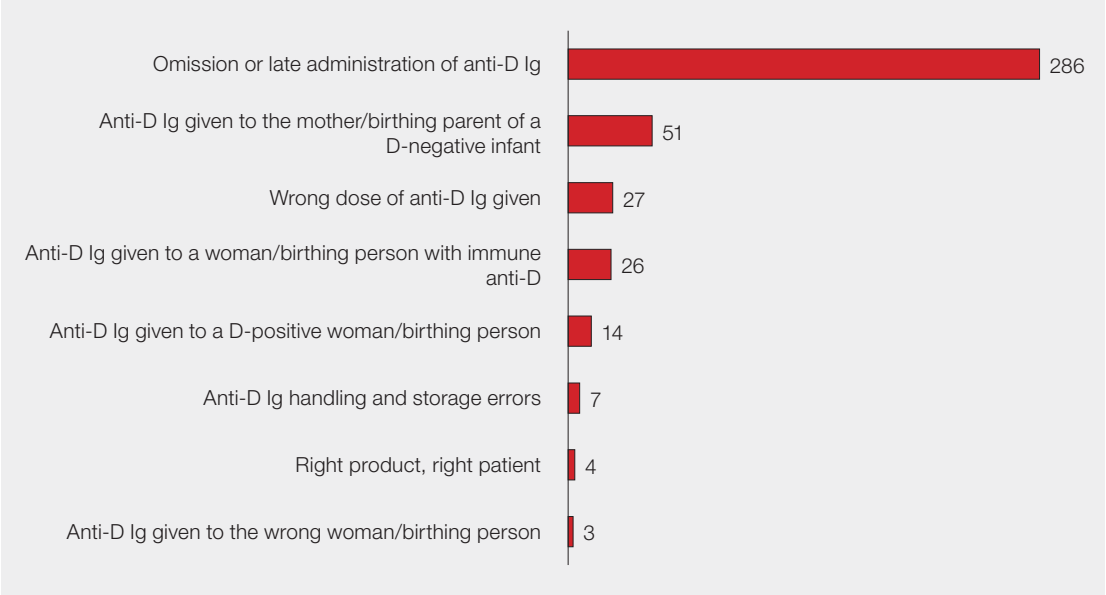
The final case occurred when follow-up testing after a large fetomaternal haemorrhage (FMH) was delayed as the sample was rejected. The sensitisation was discovered when the patient was followed up 6 months later and was found to have developed anti-D.

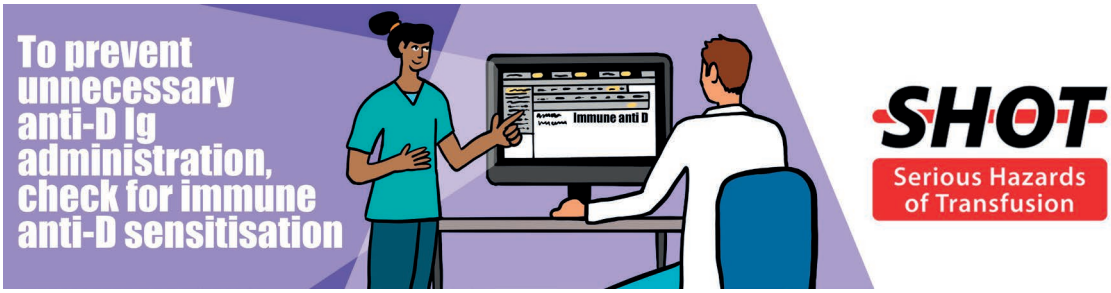
Delays, omissions, under-dosing, and failures to perform follow-up testing in a timely manner after a FMH of more than 4mL have the potential to result in development of immune anti-D and haemolytic disease of the fetus and newborn (HDFN). The impact of anti-D Ig and RAADP errors should not be underestimated.

Overview of cases n=418

A total of 418 cases have been analysed in this category, the majority of these were related to inappropriate anti-D Ig management during pregnancy. Most errors occurred in the clinical area, 330/418 (78.9%) compared to laboratory, 88/418 (21.1%). Figure 8.1 shows the distribution of cases by anti-D Ig error category.

Figure 8.1: Distribution of anti-D immunoglobulin (Ig) related error reports in 2024 (n=418)





As in previous Annual SHOT Reports the majority of errors resulted in omission or late administration of anti-D Ig, and these are further broken down in Table 8.1.

Table 8.1: Causes of omission or late administration of anti-D Ig in 2024 (n=286)

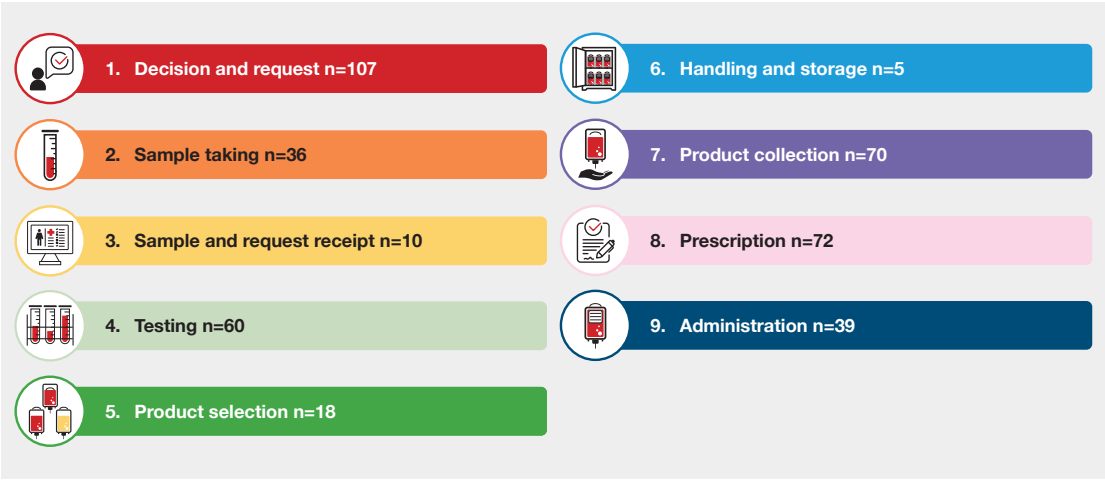
Reason for omission or late administration	Number of reports	Percentage of cases
Failure to order anti-D Ig	79	27.6%
Discharged before anti-D Ig administration	77	26.9%
Maternal or neonatal results misinterpreted or not checked	29	10.1%
Anti-D Ig ordered but not administered	26	9.1%
Incorrect decision to omit anti-D Ig administration	19	6.6%
Errors related to cffDNA testing or results	15	5.2%
Transcription errors	15	5.2%
Partial D/weak D	13	4.6%
Failure in laboratory processes	10	3.5%
Anti-D Ig errors in transplant patients	1	0.4%
Anti-D Ig stored incorrectly	1	0.4%
Failure to carry out positive patient identification	1	0.4%
Total	**286**	**100%**

From the 418 cases reported, there were 14 cases related to errors with the interpretation of D-typing results, 11 of these were partial D-type where anti-D Ig should have been given but was omitted and 3

were typed as weak D. Of the 3 cases identified as weak D, 1 was reported as D-negative and anti-D Ig given inappropriately. In 2 cases, the cord samples tested D-negative, contradictory to the D-type predicted by cffDNA screening. In 1 case, this was investigated locally and identified but anti-D Ig was not given in a timely manner, in the other case it was identified when the baby was tested in another hospital. British Society for Haematology guidelines provide an algorithm for anomalous D-typing for compatibility testing which should be reflected in local policies (Milkins, et al., 2013). No differences in error rates were seen with RAADP, 133/418 (31.8%) or with anti-D Ig given for PSE, 146/418 (34.9%) or post-birth, 139/418 (33.3%).

Anti-D Ig errors have been reported following errors at all steps in the transfusion pathway. Figure 8.2 shows the distribution of these errors. Of note, most errors occurred in clinical decision-making and requesting anti-D Ig highlighting the need for better education of staff.

Figure 8.2: Steps in the transfusion pathway when the anti-D Ig errors occurred in 2024



In 1 miscellaneous case (not included in Figure 8.1) there were two missed RAADP appointments, however it was not confirmed whether the woman had been thoroughly informed of the potential consequences of not receiving anti-D Ig in a timely manner

Information about investigation of incidents was reported in 394 cases. Of these, 295/394 (74.9%) had completed a formal investigation. Denominators for the numbers provided here is variable as this depends on whether the relevant question/s have been answered by reporters. There were 213/360 (59.2%) cases that had been discussed at a maternity governance meeting. In 96 cases, good practice was noted. The examples of good practice were varied but included individuals involved in the event being open and honest about the errors enabling effective investigations, and collaborative working to identify and implement improvement actions. Where the contribution of human factors was recorded this mainly related to:

- Failures in team function, 129/370 (34.9%)
- Gaps with staff skill or knowledge, 122/364 (33.5%)
- Inadequate written or verbal communication, 153/364 (42.0%)
- Incomplete handover, 111/394 (28.2%)

Non-invasive prenatal screening for RHD n=54

Errors related to cffDNA screening were identified in 54 cases; divided equally between laboratory (n=27) and clinical (n=27). False cffDNA results accounted for 22/27 laboratory cases, 18 false-positive cffDNA results, and 4 false-negative cffDNA negative results. The cffDNA screening test is provided by three centres in the UK, as the Welsh Blood Service introduced this test in May 2024. However, the majority of samples are tested at the International Blood Group Reference Laboratory (IBGRL). In 2024, IBGRL confirmed that there were 28 false-positive and 7 false-negative cffDNA results. This indicates an under-reporting of these events to SHOT. There was one case where the result was inconclusive and another where the cffDNA result checked was from a different pregnancy.

The main gaps identified (excluding the false-negative and false-positive cases) were related to IT where

staff did not have access to the IT system to check the result or were not trained to perform this task. Also, there were transcription errors that could have been prevented by interoperability between laboratory (reference and hospital blood transfusion laboratories) and clinical IT systems. There were also cases where the cause of error was either misinterpretation of the result or accessing results from a previous pregnancy. However, the most common cause continues to be events where cffDNA results are available but not checked prior to issuing or administration of anti-D Ig. This might reflect an ineffective process, suboptimal use of safety checks or lack of clarity in local protocols.

Investigation of cffDNA discrepancies was noted in 9 cases. The type of investigations performed in the cord samples were as follows; weak/partial D testing in 1 case, WBIT in 3 cases, WBIT and Rh (CcEe) phenotyping in 2 cases and WBIT, weak/partial D testing and Rh phenotyping together in 3 cases. It should be noted that Chapter 15a, Near Miss – Wrong Blood in Tube (WBIT) in this Annual SHOT Report describes a further 2 cases where the WBIT was identified during the investigation of discrepant cffDNA and baby's blood group results.

Further details of the cffDNA errors can be found in the supplementary chapter.

Involvement of information technology n=140

IT was noted as being involved in errors in 140/418 (33.5%) of cases (see supplementary information for details of IT issues). In 51/140 (36.4%) of these cases it was noted that IT could have prevented the error had it been in place or used. Other main contributory factors included lack of functionality/ algorithms to support safe practice, 24/140 (17.1%), lack of interfacing/interoperability, 16/140 (11.4%) and systems not being used correctly, 14/140 (10.0%).

Informed decision-making

People who are D-negative need to be informed about the benefits and risks of anti-D Ig at the earliest opportunity in pregnancy, or pre-conception. This enables them to become experts in their own health and pregnancy. Healthcare professionals have a responsibility to ensure women and birthing people have the information they need, to make informed choices about their care. It can give people the confidence and space to ask questions and establish what matters to them. Communication using plain language, reinforced with resources in their preferred format can support decision-making. The UK and Ireland Blood Transfusion Network have created a nationally agreed information leaflet about receiving anti-D Ig in pregnancy (see 'Recommended resources'). The Royal College of Midwives (RCM) provides guidance on how to support women and birthing people's informed decision-making (RCM, 2022).

Case 8.2: Delay in administering anti-D Ig

A woman was discharged from the labour ward following a vaginal bleed at 20^{+1} weeks gestation, without receiving anti-D Ig, or being advised by staff about the need for anti-D Ig. No follow up was arranged. Discharge had been recommended by the consultant overseeing the care. An FMH test had been requested but the results were not followed up by staff discharging the patient. Anti-D Ig was available after the woman was discharged. The plan of care and information given to the woman was not questioned by the midwife on duty, who was a new member of staff. The failure to administer anti-D Ig was identified by laboratory staff who checked the blood refrigerator at 72 hours. The woman was contacted by the community midwife to explain that anti-D Ig was indicated but declined to attend until the routine appointment which would have been 14 days after the PSE. Following further discussion with a haematologist, the woman agreed to come in the next day, 6 days after the PSE to receive anti-D Ig.

Knowledge gaps among staff about the need for anti-D Ig and the relevance of timing contribute to error. This case additionally highlights the importance of clear communication between all staff involved in the care pathway. Using closed loop communication, or a check-back could have ensured that the healthcare professionals accurately understood the appropriate plan of care, without assumptions being made. Open discussions and providing written information support informed and shared decision-making.

Learning points

- Working together: laboratory, gynaecology, maternity services, Trusts, Health Boards, and Integrated Care Boards should collaborate to ensure that processes and systems, including IT, are optimised to support safe practice and reduce the risk of error
- Informed decision-making: women and birthing people should be provided with the information they need to make informed choices about their care

Case 8.3: D-negative mother of D-negative baby erroneously given anti-D Ig

A woman with a predicted D-negative fetus had a PSE. Anti-D Ig was issued despite the cffDNA result being available. Following birth an order was placed in the clinical computer system for a Kleihauer, cord bloods and anti-D Ig. The system flagged a warning stating the fetus was D-negative and asking if anti-D Ig was required. The midwife on duty instructed a registered nurse caring for the woman to administer anti-D Ig. The anti-D Ig that had been issued for the antenatal PSE was used. Neither healthcare professional had noted the earlier error or heeded the warning on the IT system.

This case highlights how warning messages can be overlooked and overridden. It is not clear if the person administering the anti-D Ig had observed the system warning or had reviewed the woman's notes before administering anti-D Ig. This would have given another opportunity for the earlier error and warning message to be recognised.

The woman accepted the anti-D Ig, which underlines the importance of birthing parents and their support people understanding all aspects of their care, to enable them to make informed decisions.

Case 8.4: Unfamiliarity with managing large FMH and misinterpretation of instruction

A large FMH of 44mL was detected following birth and 1500IU anti-D Ig was given in the first instance. Upon confirmation of the FMH volume by the reference laboratory, 6500IU was advised, to be given intravenously (IV). The staff were not familiar with administering anti-D Ig IV and did not escalate this. The midwife misinterpreted the instruction to give anti-D Ig within 72 hours, as to give after 72 hours, and placed the anti-D Ig in the ward refrigerator which was not temperature controlled. The midwife documented their interpretation into the electronic patient record, and this was copied and pasted in the record across multiple shifts by other staff. The error was detected by the charge nurse after finding the anti-D Ig in the ward refrigerator, more than 72 hours after it was due to have been administered. Consultation with the reference laboratory led to a reduced dose being administered IV, after the 72-hour window had elapsed.

This case highlights the importance of a clear escalation pathway when uncommon events occur and the need for effective communication. The practice of cutting and pasting instructions in an electronic record allows incorrect decisions and misunderstanding to be perpetuated, without question. Collaboration between departments, including the laboratory and haematology staff can facilitate specialist advice as appropriate.

Near miss anti-D Ig cases n=40

There were 40 near miss cases analysed in 2024, which is similar to the numbers in 2023 (n=41). Errors were detected by laboratory staff in 8/40 (20.0%) cases, by a registered nurse or midwife in 27/40 (67.5%) and a transfusion practitioner in 3/40 (7.5%). In 2 cases, the error was detected by the woman/birthing person.

Conclusion

Errors related to anti-D Ig continue to be reported, with numbers similar to previous years despite implementation of cffDNA screening and targeted administration. SHOT has previously recommended that safe and appropriate management of anti-D Ig requires a collaborative approach with clear communication between the laboratory and other services, including maternity and gynaecology. Considering a systems approach, including application of human factors and ergonomics principles

enables implementation of barriers to error at each step in the process and enhances safety (Narayan, et al., 2024). Organisations are replacing current IT systems and implementing electronic patient record systems to better support safe practice. It is important to remember that IT systems need to be configured, maintained and used correctly to optimise benefit. Interoperability must consider all safety aspects of the system; results must file into the relevant data fields for algorithms to work without the need for additional manual transcription. IT does not replace staff knowledge, training remains key to safe practice, induction training and refresher training is critical as processes may be different across organisations.

D-negative mothers/birthing parents, or their carers, should be provided with clear information about anti-D Ig, including the risks of missing routine appointments. Every effort should be made to offer opportunities for women/birthing people to actively participate in their care. Discharge checklists should include confirmation that anti-D Ig has been administered. Reports related to anti-D Ig consistently account for a high proportion of errors reported to SHOT. SHOT provide resources to support safe practice and improvements which are all free to access on the SHOT website. Organisations are encouraged to use the available resources to build effective systems and support best practice in anti-D Ig management.

Recommended resources

SHOT Safety Notice 03: Safe, appropriate, and timely administration of anti-D Immunoglobulin during the perinatal period
https://www.shotuk.org/resources/current-resources/safety-notices/

Anti-D Immunoglobulin (Ig) Administration to avoid sensitisation in pregnancy - an aide memoire SHOT 2023
https://www.shotuk.org/resources/anti-d-immunoglobulin-ig-administration-in-pregnancy-an-aide-memoire/

The United Kingdom and Ireland Blood Transfusion Network (UKIBTN) patient information leaflet Anti-D immunoglobulin during pregnancy
https://hospital.blood.co.uk/the-update/a-new-patient-information-leaflet-anti-d-immunoglobulin-during-pregnancy/

Incorrect Blood Component Transfused (IBCT) n=359

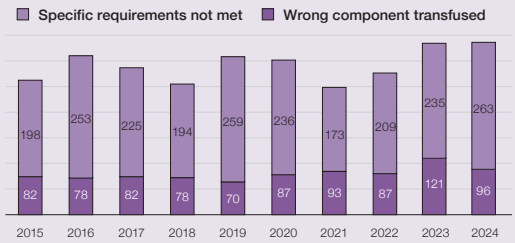
9

Authors: Nicola Swarbrick and Victoria Tuckley

Headline data 2024

Number of reports n=359
Deaths n=0
Major morbidity n=2

IBCT reports by year



Demographic data

Male n=170
Female n=186
Unknown n=3

Adults n=309
Paediatric n=48
Unknown n=2

Blood component data

Red cells n=290
Platelets n=42
Fresh frozen plasma (FFP) n=8
Solvent-detergent FFP n=4
Cryoprecipitate=2
Multiple components n=13

Key findings:

- Clinical errors at the request step have led to an increased number of missed specific requirements
- ABO-incompatible (ABOi) plasma component transfusions continue to be reported
- ABOi red cell transfusions have reduced
- Errors where transfusions are administered to the wrong patient persist
- Laboratories issuing D-positive blood components to D-negative patients in error, and not meeting transplant grouping requirements, continue to be of concern

Gaps identified:

- Transfusion request, collection and administration steps in the clinical area
- Testing and component selection steps in transfusion laboratories
- Issues with communication, staffing, skills, training, recruitment, lone working
- Overriding information technology (IT) alerts inappropriately and lack of IT functionality
- Deficiencies in and lack of effective use of checklists

Good practice:

- Pre-administration checklists, when used appropriately, have prevented many transfusion errors and potential patient harm
- Implementation of a laboratory exit check is increasing

Next steps:

- Review IT system alerts – they must be current, clear and actionable
- Ensure staffing numbers and skill mix are accurately reflected in capacity plans to allow safe completion of tasks
- Include the consequences of not meeting specific requirements in staff training
- Review and improve communication processes between teams to enhance safety

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

Wrong component transfused (WCT)

Where a patient was transfused with a blood component of an incorrect blood group, or which was intended for another patient and was incompatible with the recipient, which was intended for another recipient but happened to be compatible with the recipient, or which was other than that prescribed e.g., platelets instead of red cells.

Specific requirements not met (SRNM)

Where a patient was transfused with a blood component that did not meet their specific requirements, for example irradiated components, human leucocyte antigen (HLA)-matched platelets when indicated, antigen-negative red cell units for a patient with known antibodies, red cells of extended phenotype for a patient with a specific clinical condition (e.g., haemoglobinopathy), or a component with a neonatal specification where indicated. (This does not include cases where a clinical decision was taken to knowingly transfuse components not meeting the specification in view of clinical urgency).

Introduction

IBCT events have the potential to lead to serious patient harm including major morbidity and death, as seen in serial Annual SHOT Reports. These errors accounted for 359/3998 (9.0%) reports in 2024, which is similar to the previous year's data. The total number of IBCT-WCT reports has decreased in 2024 to 96/359 (26.7%) from 121/356 (34.0%) in 2023, with a continued increase in the number of IBCT-SRNM reports to 263/359 (73.3%) from 235/356 (66.0%) in 2023. Figure 9.1 provides an overview of reports submitted to SHOT in 2024 where an incorrect blood component was transfused, and Figure 9.2 outlines the step in the transfusion process where the error occurred.

Figure 9.1: Overview of reports where an incorrect blood component was transfused in 2024 (n=359)

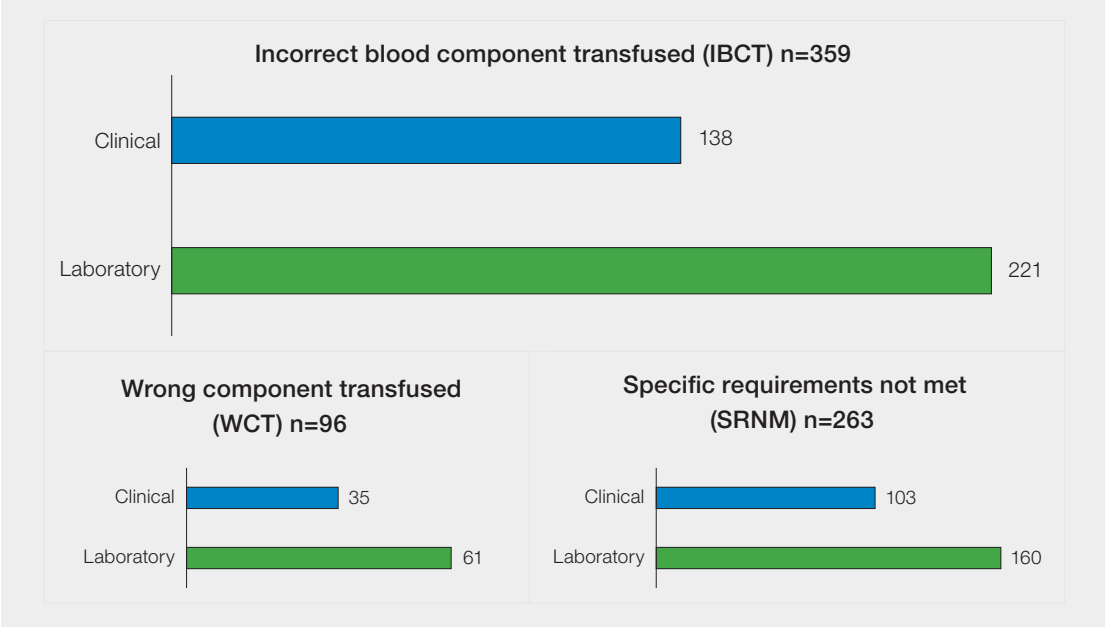
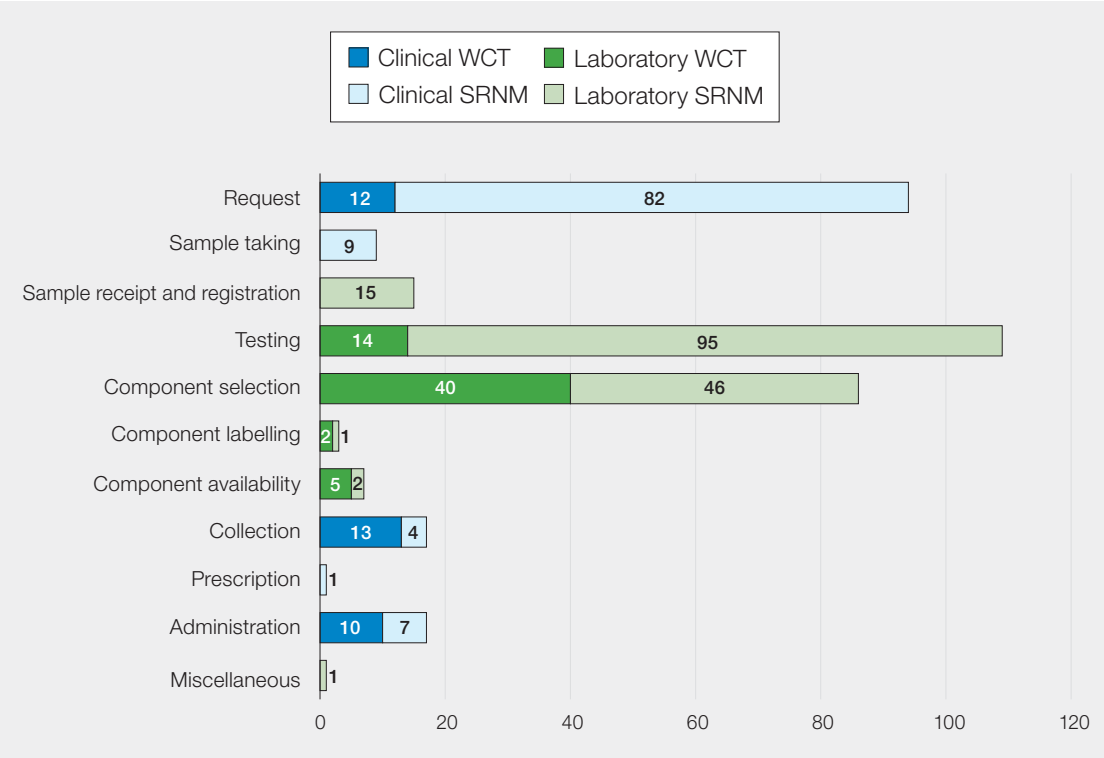


Figure 9.2: Total IBCT errors in 2024 categorised by the step in the transfusion process where the primary error occurred (n=359)



WCT=wrong component transfused; SRNM=specific requirements not met

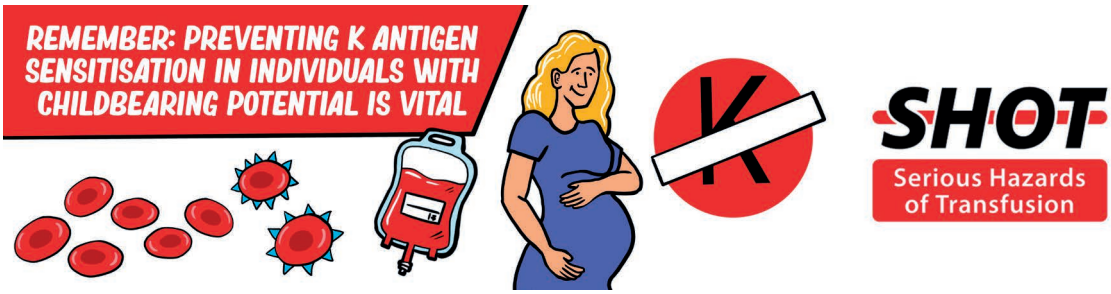
Deaths related to transfusion n=0

There were no deaths related to transfusion in the IBCT category.

Major morbidity n=2

There was 1 case of major morbidity due to a clinical administration error which resulted in a D-negative female receiving two units of D-positive red cells as an emergency in theatre. The patient required an exchange transfusion and intensive care monitoring post transfusion.

The 2nd case of major morbidity occurred following a laboratory component selection error which resulted in sensitisation to the K antigen in a patient of childbearing potential.



ABO-incompatible (ABOi) transfusions n=4

There was 1 red cell and 3 plasma (2 FFP and 1 solvent detergent FFP) ABOi transfusions in 2024. The red cell ABOi transfusion was due to a clinical administration error with the unit being connected to the wrong patient. The plasma ABOi transfusions were due to component selection errors in the laboratory resulting in group O plasma being issued to non-group O patients. All these cases were related to adult patients. Key points of these cases are covered in Table 9.1.

Table 9.1: ABOi transfusions reported in 2024 (n=4)

Case number	Case 1	Case 2
Component transfused	Red cells 	FFP 
Patient group	O D-positive	A D-positive
Unit group	A D-negative	O
Volume transfused	0mL*	2 units
Primary error	Administration (Clinical)	Component selection (Laboratory)
Error detection	Administration, using checklist	When laboratory staff realised error
Patient impact	No reaction	No reaction
Urgency	Routine	Emergency
MHP	No	Yes
Department	Ward	Emergency department
Administration checklist used	Yes - electronic	Yes - electronic
How many check	2-person check not completed	2-person check
Laboratory exit check in place	Not applicable	Yes
ID band in place	Yes	Yes
Did IT contribute?	Yes - nurse 1 had scanned unit using electronic system, and nurse 2 did not recheck unit	Yes - LIMS alert overridden
Details	Nurse helping out over break, attached a unit to the wrong patient. Trainee nurse was observing. Occurred at handover for staff break time	BMS 2 offered to get FFP out of freezer to help during MHP activation, but was told the wrong ABO group by BMS 1

Case number	Case 3	Case 4
Component transfused	FFP 	Octaplas (SD-FFP) 
Patient group	A D-positive	B D-positive
Unit group	O	O
Volume transfused	8 units	1 unit
Primary error	Component selection (Laboratory)	Component selection (Laboratory)
Error detection	When laboratory staff realised error	Administration
Patient impact	No reaction	No reaction
Urgency	Emergency	Routine
MHP	Yes	No
Department	Emergency department	Intensive care unit
Administration checklist used	Yes - paper	Yes - paper
How many check	1-person check	Not stated
Laboratory exit check in place	Yes	No

ID band in place	Yes	Yes
Did IT contribute?	Yes - LIMS notes not actioned. Lack of functionality within LIMS to stop O FFP to undetermined group. LIMS required an authorised group to issue blood components	Yes - there were no LIMS ABO-compatibility tables available for Octaplas
Details	Undetermined ABO/D group due to emergency stock use. Distractions in the laboratory due to issue refrigerator out of action. BMS had worked overtime due to staff sickness	Plasma exchange requiring large volumes of Octaplas with three units of incorrect ABO Octaplas thawed and issued

**The red cell unit was attached to the patient, but administration not started. Case included here as per SHOT definitions*

The data indicates that the weak points in the transfusion pathway leading to ABOi transfusions are administration in the clinical area and component selection in the transfusion laboratory. Appropriate compatibility rules in the laboratory information management system (LIMS) could have prevented all the laboratory ABOi events. There should be clear IT compatibility rules within the LIMS for plasma issue which includes patients with unknown and undetermined ABO/D blood groups. Accurate patient identification is essential at every step of the transfusion pathway. Safety critical steps in the transfusion pathway identified in SHOT data has been outlined by Swarbrick, et al. (2024), and included sample taking, component collection, and administration in the clinical area, and component selection in the transfusion laboratory.

Clinical IBCT errors n=138

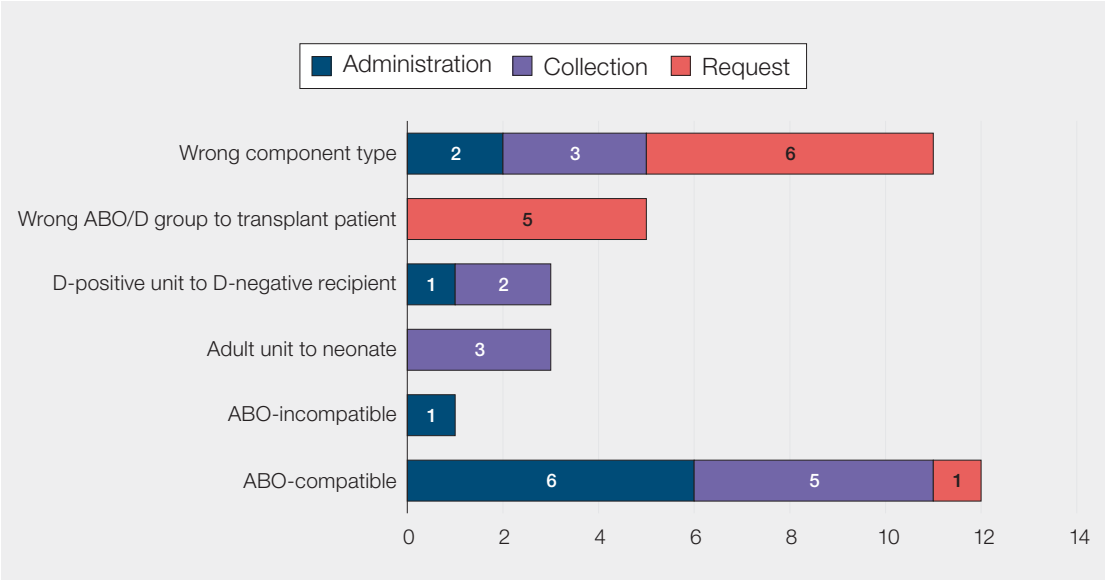
Of the 359 IBCT cases reported to SHOT in 2024, 138 were due to errors in the clinical area (38.4%), which is an increase from 129/356 (36.2%) in 2023.

Clinical IBCT-WCT errors n=35

There has been a decrease in clinical errors reported from 50 in 2023 to 35 in 2024. Of these, 14/35 (40.0%) were transfusions to the wrong patient, 14/35 (40.0%) were the wrong component type and 7/35 (20.0%) were the wrong blood group.

When considering the transfusion pathway, certain steps stand out as more prone to errors, necessitating greater attention due to their safety-critical nature. Clinical steps in the transfusion process that were most prone to IBCT-WCT errors were collection, 13/35 (37.1%), transfusion request, 12/35 (34.3%) and administration, 10/35 (28.6%) (Figure 9.3). One administration error led to an ABOi transfusion and 1 to major morbidity requiring an exchange transfusion.

Figure 9.3: Clinical IBCT-WCT errors and transfusion step where the error occurred in 2024 (n=35)



Of the clinical IBCT-WCT errors, 17/35 (48.6%) were routine transfusions and 17/35 (48.6%) either urgent or emergency transfusions. In 1 case, the urgency of transfusion was not specified. Most transfusions, 26/35 (74.3%) occurred between 08:00 and 20:00.

Pre-administration checklists were used in 19 events yet failed to detect the error. This was mainly due to the checklist not requiring staff to check the prescription, therefore prescribing errors were not identified.

Case 9.1: Multiple errors during major haemorrhage led to a wrong blood transfusion

A major haemorrhage protocol was activated for patient A in the emergency department (ED) with a suspected ruptured abdominal aortic aneurysm. Two units of emergency O D-negative red cell units were administered appropriately. A further six red cell units were issued under the name 'unknown, unknown' and placed in the ED blood refrigerator. A group and screen sample was sent to the transfusion laboratory but rejected due to an incorrect hospital number. The electronic blood management system (EBMS) alerted laboratory staff that the ED blood refrigerator had been accessed using the emergency function. It was evident that none of the blood components allocated for patient A were removed. This prompted laboratory staff to contact the ED where they identified that two units for patient B had been removed without being scanned and administered to patient A. Both patients were group O D-positive. The patient's death was not related to transfusion.

Multiple factors were identified as having contributed to this event. It became apparent that one unit of red cells had burst whilst using the rapid infusion set, causing the team to panic, which contributed to staff not following the pre-administration checklist appropriately. The local investigation identified that staff had not received sufficient training to use the rapid infusers. The patient deteriorated quickly and there was a lack of leadership to delegate tasks and manage the situation effectively. There had been lapses in local e-learning transfusion training, which may have impacted on the awareness of the importance of accurate patient identification. The local policy was to issue blood components to unknown patients with the name 'unknown, unknown'. As no collection slip had been issued during this emergency, blood components could not be collected from the ED blood refrigerator using the EBMS. This resulted in staff using the emergency function to access the units. The ED staff member collecting the emergency red cell units was also holding the department's bleep and was distracted at the collection step by an additional bleep. Patient B's red cells were no longer required and should have been returned to the laboratory the previous day, but there were insufficient laboratory staff numbers to complete this due to a bank holiday.

In 2018, NHS England issued the Patient Safety Alert: Safer temporary identification criteria for unknown or unidentified patients, using a randomly generated combination of first and second names from an edited phonetic alphabet, to improve patient safety (NHS Improvement, 2018).

Learning points

- Training must be provided to complete transfusion-related tasks safely and competently. Staff will need appropriate refresher training
- Appropriate policies and processes must be in place for managing unknown patients
- Pre-transfusion safety checks are the last chance to pick up any upstream errors. For these to be effective, staff should carry out the appropriate checks even in emergencies

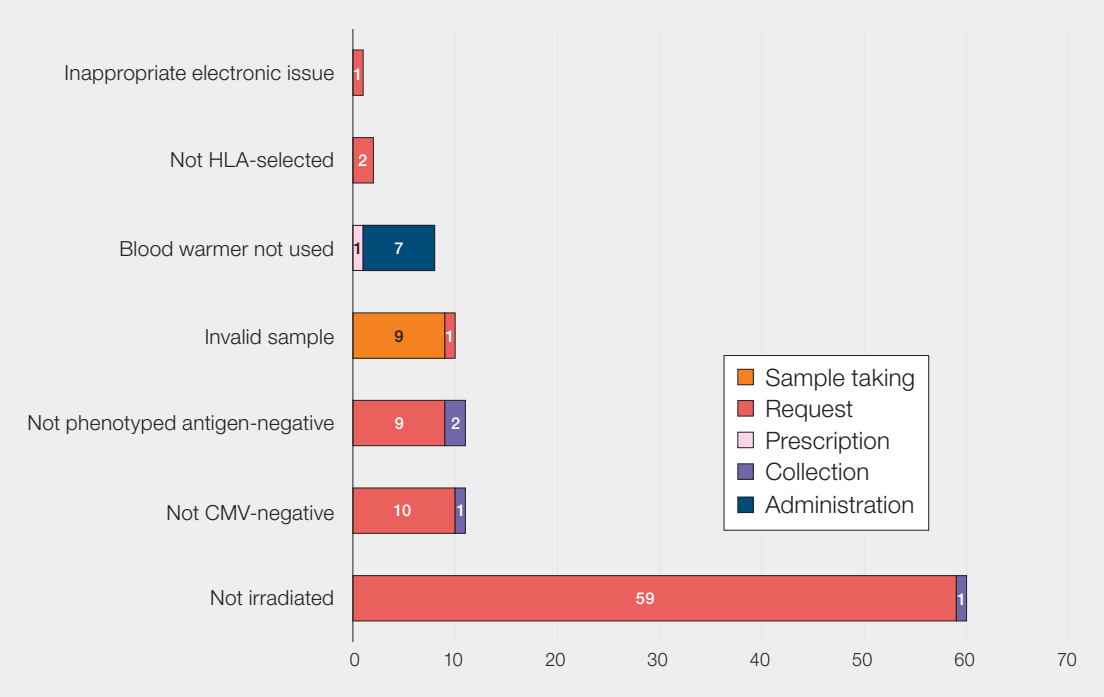
Clinical IBCT-SRNM errors n=103

There has been an increase in the number of clinical errors to 103 in 2024, from 79 in 2023. Of these 60/103 (58.3%) resulted in non-irradiated blood components being transfused, of which 21/60 (35.0%) were to patients with a diagnosis of Hodgkin lymphoma. Clinical errors also resulted in patients not receiving phenotyped units, 11/103 (10.7%); cytomegalovirus (CMV)-negative blood components not issued when required, 11/103 (10.7%); using an invalid sample, 10/103 (9.7%), of which 7 were expired sample tubes; and not using a blood warmer when required, 8/103 (7.8%) (Figure 9.4). Common reasons for these errors included communication issues between clinical and laboratory teams, and shared-care teams. This was compounded by knowledge gaps among staff about the importance of specific transfusion requirements.

Most errors occurred at the request stage of the transfusion pathway, 82/103 (79.6%), where the request to the laboratory did not state the specific requirement.

Pre-administration checklists were used in 76/103 (73.8%) events yet failed to detect the error. Checklists used either did not include the need to check for specific transfusion requirements, or the safety checks were not carried out effectively due to difficulty in accessing the specific requirements for individual patients.

Figure 9.4: Clinical IBCT-SRNM errors and transfusion step where the error occurred in 2024 (n=103)



HLA-human laecocyte antigen; CMV=cytomegalovirus

Case 9.2: Delayed transplant due to communication issues regarding specific transfusion requirements

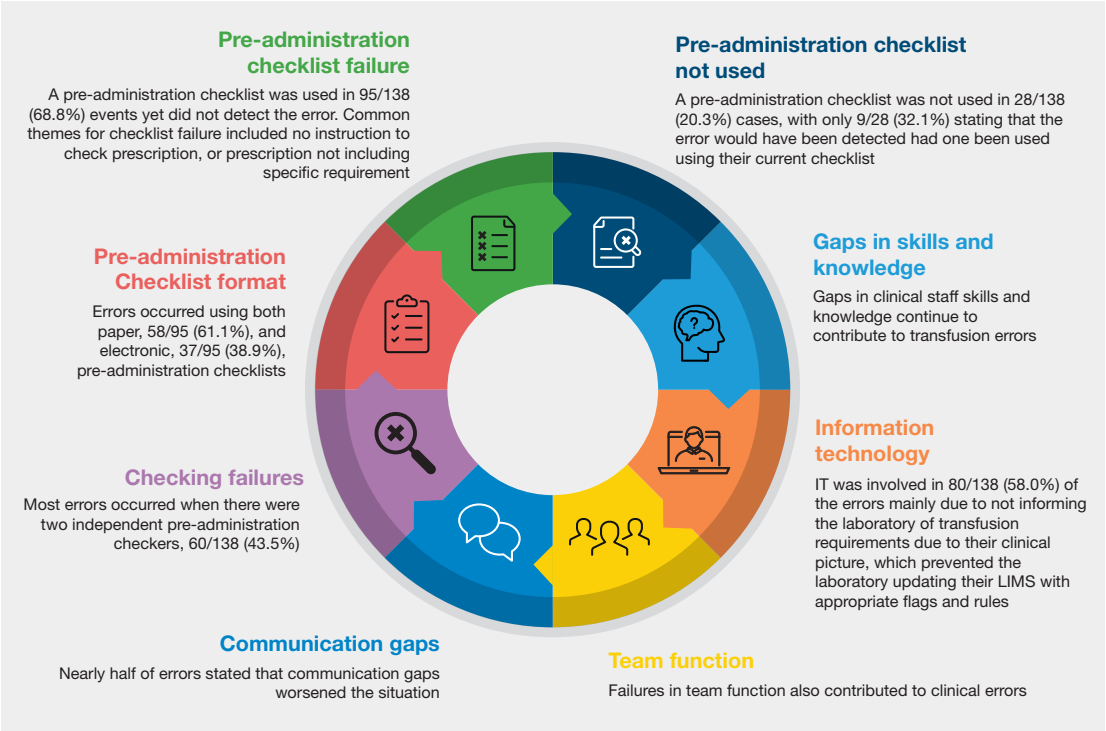
An autologous haemopoietic stem cell transplant (HSCT) harvest was scheduled for a patient with lymphoma, but the clinical area had not informed the transfusion laboratory of the planned harvest. A request was received in the laboratory for one unit of irradiated red cells. The laboratory queried this with the clinical area as this requirement was not previously recorded, but the ward staff stated that the patient did not require irradiated components, and a standard red cell unit was issued. The HSCT harvest was commenced. During the procedure, a nurse completing a blood request order for the patient for the following day queried if the patient now needed irradiated components. The apheresis nurse then realised that a non-irradiated red cell unit had been transfused. The procedure was stopped, and the collected cells were discarded. The harvest was deferred for 3-4 weeks, following which the patient was very upset. The treating team deemed that the delay would be unlikely to change the clinical course in the patient.

Learning points

- Clear communication to all teams involved in the patient's care is essential
- Staff training and competency assessments should include the importance of specific transfusion requirements and the potential clinical impact if these are not met

Causal and contributory factors for IBCT clinical errors

Figure 9.5: Causal and contributory factors for IBCT clinical errors in 2024



Case 9.5: Skill mix gaps and organisational pressures led to wrong blood being transfused

Patient 1 (group B) and patient 2 (group O) both required two red cell unit transfusions postoperatively, with both receiving their first units as required. The day shift had not had sufficient staff numbers to complete required tasks, which resulted in these transfusions being completed during the evening. Due to challenges across the organisation the patient flow co-ordinator arrived on the ward during the night shift to explore whether any staff could be redeployed to other areas. The high workload and acuity of the patients meant that a decision was made to keep all remaining staff on the ward. Although the staffing levels met establishment, there was only one transfusion trained registered nurse, a substantive band 5 nurse and a bank band 5 nurse.

A second unit of red cells arrived on the ward for patient 2. The patient flow co-ordinator who was a registered nurse, offered to help with the transfusion administration as no other trained staff were available on the ward, but their transfusion administration competency had expired. The nurses entered the room of patient 1 in error. Transfusion of one unit of red cells had already been completed, and staff took this unit down and placed it on a tray next to the full red cell unit ready to be administered. Erroneously using the label from the completed red cell unit, the two staff members checked patient identification verbally with the patient, and the patient's identification band. The full red cell unit was transfused but fortuitously, there was no ABO-incompatibility, and no adverse reaction was reported in the patient. The error was only identified when the nurse came to document the unit as transfused. In addition, an initial delay in seeking medical review was evident as staff waited for the patient flow co-ordinator to respond before contacting resident medical staff. This incident was investigated, and improvement actions were undertaken. Learning from the incident was shared across various teams.

Laboratory IBCT errors n=221

The number of laboratory IBCT errors in 2024 was very similar to 2023. 2023 data had shown a marked increase in laboratory IBCT errors, and this remains unchanged. There has been a slight reduction in IBCT-WCT errors from 71 in 2023 to 61 in 2024, which has been offset by a marginal increase in IBCT-SRNM errors from 156 in 2023 to 160 in 2024.

Laboratory IBCT-WCT errors n=61

There were 61 laboratory IBCT-WCT errors, the most common errors occurred at the component selection step, 40/61 (65.6%) and testing step, 14/61 (23.0%) (Figure 9.6).

Figure 9.6: Laboratory IBCT-WCT errors by transfusion step in 2024 (n=61)

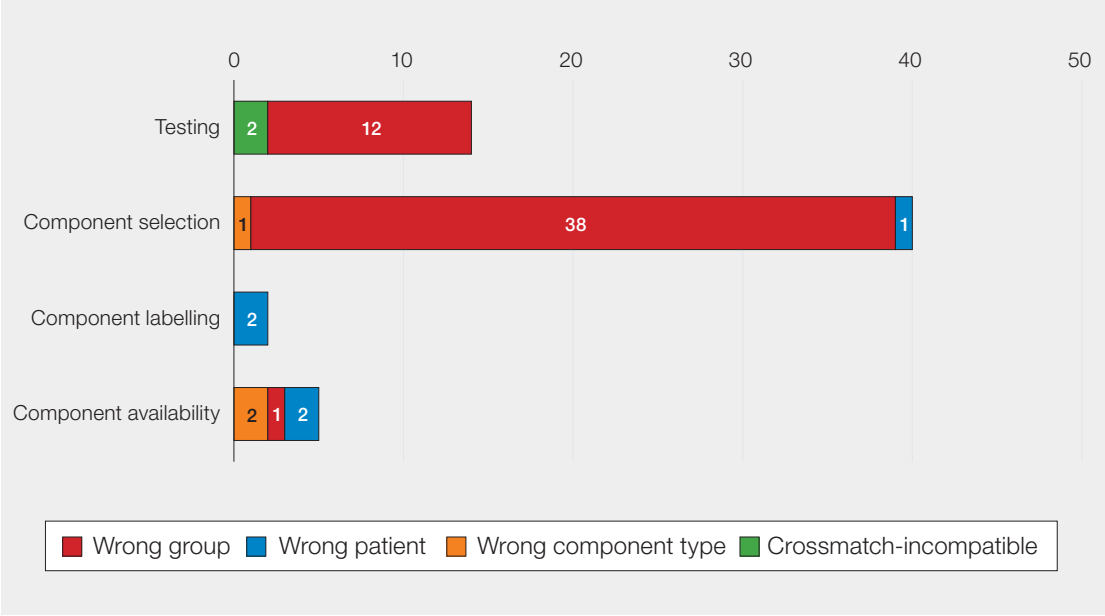
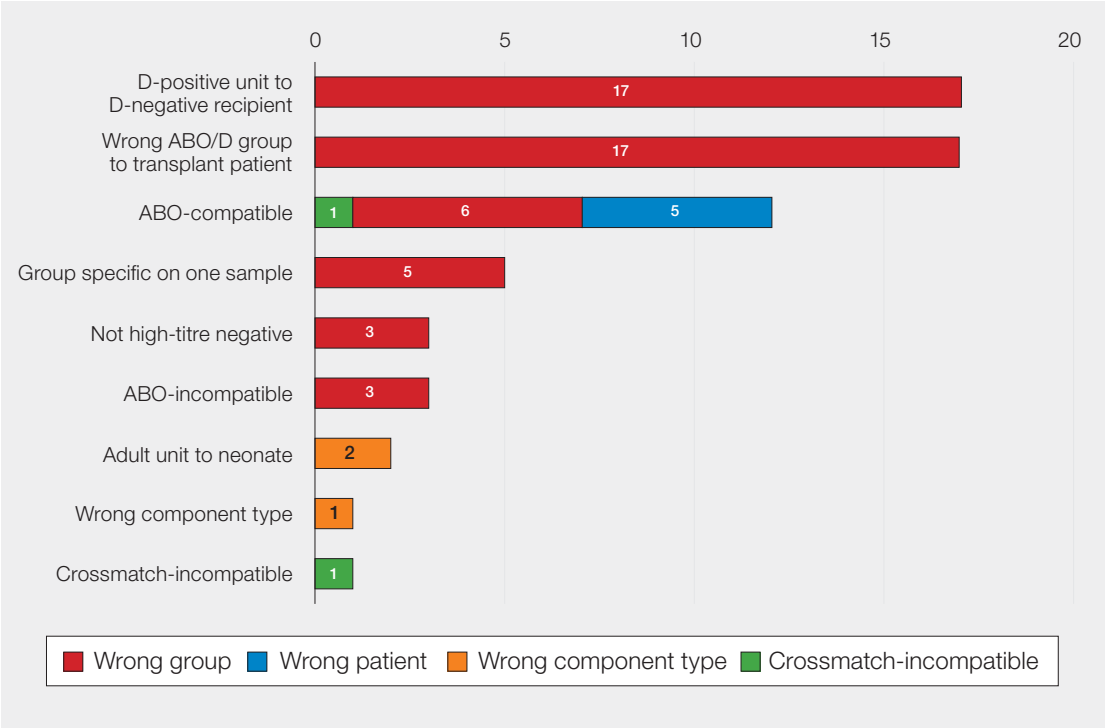


Figure 9.7: Laboratory IBCT-WCT error by category in 2024 (n=61)



Wrong group n=51

Most IBCT-WCT laboratory errors involved wrong group components being issued, 51/61 (83.6%). Of these, 17/51 (33.3%) were D-positive components to D-negative patients, 6/51 (11.8%) involved ABO-compatible transfusions and 3/51 (5.9%) ABOi transfusions. In addition, 17/51 (33.3%) involved incorrect ABO/D components to transplant patients (Figure 9.7). Where the wrong group was issued, 38/51 (74.5%) were due to component selection errors, 12/51 (23.5%) testing errors and 1/51 (2.0%)

availability error. Of the wrong group errors at the component selection step, 33/38 (86.8%) involved IT, of which 13/33 (39.4%) had a LIMS warning flag in place which was not heeded, and 6/33 (18.2%) were due to a lack of LIMS functionality to support safe practice.

Of the 17 cases where a D-positive component was issued to a D-negative patient in error, 11 were due to component selection errors and 6 due to testing errors. Red cells were involved in 13, and platelets in 4 cases. IT was a contributory factor in 13 cases, with 6 involving overriding of LIMS alerts.

Case 9.3: Knowledge gaps in inexperienced staff working alone and overriding IT alerts led to wrong D-group issue

A recently qualified biomedical scientist (BMS) was lone working in the transfusion laboratory over a lunch period when they received a request for one unit of red cells from the ED. The request was for a female patient, less than 50 years old, with chronic haemolytic anaemia and a haemoglobin of 66g/L. The patient was A D-negative with known red cell antibodies (anti-C, -E and -Jk^{a}). An electronic search of red cell stock inventory indicated that there were no suitable units on site. Due to the perceived urgency of the request, the BMS selected partially phenotype-matched D+ C+ E- Jk(a-) red cell units without meeting the C and D requirements. Advice from the haematology consultant was not sought nor was a concessionary release chosen. Two LIMS alerts about issuing D-positive to D-negative and not meeting the patient's phenotype requirement were not heeded. The discrepancy was not detected by the clinical area. There was no reaction reported in the patient.

Several contributory factors were evident in this case: the staff member involved was inexperienced and working alone, the complexity of the case, the clinical area repeatedly telephoned the BMS asking for the red cell units leading to distraction and additional pressure. The report stated that having several new starter BMS staff at the same time had placed an additional training burden on the department but could not be avoided due to previous capacity issues.

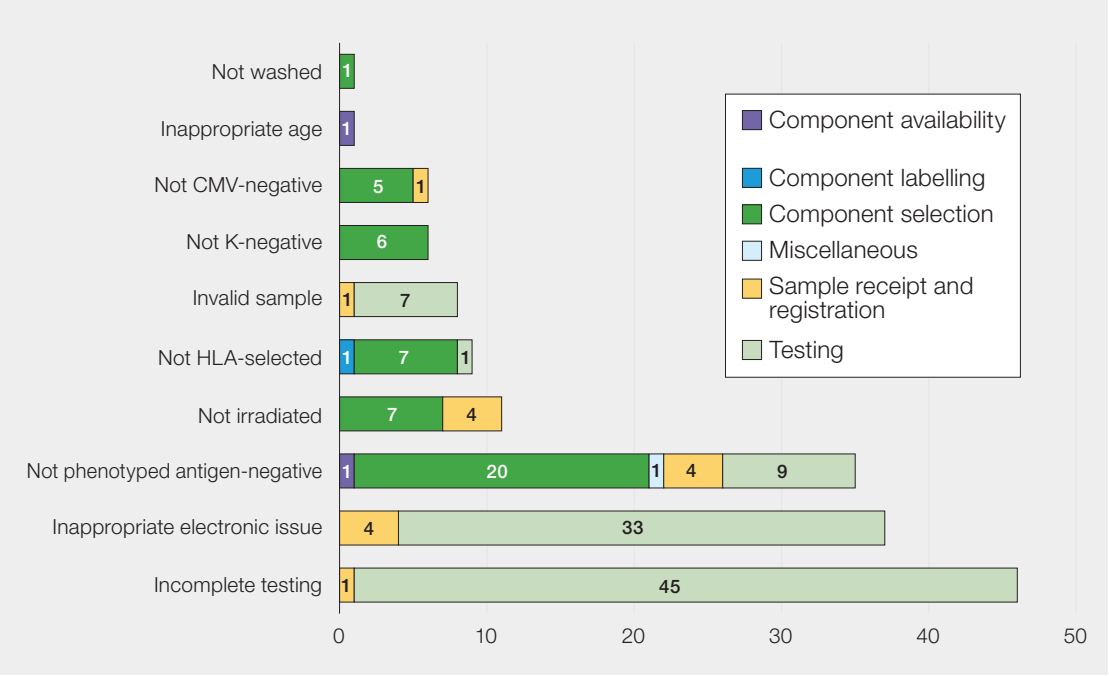
Learning points

- When planning staff rota allocations, it is important to account for the training time required for new starters to ensure adequate support and maintain overall team performance
- Laboratory staff should understand the impact of overriding alerts on LIMS and appropriate justification needs to be recorded
- The laboratory capacity plan should be reviewed regularly for any changes to workload and escalated when necessary for it to be effective
- A laboratory exit checklist can help ensure the correct blood components meeting the patients' requirements are issued. The checklist must be used correctly, reviewed regularly and assessed for effectiveness

Laboratory IBCT-SRNM errors n=160

There were 160 laboratory errors which led to patients receiving blood components that did not meet their specific requirements. Most were due to testing errors, 95/160 (59.4%) and component selection errors, 46/160 (28.8%).

Figure 9.8: Laboratory IBCT-SRNM errors by transfusion step in 2024 (n=160)



HLA-human laecocyte antigen; CMV=cytomegalovirus

Testing errors n=95

Testing errors mainly included issuing blood components when testing was incomplete, 45/95 (47.4%) and inappropriate electronic issue, 33/95 (34.7%). There were 9 testing errors which led to the wrong phenotype being issued. Of the incomplete testing, 21/45 (46.7%) were related to antibody investigations. Other cases included incomplete validation, use of the wrong antigram and failing to crossmatch units.

Case 9.4: BMS expedited to working alone inappropriately due to staffing issues

A BMS 1 who was lone working in blood transfusion over a weekend shift issued two M-negative red cell units to a patient with anti-M. The BMS had not completed testing to exclude anti-S from the antibody identification panels at this point but did not issue S-negative units as per local policy. Further investigation carried out on the following day indicated that anti-S could have been excluded using additional extended panel cells that were available in the laboratory. A fully competent and transfusion trained BMS 2 was available in another department when the event occurred to answer any queries. However, the advice was not sought because it was not deemed necessary. During the event review, the BMS 1's competencies showed gaps in antibody identification, including the relevance of heterozygous and homozygous panel cells, and selection of red cells when a red cell antibody is present. This training need had been identified 6 months previously, but no action had been undertaken to rectify. The responsibility for training junior staff members had recently rotated and may have contributed to this.

From the investigation summary that was submitted with the incident report, it was noted that BMS 1 stated that they had not been signed off as able to perform the task unsupervised. The transfusion laboratory manager had taken responsibility for these training gaps so that they could be expedited on to the shift rota. BMS 1 also said that the red cell units were serologically crossmatch-compatible which, from previous knowledge and experience at another organisation, was deemed to be acceptable practice. It further became evident that other haematology staff were only being trained in transfusion emergency procedures, such as management of major haemorrhage activations, before being allowed on shift. Due to extreme staffing pressures, which had been raised on the local risk register, a corrective action was implemented regarding out-of-hours working. This stipulated that staff will be allowed on the 24/7 shift rota with selected competencies completed, with support of a fully trained staff member being available for queries (who may be working in another department).

Whilst staffing pressures persist, actions undertaken to provide cover for shifts must also include the impact on patient safety. Such a solution may leave vulnerabilities for staff members whose decision-making may be incomplete due to unfinished training. In these circumstances, staff members may not think to seek help as they may not be aware of the full impact of decisions made. Further review of this case showed signals of blame culture prevalent within the team, as the local investigation assigned responsibility of the event to BMS 1. It stated they should not have undertaken tasks they were not signed off on, even though they had been required to participate in lone working without a full competency assessment.

The MHRA Good Practice Guide outlines the requirements of a transfusion laboratory quality system, which includes ensuring that there are adequate number of personnel, with the necessary qualifications and experience, and the importance of maintaining business continuity through an adequate capacity plan (MHRA and Department of Health and Social Care, 2014). The United Kingdom Transfusion Laboratory Collaborative produce minimum standards for transfusion laboratories in the UK, covering staffing levels including capacity planning, qualifications, knowledge and skills required to ensure service provision. Both guidance should be considered when determining capacity requirements for laboratories and quality management systems (SHOT, 2025a).

Component selection errors n=46

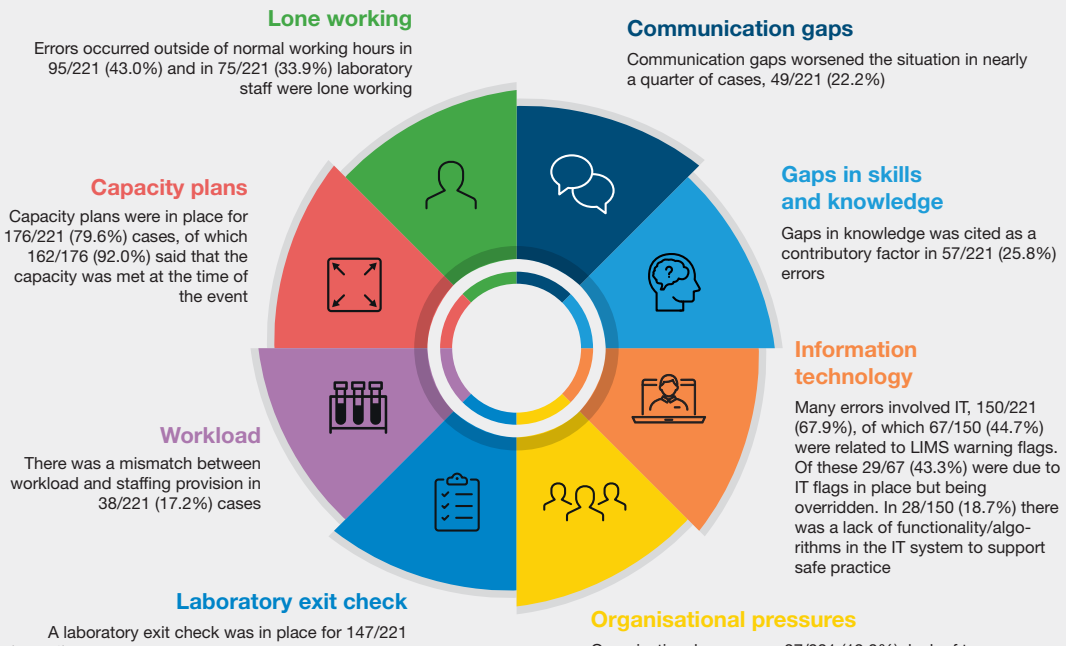
Component selection errors included not meeting the required phenotype, 20/46 (43.5%), not irradiated, 7/46 (15.2%), not HLA-selected, 7/46 (15.2%) and K-positive units to patients of childbearing potential, 6/46 (13.0%).

Learning points

- Laboratory staff working alone must be competency assessed and deemed competent to carry out all required tasks prior to working alone
- Competency should include aspects of theoretical practical assessments, including antibody identification and subsequent component selection and testing

Causal and contributory factors for IBCT laboratory errors

Figure 9.9: Causal and contributory factors to IBCT laboratory errors in 2024



Near miss (NM) IBCT errors n=196

In 2024, there were 196 NM IBCT events due to 93 clinical and 103 laboratory errors.

Near miss IBCT-WCT n=135 (76 clinical and 59 laboratory)

Clinical errors mainly occurred at the collection, 50/76 (65.8%), administration, 13/76 (17.1%) and request, 12/76 (15.8%) steps. Of these, 60/76 (78.9%) involved potential transfusion to the wrong patient.

Laboratory errors mainly occurred at component labelling, 22/59 (37.3%) and component selection, 17/59 (28.8%) steps. Of these, 29/59 (49.2%) involved potential transfusion to the wrong patient and 25/59 (42.4%) potential transfusions of the wrong group.

Most errors were detected at the pre-administration stage, 89/135 (65.9%) with 68/89 (76.4%) detected using a pre-administration checklist.

Near miss IBCT-SRNM n=61 (17 clinical and 44 laboratory)

Clinical errors mainly occurred at the request step, 15/17 (88.2%), and 13/17 (76.5%) involved potential transfusion of non-irradiated blood components.

Laboratory errors mainly occurred at the component selection step, 32/44 (72.7%). Error types included potential transfusion of non-irradiated blood components, 26/44 (59.1%) and 7/44 (15.9%) of which were not CMV-negative.

Most errors were detected at the pre-administration stage, 43/61 (70.5%) with 36/43 (83.7%) detected using a pre-administration checklist.

Conclusion

Effective patient safety checks are shown to detect discrepancies and prevent transfusion errors (CMO Messaging, 2017). In 2024, pre-administration checks prevented 62 transfusions to the wrong patient, 15 transfusions of the wrong group and 11 transfusions of the wrong component. Included in these numbers were 12 ABOi and 50 ABO-compatible transfusions. Additionally, transfusions of 31 standard components when irradiated units were required were prevented due to pre-administration checks. Conversely, nearly 70% of IBCT errors in the clinical area occurred even though a pre-administration checklist was in place but not used effectively. A laboratory exit check was used in nearly 70% of laboratory errors yet failed to detect the error. This stresses the need for pre-administration checklists to be thorough and used effectively. They should be reviewed regularly for gaps especially after an error or near miss event. These safety checks should not be a tick-box exercise, with their importance and impact on patient safety included in competency assessments. Checklists ensure consistency, efficiency, accountability and give guidance for training and competency, which in turn improves transfusion safety.

Gaps in communication between clinical areas and the laboratory in relation to patient clinical diagnoses or treatments requiring specific blood requirements continue to put patients at risk. Human factors such as multitasking, insufficient staff numbers or skill mix, poor communication, and lack of clear escalation processes also impact on communication. Non-technical skills training should include communication techniques such as the probe, alert, challenge and escalate (PACE) model to improve patient safety (Narayan, et al., 2023)

Laboratory IBCT errors have remained high after their dramatic increase in numbers in 2023. Component selection and testing errors, in particular, the blood components being issued when testing was not complete or inappropriate electronic issue continue to be areas of concern. Basic errors such as issuing of D-positive red cells to D-negative patients have increased, highlighting warning signs that suboptimal staff knowledge or overreliance on IT alerts to identify discrepancies is leading to errors.

All laboratories should have a capacity plan in place (SHOT, 2025a). Most (~80%) laboratories reported that they have a capacity plan in place and stated their staffing levels met this plan at the time of error. However, 20% of these reporters identified that there was a mismatch between workload and staffing provision. This highlights the importance of regularly reviewing the capacity plan, identifying, and raising awareness of gaps in staffing to meet requirements. Staff working out-of-hours or lone working should

be sufficiently trained and there must be protective measures in place for lone-working staff including risk assessments of tasks, regular reviews with feedback loops, availability of out-of-hours advice or support, clearly defined standard operating policies and sufficient training and competency to equip staff to work alone. Recruitment and retention issues and staff being expedited onto shifts prior to completion of necessary competency are also mentioned in reports.

Gaps in knowledge and skills within both clinical and laboratory staff groups continue to contribute to IBCT errors and patient harm. Training and competency should be reviewed for gaps and updated accordingly. The National Blood Transfusion Committee (NBTC) Transfusion Training Hub (see 'Recommended resources') has been created to support education and training for all healthcare professionals working within blood transfusion, covering a wide variety of transfusion related topics, at a variety of knowledge levels, and should be utilised to bridge these gaps. Most reports stated that staff were deemed competent for the task they were undertaking, yet errors continue to occur highlighting the need for continued refresher training and review content of competency assessments to check if they are fit for purpose.

Suboptimal use of safety features in transfusion IT systems continue to contribute to errors. In addition, errors occur when staff inappropriately override the safety feature/s. Lack of interoperability between IT systems continues to impact on transfusion safety. Teams should review existing IT systems, liaising with suppliers to maximise the potential of incumbent systems to improve transfusion safety and transfusion processes.

Recommended resources

Good practice guidance document for managing indeterminate ABO blood groups to support safe decision-making
https://www.shotuk.org/resources/good-practice-guidance-document-for-managing-indeterminate-abo-blood-groups-to-support-safe-decision-making/

NBTC Transfusion Training Hub
https://nationalbloodtransfusion.co.uk/transfusion-training-hub

Handling and Storage Errors (HSE) n=311

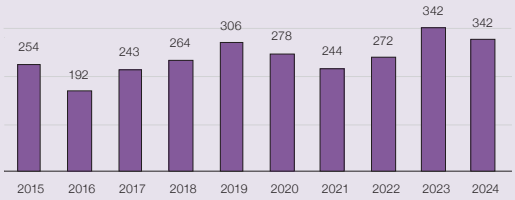
10

Authors: Heather Clarke, Nicola Swarbrick and Victoria Tuckley

Headline data 2024

Number of reports n=311
Deaths n=0
Major morbidity n=0

HSE reports by year



Demographic data

Male n=154
Female n=152
Unknown n=5

Adults n=289
Paediatric n=20
Unknown n=2

Blood component data

Red cells n=247
Platelets n=31
Fresh frozen plasma (FFP) n=18
Cryoprecipitate n=7
Multiple components n=8

Key findings:

- Recurring error patterns in clinical and laboratory areas remain consistent with those observed in previous years
- Most clinical errors were technical administration errors and excessive time to transfuse
- Cold chain errors accounted for most of the laboratory HSE

Gaps identified:

- Mismatch between workload and staffing in the clinical area and the laboratory
- Inadequate training and gaps in competency assessments resulting in deficiencies in staff knowledge
- Inadequate equipment monitoring during transfusion with staff failing to notice or respond effectively to alerts within electronic blood management systems

Good practice:

- Near miss errors showed that cold chain errors and expired blood components are being identified in the pre-administration stage

Next steps:

- Review policies and procedures to ensure a check for transfusion administration rate is included
- The transfusion end time must be communicated during handover to staff caring for the patient
- Use of pumps for transfusions should be included in transfusion training programmes
- Blood giving sets should be clearly distinguishable from all other giving sets

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

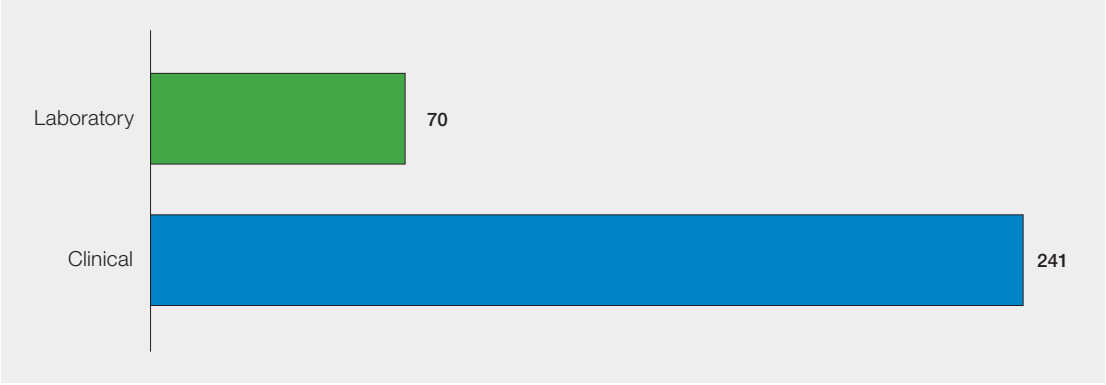
Definition:

All reported episodes in which a patient was transfused with a blood component or plasma product intended for the patient, but in which, during the transfusion process, the handling and storage may have rendered the component less safe for transfusion.

Introduction

There was a decrease in errors reported from 342 in 2023 to 311 in 2024. HSE accounted for 311/3998 (7.8%) errors in 2024 compared with 342/3833 (8.9%) in 2023. The variation between clinical errors, 241/311 (77.5%), and laboratory errors, 70/311 (22.5%), is illustrated in Figure 10.1 and reports are broken down by HSE category in Figures 10.2 and 10.3.

Figure 10.1: Breakdown of 2024 handling and storage error (HSE) reports (n=311)



There continues to be a mismatch between workload and staffing in both the clinical and laboratory areas. Data highlights that even though staff are trained, and competency assessed, similar trends continue. Inadequate training resulting in gaps in knowledge is once again seen in this Annual SHOT Report.

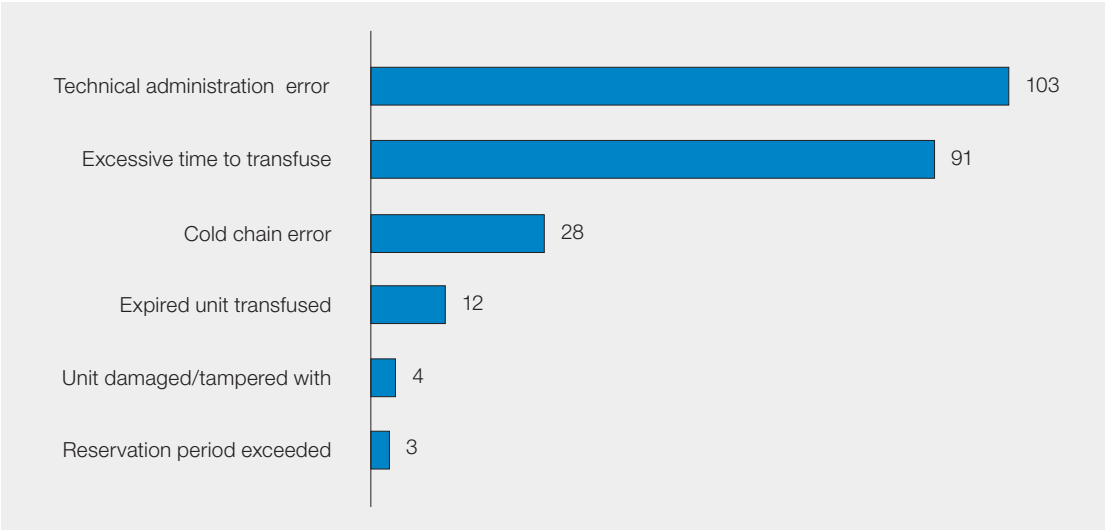
Deaths or major morbidity related to transfusion n=0

There were no deaths or major morbidity cases associated with HSE in 2024.

Clinical HSE n=241

The number of clinical errors has seen a slight fall (from 259 in 2023 to 241 in 2024) and there has been a decrease in technical administration errors, 103/241 (42.7%) in 2024 compared to 118/259 (45.6%) in 2023.

Figure 10.2: Breakdown of clinical HSE by category in 2024 (n=241)



Technical administration errors have been further categorised in Table 10.1.

Table 10.1: Clinical technical administration errors in 2024 (n=103)

Technical administration error	Number of cases
Pump programming error	72
Errors or defects with giving sets	24
Miscellaneous	2
Concurrent administration of IV fluids using the same venous access as blood administration	2
Manual drip rate incorrect	1
Prescribed too fast	1
No information provided	1
Total	**103**

There were 72 administration pump errors, 64/72 (88.9%) had a correct prescription but the pump had been set incorrectly. Of these, 11/64 (17.2%) stated that setting up of the pump was not included on the pre-administration checklist. There were 24/103 (23.3%) errors related to giving sets, this was a decrease from 39/118 (33.1%) reported in 2023. Of the 24 reported, 20 were due to the incorrect giving set being used.

Of the 91 excessive time to transfuse errors reported, 49/91 (53.9%) occurred within routine hours, 41/91 (45.1%) outside routine hours, and in 1 case the timing was not stated. There were 5/91 (5.5%) classified as an emergency transfusion, 29/91 (31.9%) as urgent, 49/91 (53.8%) were routine transfusions, and in 8/91 (8.8%) the priority was unknown or not stated.

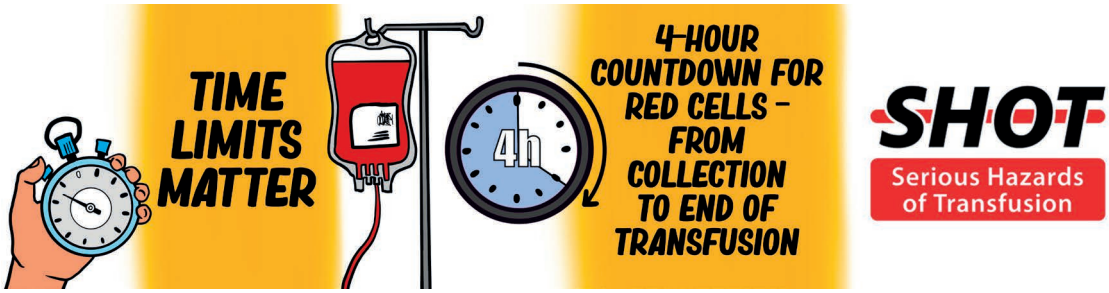
Case 10.1: Transfusion in progress for 7 hours 10 minutes

A unit of red cells was collected from the blood refrigerator at 13:02 and the transfusion was commenced at 13:09. After handover from the day shift to the night shift, it was realised that the red cell unit was being transfused for over 7 hours. The alarm on the pump was sounding, indicating that the bag was empty. The bag was taken down at 20:20.

On investigation there was a mismatch between workload and staffing at the time of the incident and a staff member involved had not fully completed their transfusion training.

Learning points

- Staff transfusion training should include the appropriate use of pumps
- Pump settings should be double checked against the prescription before commencing the transfusion
- Pre-administration checklists should include a check of the pump settings
- Staff handovers should include in progress transfusions and their scheduled finish time



Laboratory errors n=70

The number of laboratory errors have decreased to 70 in 2024 from 83 in 2023 and are broken down by HSE category in Figure 10.3. The majority were cold chain errors, 47/70 (67.1%) which have been further categorised in Table 10.2.

Figure 10.3: Breakdown of laboratory HSE by category in 2024 (n=70)

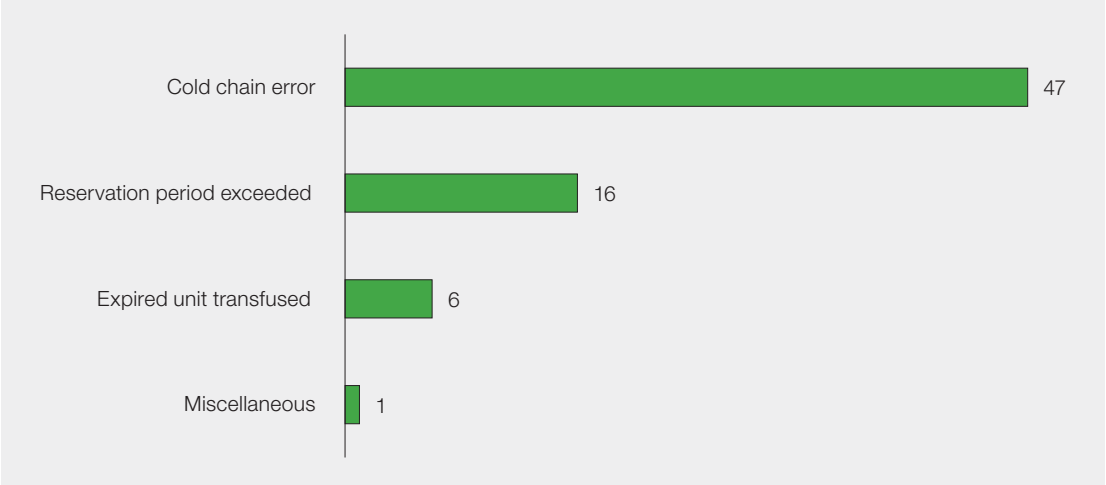


Table 10.2: Laboratory cold chain errors in 2024 (n=47)

Cold chain error	Number of cases
Refrigerator/equipment failure	20
Inappropriate return to stock	10
Incomplete cold chain	8
Transport and delivery	6
Inappropriate storage	3
Total	**47**

Of the 20 refrigerator/equipment failure errors, 15 resulted in the transfusion of a component which was confirmed to be outside of accepted temperature limits. In 5 cases the cold chain could not be confirmed. In 10 inappropriate return to stock errors, 7 resulted in the transfusion of a component which was confirmed to be outside of accepted temperature limits, and in 3 the cold chain could not be confirmed.

Case 10.2: Red cell unit transfused after the blood sample had expired

A unit of red cells remained in the blood issues refrigerator available for collection after the blood sample expiry had passed. A clinical staff member came to collect the unit from the refrigerator and the electronic blood management system (EBMS) alerted that the unit should not be transfused. The laboratory staff member did not understand the alert and continued to release the unit manually and it was then transfused to the patient.

On investigation it was identified that there was no competency assessment for the use of the EBMS and the standard operating procedure (SOP) was also not clear on how to deal with the alerts generated.

Learning points

- Competency assessments for laboratory staff should be reviewed regularly to ensure that they cover all laboratory processes
- Laboratory SOP should be clear and give clear instructions on how to deal with any system alerts/ alarms generated

Near miss n=132

There were 132 HSE near miss events in 2024, including 101/132 (76.5%) clinical errors and 31/132 (23.5%) laboratory errors. Clinical errors were mainly due to cold chain errors, 87/101 (86.1%), where units were stored in inappropriate conditions in the clinical area, 68/87 (78.2%). Laboratory errors were mainly due to expired units issued, 22/31 (71.0%) and 6 cold chain errors.

Conclusion

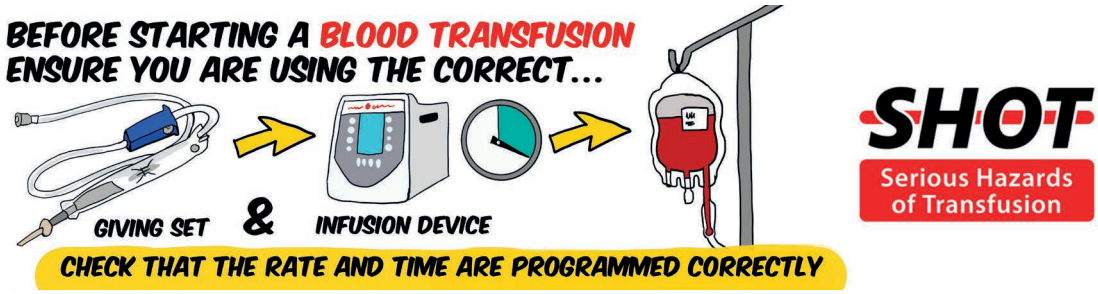
The findings overall remain consistent with previous years' Annual SHOT Reports. Handling and storage errors in transfusion can pose serious risks to patient safety and must be addressed through effective improvement actions. SHOT reinforces the message that all staff who participate in the handling and storage of blood components throughout the transfusion process should adhere to the correct procedures that are outlined in guidelines and their local transfusion policy. Transfusion policies must be based on the most current published guidance available (Robinson, et al., 2018).

Recommended resources

Patient Blood Management - Blood Assist app
Apple (https://apps.apple.com/gb/app/blood-assist/id1550911130)
Google play (https://play.google.com/store/apps/details?id=uk.nhsbt.bloodassist)
Web based (https://www.bloodassist.co.uk/)

NHS Institute for innovation and improvement Safer care SBAR Situation, Background, Assessment and Recommendation implementation and training guide
https://www.england.nhs.uk/improvement-hub/wp-content/uploads/sites/44/2017/11/SBAR-Implementation-and-Training-Guide.pdf

Cautionary Tales: Transfusion of damaged blood components
https://www.shotuk.org/resources/safety-alerts-and-safety-notices/cautionary-tales/



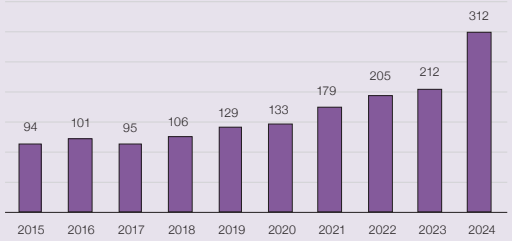
11 Delayed Transfusions n=312

Authors: Josephine McCullagh, Paula Bolton-Maggs and Vera Rosa

Headline data 2024

Number of reports n=312
Deaths n=18
Major morbidity n=12

Delayed transfusion reports by year



Demographic data

Male n=132
Female n=179
Unknown n=1
Adults n=282
Paediatric n=30

Blood component data

Red cells n=214
Platelets n=47
Fresh frozen plasma (FFP) n=9
Cryoprecipitate n=2
Solvent-detergent FFP n=1
Granulocytes n=1
Multiple components n=38

Key findings:

- There was a striking increase in the number of delays particularly in the laboratory
- There was an increase in the number of serious adverse patient outcomes
- Transfusion delays in major haemorrhage (MH) continue to rise

Gaps identified:

- Communication failures were the most frequently cited issue, affecting decision-making, blood component requests, and sample processing
- Lack of training, understaffing, and unfamiliarity with emergency protocols significantly impacted transfusion response times in both clinical and laboratory areas
- Failure to effectively implement major haemorrhage protocols (MHP)
- Many delays resulted from failure to identify and escalate cases early, leading to late transfusion initiation

Good practice:

- Increased levels of recognition of delays and reporting of such events
- Improved staff awareness
- Increasing recognition of causal and contributory factors that can help improve safety

Next steps:

- Ensure recommendations from the Central Alerting System (CAS) patient safety alert: Preventing transfusion delays in bleeding and critically anaemic patients (SHOT/2022/001) are fully implemented

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

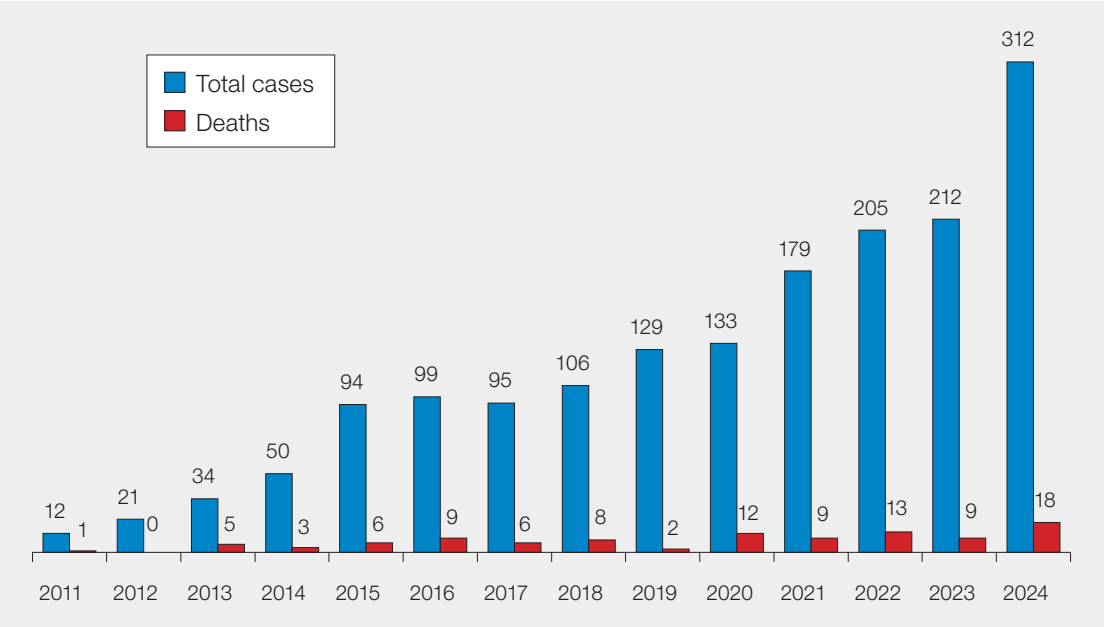
Definition:

Where a transfusion of a blood component was clinically indicated but was not undertaken or non-availability of blood components led to a significant delay (e.g., that caused patient harm, resulted in admission to ward, or return on another occasion for transfusion).

Introduction

Increasing reports of delays prompted the publication of a CAS patient safety alert, with actions for hospitals (SHOT, 2022). The number of delays in transfusion reported to SHOT has further increased (n=312) when compared to previous years (Figure 11.1). The substantial increase in reports and the increase in deaths associated with transfusion delays is alarming and concerning. Delays in transfusion are often not attributed to a single point of failure but are commonly a result of multiple issues that contribute to a delay in care. The key themes identified in previous Annual SHOT Reports such as ineffective communication, delay in the recognition of bleeding and lack of relevant staff knowledge continue to be factors in 2024.

Figure 11.1: Delayed transfusions by year 2011-2024



Deaths related to transfusion n=18

There were 18 deaths reported due to delays: 8 imputability 2 (probable) and 10 imputability 1 (possible). This is a steep increase from 9 deaths related to delays in 2023 and 13 in 2022. The majority (n=15) were associated with delays in urgent or emergency transfusions. Common themes were delays in decision-making and missing vital steps in the transfusion process due to lack of knowledge, training, and poor staffing levels. In 12 cases there were delays in transfusion in patients with acute bleeding.

There were 3 deaths due to laboratory-related errors associated with delays in making blood components available. Lack of knowledge of alternative options in emergency settings was a key theme in these events.

Case 11.1: Delay in provision of alternative blood component contributes to the death of a paediatric patient (imputability 2 – probable)

A neonatal consultant requested platelets for an unwell neonate who was waiting to be transferred to a specialist unit. The urgency of the transfusion was not clearly communicated by the clinical team initially. In addition, the transfusion biomedical scientist (BMS) was not aware of alternative options available.

This case is discussed further in Chapter 17, Laboratory Errors (Case 17.1) and Chapter 25, Paediatric Cases (Case 25.1).

Fifteen deaths were related to clinical errors resulting in avoidable delays, most of these were associated with patients who were actively bleeding (n=9). There were 11 errors at the request stage, 3 at sample taking and 1 at prescription. All incidents were multifaceted, most commonly associated with delay in recognising bleeding, communication failures, and lack of knowledge of local processes.

Case 11.2: Failure to recognise bleeding contributed to the death of a new mother (imputability 1 – possible)

A woman experienced a significant bleed following the birth of her baby. There was a delay in the clinical team recognising the severity of bleeding and escalating care appropriately. This was due to multiple factors including issues with equipment and focus on an alternative diagnosis. The MHP was not activated, delaying appropriate transfusion support. Coagulopathy was not promptly recognised and addressed; fibrinogen replacement was initiated too late to be effective. The patient suffered multiple cardiac arrests, and despite surgical intervention and intensive care, she died a few days after giving birth with disseminated intravascular coagulation.

Maternal deaths from haemorrhage are uncommon. A recent national report on maternity care (MBRRACE-UK, 2024) noted 6.5% deaths were due to maternal haemorrhage (18 of 275) in the period 2020 to 2022, a rate of 0.89 per 100,000 maternities.

Case 11.3: Multiple issues contributed to the delay in transfusion during major haemorrhage (imputability 2 – probable)

A patient with postoperative bleeding failed to receive a timely blood transfusion out-of-hours. There was a 3-hour delay in recognising the severity of bleeding and therefore the MHP was not activated. The initial group and screen (G&S) sample was rejected, and the urgency of the transfusion was not clearly communicated to laboratory staff. The clinical team on the ward were unfamiliar with the management of patients with major bleeding and were not aware of the procedures for accessing emergency blood components. The patient suffered a cardiac arrest and died.

Case 11.4: Assumption resulted in a 10-hour transfusion delay (imputability 2 – probable)

An elderly patient with a gastrointestinal (GI) bleed and a haemoglobin (Hb) of 45g/L was prescribed a unit of red cells. There was a misunderstanding regarding who should request the red cell units from the transfusion laboratory. The prescribing doctor assumed the nurses would request the blood as this was routine practice in the clinical area where they previously worked. Conversely, the nurses assumed the doctor would be requesting the blood as this was routine practice on the current ward. The error was noticed when the doctor reviewed the patient 10 hours later, the Hb had dropped to 38g/L. The patient was transfused one unit of red cells but suffered a cardiac arrest and died.

Major morbidity n=12

Major morbidity was reported in 3 cases associated with delays in the transfusion laboratory in making blood components available. Two of these delays were associated with an urgent need for blood components and occurred during MH.

Case 11.5: Multiple issues during major haemorrhage resulted in avoidable delays in accessing blood components

A patient with a suspected ruptured ectopic pregnancy presented to the emergency department (ED). O D-negative red cells were requested for immediate transfusion, but staff were unable to access units from the blood refrigerator despite multiple attempts. Similar issues occurred when trying to obtain red cells from the theatre and maternity refrigerators. The MHP was activated, but the incorrect obstetric alert was issued, delaying an appropriate response. The patient was transferred to theatre, where blood components were finally administered. The patient had lost 3L of blood and required intensive care unit (ICU) admission. A subsequent investigation revealed that an electronic blood management system upgrade had prevented units from being removed from the blood refrigerator.

Major morbidity was reported in 9 cases associated with delays due to clinical errors in the following processes, blood collection (n=2), sample taking (n=3), requesting components (n=3) and prescribing/

authorisation (n=1). Seven out of the 9 delays were associated with urgent cases in patients who were bleeding.

Case 11.6: Multiple issues and delayed decision-making contributed to a delay in blood component provision during a MH

A patient with significant bleeding required an urgent transfusion, but rejection of multiple samples delayed the provision of crossmatched red cell units. When emergency red cell units were requested, further delays occurred due to problems accessing the remote blood refrigerator. By the time emergency red cell units were obtained, the patient had lost approximately 1000mL of blood, suffered a cardiac arrest and was admitted to the ICU.

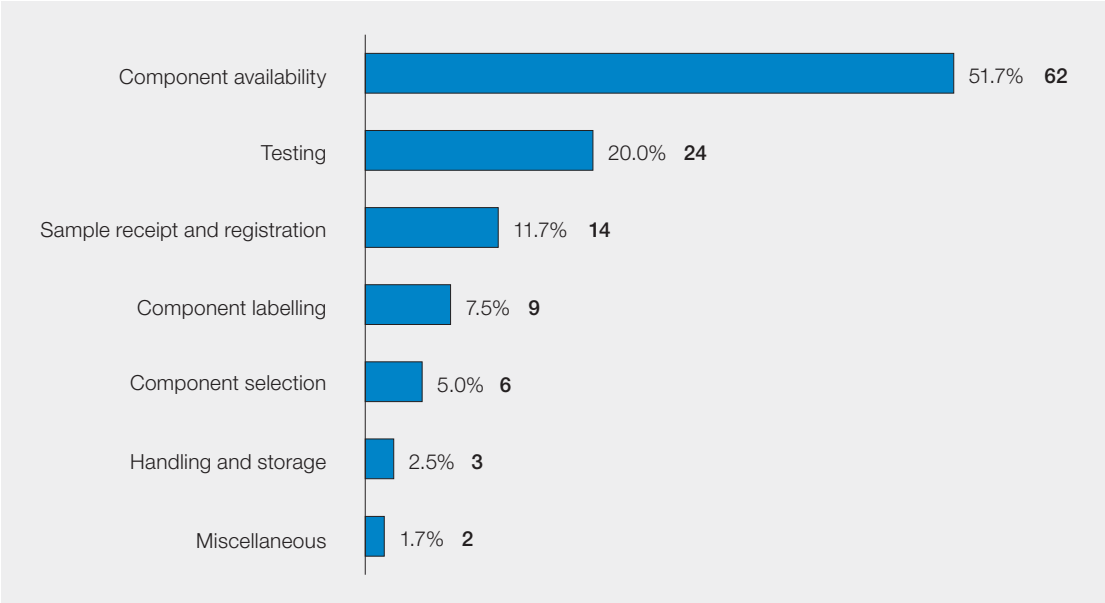
Case 11.7: Failure to contact the laboratory during MH resulted in blood component delays

A patient was found in the hospital grounds with a massive upper gastrointestinal bleed. The MHP was activated, but no blood components were sent from the laboratory. Upon investigation, the transfusion laboratory had not received the notification of the activation, leading to a significant delay in blood provision. Emergency O D-negative red cells units were administered from the ED, but the patient required further transfusion support and ICU admission. Multiple follow-up calls with communication gaps, compounded by confusing terminology contributed to the delay. In-person visits to the laboratory were necessary to clarify the request and obtain the required components.

Laboratory errors n=120

The number of laboratory errors that resulted in delays has more than doubled since the previous Annual SHOT Report (2024 n=120, 2023 n=56) with common themes. Failure in communication was the most common issue. Problems specifically occurred during handover in 26 cases. SHOT data have previously shown that incomplete handover is a contributory factor in many laboratory errors (Tuckley, et al., 2022). The availability of blood components was a key step in the transfusion process where errors occurred. Poor communication between clinicians, transfusion laboratories, and porters or couriers frequently led to delayed decision-making and blood availability.

Figure 11.2: Transfusion process step where laboratory errors occurred resulting in transfusion delays in 2024 (n=120)



Case 11.8: Delay in provision of blood components during a MH due to red cell antibodies

Provision of emergency blood components caused delays for a woman with a massive obstetric haemorrhage. A new red cell antibody was identified in the G&S sample. The clinical team was advised that they needed approval from the haematology specialist registrar before emergency

group O or group-specific red cell components could be issued. This led to a delay in blood provision for a bleeding patient.

Case 11.9: Patient put at risk due to staffing issues in the laboratory

A woman with suspected ectopic pregnancy presented to the ED out-of-hours. G&S samples were sent to the transfusion laboratory for urgent crossmatch. The transfusion laboratory was not staffed and a lone-working BMS in the biochemistry department received undue pressure to also cover the transfusion service. Clinical site managers at the hospital were not aware of the situation. The clinical team knew how to access emergency blood components, and the patient was transfused with full recovery.

A more detailed case study is provided in Chapter 17, Laboratory Errors (Case 17.3).

Case 11.10: Multiple issues resulted in a delay in blood for a patient with a GI bleed

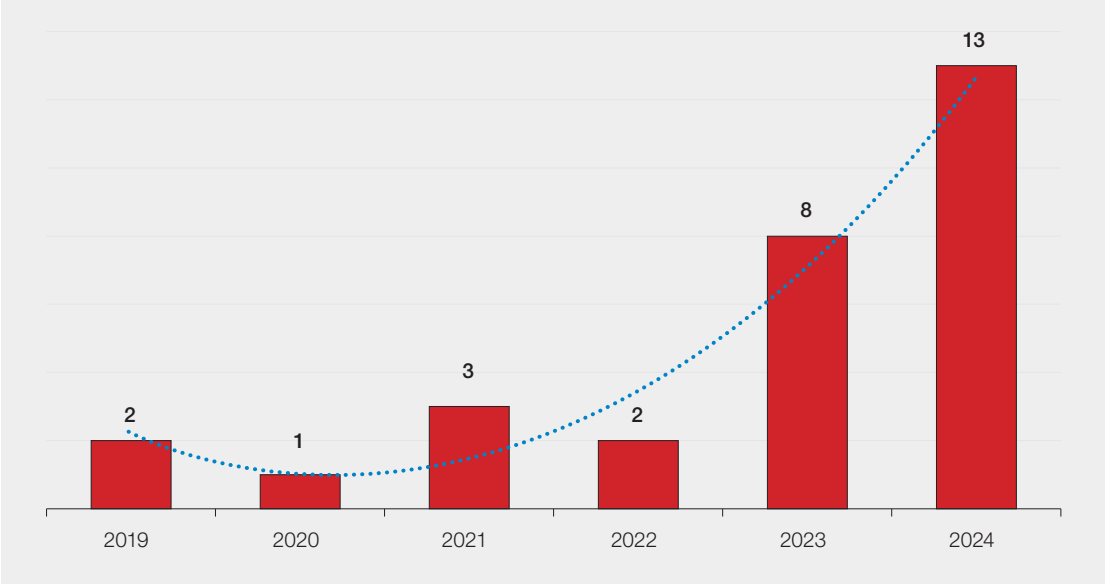
A patient with multiple co-morbidities and an upper GI bleed due to varices required blood components. The MHP was activated, and multiple clinical specialties were involved in his care. There was a delay in accessing blood components, the patient did not have a valid G&S and the laboratory requested a G&S sample. The porter was subsequently unable to access the blood refrigerator. The patient suffered cardiac arrest as the blood was being transfused and was transferred to ICU where he died, unrelated to the delay.

Blood Service errors n=13

There were 13 delayed transfusions due to errors in Blood Services (Figure 11.3). In many of these cases the delays were a combined result from errors in the hospital as well as in the Blood Services. In 3/13 cases the patients were paediatric, all requiring red cell units for neonatal exchange transfusion. Of the 13 cases, there were 3 patients affected by the national platelet shortage, 2 haematology patients and 1 major obstetric haemorrhage patient who was issued a B D-positive adult therapeutic unit of platelets (the patient's blood group was O D-positive). This was reserved for a different patient, but at that time, the transfusion laboratory did not hold any other unit in stock. One sickle cell disease patient with multiple red cell antibodies received a lower volume transfusion in two exchange transfusions than indicated during the national amber alert. This was due to unavailability of suitable red cell units.

Communication issues including miscommunication about urgency of the transfusion request, unclear timelines from the Blood Services and specialised blood components required were the most common contributory factors identified. In 1 case, the red cell units crossmatched by the reference laboratory were delivered to the wrong hospital. Even though there was no major clinical impact reported in these patients, they had to return on a different day for their appointment or be transfused later on the same day with potential risk for harm.

Figure 11.3: Trend in Blood Service-related errors 2019-2024



Delays associated with MH n=73

Delays associated with MH continue to rise year-on-year (Figure 11.4). Several recurring themes have emerged in this year's Annual SHOT Report, highlighting the systemic, procedural, and logistical issues contributing to delays in blood transfusion during MH cases. These high-pressure, time-sensitive scenarios reveal that each case is not simply a result of a single error but rather a multitude of factors resulting in delayed care. These common factors are highlighted in Figure 11.5.

Figure 11.4: Delays associated with MHP 2016-2024

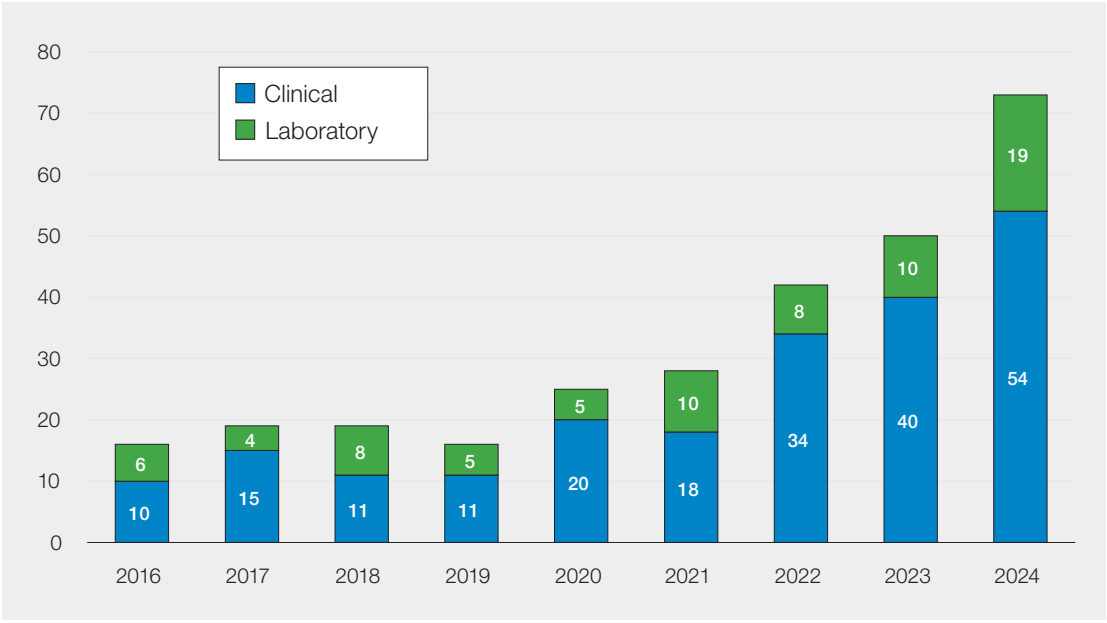
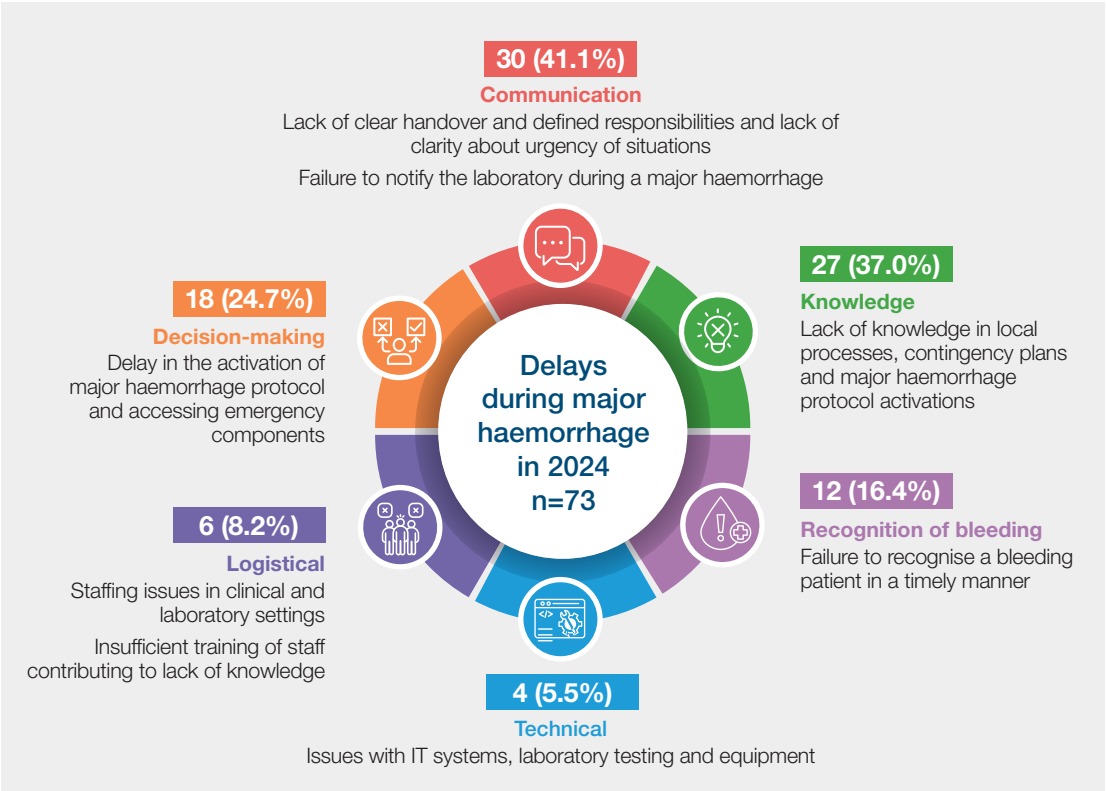


Figure 11.5: An image depicting the multiple contributing factors that resulted in delays during major haemorrhage in 2024 (n=73)



IT=information technology; MH=major haemorrhage; MHP=major haemorrhage protocol

Learning points

- Effective handover is essential especially when serious bleeding occurs out-of-hours
- All clinical and laboratory staff working in transfusion must have adequate knowledge and skills to ensure safety
- Prompt recognition of bleeding is crucial for timely and appropriate treatment
- Awareness of contingency plans is essential to ensure smooth processes when technical issues arise
- Clear protocols should be in place to support laboratory staff when issuing blood components in emergency situations, especially for patients with red cell antibodies

Conclusion

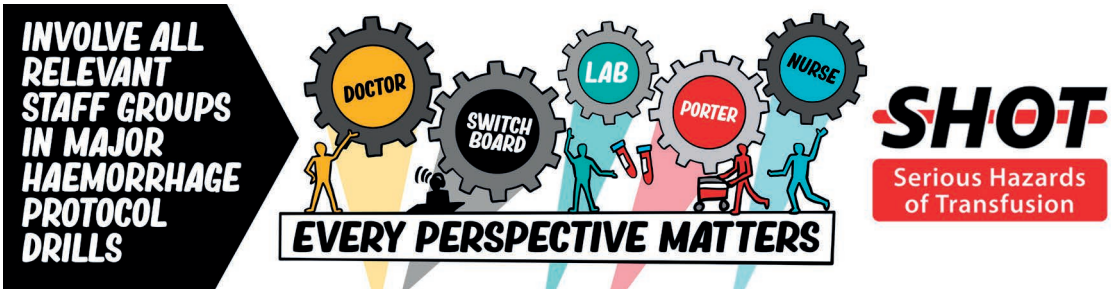
Patients should not die or suffer harm from transfusion delays. Poor communication, lack of clinical knowledge, and workforce issues continue to be key contributors. Urgent action is required to improve transfusion safety, particularly during MH and emergency situations.

Any delay initiating a necessary blood transfusion can cost lives. Timely transfusion support is not optional; it is a critical, life-saving intervention. All systems, processes and staff must prioritise immediate access to blood components to prevent avoidable harm or death. The steep increase in laboratory errors leading to delays is a cause of concern and calls for urgent action.

Ensuring laboratory safety is fundamental to patient care. Every incident is a signal, not just of risk but of opportunity to strengthen systems, eliminate hazards and build a culture where safety is everyone's responsibility. A safe laboratory is essential for trust, quality and care without harm.

Reliable and safe transfusion information technology (IT) is vital to ensure patient safety. System failures, delays or design flaws can directly compromise patient safety. Every effort must be made to ensure transfusion IT systems are robust, effective, and resilient.

The SHOT CAS alert provides clear recommendations to mitigate these risks (SHOT, 2022), but effective implementation is dependent on addressing staffing levels, training gaps, and improving communication pathways within transfusion laboratories and across clinical services.



Recommended resources

Avoidable, Delay and Under or Overtransfusion (ADU) Cumulative Data
https://www.shotuk.org/resources/avoidable-delay-and-under-or-overtransfusion-adu-cumulative-data/

SHOT Bite No. 8: Massive Haemorrhage Delays
https://www.shotuk.org/resources/shot-bite-no-8/

SHOT Video: Delayed Transfusion in Major Haemorrhage
https://www.shotuk.org/resources/delayed-transfusions-in-major-haemorrhage/

SHOT Webinar: Every Minute Counts
https://www.shotuk.org/resources/every-minute-counts-webinar-2021/

SHOT
Serious Hazards of Transfusion

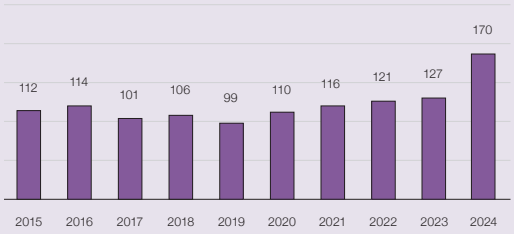
12 Avoidable Transfusions n=170

Authors: Catherine Booth, Paula Bolton-Maggs and Vera Rosa

Headline data 2024

Number of reports n=170
Deaths n=0
Major morbidity n=0

Avoidable transfusion reports by year



Demographic data

Male n=76
Female n=93
Unknown n=1
Adults n=158
Paediatric n=12

Blood component data

Red cells n=128
Platelets n=33
Fresh frozen plasma (FFP) n=3
Cryoprecipitate n=1
Multiple components n=5

Key findings:

- Reports of avoidable transfusions increased by 33.9% compared to 2023
- There was an increase in reports related to avoidable platelet transfusions
- There were 124 completely avoidable transfusions and 46 involving avoidable use of emergency group O red cells

Gaps identified:

- Lack of knowledge of transfusion indications
- Failure to question unexpected results
- Inadequate or inaccurate handover, both within and between teams (medical, nursing, laboratory)
- Multiple systems, steps and staff involved in the switch to group-specific blood during major bleeding

Good practice:

- Reports reflect some detailed investigations with good insight into multiple human and systems factors involved
- Incorporation of a prompt for consent built into the prescription chart

Next steps:

- Review local policies and processes to ensure timely switch to group-specific blood components in major bleeding

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

Where the intended transfusion is carried out, and the blood component itself is suitable for transfusion and compatible with the patient, but where the decision leading to the transfusion is flawed. Every unit transfused should be an individual decision, so this might include transfusion of multiple units where not all were appropriate/necessary.

Introduction

The 170 reports of avoidable transfusions in 2024 represents a 33.9% increase compared to the 127 reported in 2023. The most notable increase was in reports related to platelets: 33 compared to 15 in 2023.

There were 124 transfusions that might have been avoided entirely: 82 involved red blood cells, 33 platelets, 3 fresh frozen plasma (FFP), 1 cryoprecipitate and 5 multiple components. In addition, there were 46 reported cases of avoidable use of emergency group O red cells.

Deaths and major morbidity related to transfusion n=0

There were no deaths and major morbidity cases related to avoidable transfusions in 2024.

Classification of avoidable transfusions n=170

Table 12.1: Classification of avoidable transfusions in 2024 (n=170)

Group	Red cells	Platelets	Plasma components	Multiple components	Total reports
Flawed decision	30	13	3	3	**49**
Decision based on inaccurate results	35	12	1	1	**49**
Failure to respond to change in circumstances	7	6	0	0	**13**
Transfusion necessitated by error	2	0	0	1	**3**
Transfusion without decision	8	2	0	0	**10**
Sub total	**82**	**33**	**4**	**5**	**124**
Avoidable use of emergency group O	46	0	0	0	**46**
Grand total	**128**	**33**	**4**	**5**	**170**

Flawed decision n=49

These included 9 avoidable transfusions for haematinic deficiencies (6 iron, 3 B12/folate), 6 unnecessary use of multiple units, 23 transfusions outside guideline thresholds, 8 related to inaccurate estimation of bleeding and 3 related to specific conditions (immune thrombocytopenia and sickle cell disease). In most cases, these related to gaps in knowledge.

Case 12.1: Unnecessary prophylactic platelet transfusion related to miscommunication and knowledge gaps

A patient with myeloma was admitted unwell and one adult therapeutic dose (ATD) of platelets was transfused as the platelet count was 11x10^9/L. The consultant's plan was to transfuse further platelets if the count was less than 20x10^9/L. This was misread as 70x10^9/L by a locum resident doctor, who lacked the knowledge to question the threshold. The patient's platelet count was 45x10^9/L and platelets were given. The consultant, who was covering for the doctors' strikes, was in a rush and did not write clearly, and the patient was on a medical admissions unit rather than the haematology ward, where staff were unfamiliar with use of platelets.

Transfusion decision based on inaccurate results n=49

These included 10 patients transfused based on results from haemodiluted samples, 9 on another patient's results, 9 erroneous results of uncertain aetiology, 6 related to point-of-care results (4 blood gas machines, 1 thromboelastography (TEG) and 1 device used in the community), 5 cases of platelet clumping, 4 old results, 3 clotted samples, 2 transcription errors and 1 verbal handover. A recurring theme was a failure to question results which were unexpected, had changed significantly from historical values or did not fit the clinical picture.

Case 12.2: Wrong blood in tube for full blood count (FBC)

Two patients on a ward required repeat blood samples to be sent for FBC and biochemistry. A nurse took the samples from patient 1 but labelled them as patient 2 and then took patients 2's samples and labelled them as patient 1. Patient 2 was noted to have a haemoglobin (Hb) drop from 90 to 70g/L and was transfused two units of red cells. The following day, the pharmacist was reviewing the blood results for biochemistry and noted that they seemed erroneous. The FBC results were then reviewed, and patient 2 had a post-transfusion Hb of 129g/L. Both patients' results were discarded. Patient 1's repeat Hb was 77g/L and transfusion was not required.

Case 12.3: Transcription error involving triplets

A premature triplet had an incorrect Hb level of 105g/L (the result of his sibling) transcribed into his notes and as a result was transfused 20mL/kg packed red blood cells. A subsequent result (delayed as the initial sample had clotted) demonstrated a pre-transfusion Hb of 136g/L, which was above the threshold for transfusion for his gestation. The post-transfusion Hb was 148g/L.

Failure to respond to change in circumstances n=13

There were 4 cases where a change of management plan was documented but not clearly communicated to nursing staff, and 1 with multiple contradictory plans. In 2 cases, prescriptions were written in advance where current results were not reviewed. One case involved a delayed procedure and in 2 cases, prescriptions for blood components were made 'just in case' that were then given routinely. Additionally, in 2 patients, clinical status had changed but transfusion occurred and in 1 case, the planned transfusion had already been given in theatre but nurses on the ward were unaware as they had no access to the separate anaesthetics chart. The final case highlights a risk when blood transfusion is not recorded in a common single patient record, which can also have implications for investigations of reactions and lookback for infections.

Case 12.4: Platelets transfused based on anticipated need without up-to-date review

A patient had a target platelet count of >50x10^9/L for treatment dose anticoagulation for a new pulmonary embolism. Platelets were ordered based on the predicted rate of fall of their count after the last transfusion. The plan following discussions on the ward round was for these to be given at 06:00 (before the anticoagulation dose was due). The night nurses asked the on-call medic to prescribe these as they had not been written up. The FBC was checked after one ATD of platelets and found the platelet count to be 126x10^9/L, well above the target threshold.

Case 12.5: Platelets in major haemorrhage pack given despite cessation of bleeding

The major haemorrhage protocol was activated for a patient with lower gastrointestinal bleeding with a platelet count >150x10^9/L, and they were on no antiplatelet medication. Four units of red cells and two FFP were issued, and two ATD of platelets were requested on blue light delivery. Upon contacting the ward to inform them they were available; the laboratory was informed they were no longer needed. The patient went on to receive additional platelets more than 12 hours after the major haemorrhage alert with no apparent indication.

Transfusion necessitated by error n=3

One patient suffered significant bleeding in the context of over-anticoagulation. Suboptimal antenatal management of iron deficiency anaemia in another patient meant transfusion was required prior to

caesarean section. A patient with von Willebrand disease suffered significant intraoperative bleeding and needed transfusion support. The patient had been taken to theatre without liaison with haematology or any prophylactic haemostatic treatment pre-operatively.

Transfusion without decision n=10

Ten patients were given a transfusion that had not been prescribed. Often this was the result of errors in verbal handover.

Case 12.6: Red cells transfused in place of intravenous (IV) iron due to erroneous verbal handover

A woman who had been anaemic throughout pregnancy had a post-delivery Hb of 74g/L, having suffered minimal blood loss. A prescription was written for IV iron but the nursing plan, which documented 'IV iron transfusion', became 'blood transfusion' during verbal handover. An agency nurse ordered and administered a unit of red blood cells, and a doctor was asked to prescribe these retrospectively.

Avoidable use of emergency group O red cells n=46

Reports related to avoidable use of emergency group O red cells have increased (33 in 2022, 37 in 2023), likely due to an increased focus on this important issue.

In 5 reports, emergency group O red cells were accessed when the transfusion was not clinically urgent.

In 18 cases, group-specific blood components were available but not collected, either due to errors during collection, difficulty in accessing red cell units from remote refrigerators or a lack of communication with clinical teams about availability. In 10 reports, there was no valid sample, often due to delays in sending or samples being rejected due to mislabelling. In 8 cases, there were laboratory delays processing the sample. Errors with information technology (IT) systems were implicated in 5 cases.

The diversity of errors illustrates the complexity of processes for providing group-specific blood components: involving many systems, steps, and staff groups. SHOT has produced a guide to describe these steps, to assist in reviewing local protocols (see 'Recommended resources').

Following the June 2024 cyberattack that disrupted laboratory information systems, several major London hospitals had to rely exclusively on group O blood for all patients. This approach was necessary due to logistical constraints, the risk of ABO-incompatible transfusions, manual crossmatching demands, staffing pressures, analyser limitations, and available bench space. The reliance on group O continued until IT systems were fully restored in late September 2024. These cases have not been reported individually as avoidable transfusions of group O. However, it is acknowledged that this unplanned use placed considerable strain on national blood supplies, exacerbating existing shortages of group O stock.

Case 12.7: Lack of communication with clinical area results in avoidable use of O D-negative red cells

Emergency O D-negative red cells were collected for a patient as the staff member was unaware that group-specific red cells were available via electronic release. There was no biomedical scientist in the hospital or on call out-of-hours, so the clinical area had not been contacted to tell them that electronic release was available. Only limited stocks of O D-negative red cells were held in the remote refrigerator, so this was depleted overnight unnecessarily, with no ability to replenish until the following day.

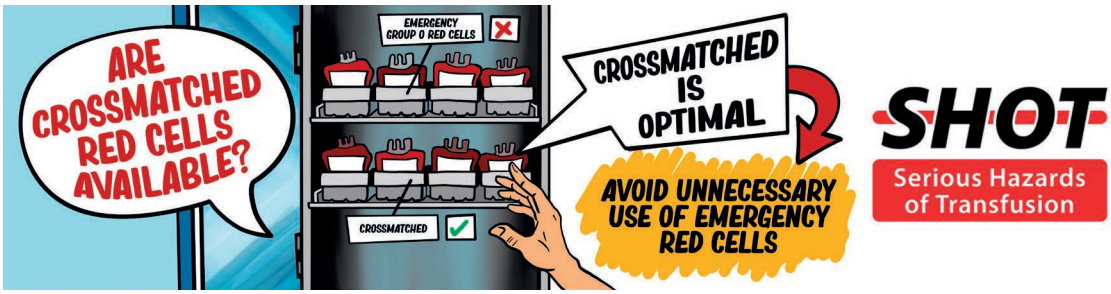
Case 12.8: Configuration of remote refrigerator prompted staff to collect group O red cells unnecessarily

A patient was actively bleeding, and staff went to collect two red cell units from the remote refrigerator via electronic issue (as there was a valid pre-transfusion sample). The refrigerator was configured not to allow multiple collections for a single named patient at the same time, to prevent transposition of labels. Staff successfully removed one unit of group-specific red cells but were unable to remove the second unit at that time. Staff assumed no other group appropriate blood components was available,

so an emergency O D-negative red cell unit was also taken for transfusion. Further O D-negative red cells were collected later in the shift, as the staff member continued to assume that no group-specific blood was available.

Learning points

- Guidance on appropriate transfusion thresholds should be made readily available to clinicians, in concise and convenient formats to support real-time decisions
- Accurate patient identification is essential during any interaction with the patient themselves or any part of their record (e.g., looking up or transcribing results, and writing a prescription)
- Unexpected results, particularly those not consistent with the current clinical picture, should be questioned and tests repeated before using them to make management decisions
- In a non-bleeding patient, the cause of thrombocytopenia should be investigated before considering platelet transfusion
- Verbal handover carries great potential for error and plans should be confirmed in writing wherever time allows
- The switch from emergency group O to group-specific red cells during major bleeding can be a complex process. The steps required should be considered in detail when designing and practising the major haemorrhage protocol



Conclusion

Two major events in 2024 placed a spotlight on avoidable transfusions and may have contributed to the increase in number of reports received this year.

England saw a prolonged amber alert for shortage of group O red cells. An amber alert is declared by the Blood Service when there is reduced availability of blood with impact on clinical activity (NHSBT, 2025b). Ready access to group O red cells may have prevented transfusion delays in many of the cases reported. Every effort should however be made to give group-specific blood components and avoid unnecessary use of emergency group O red cells.

The Infected Blood Inquiry serves as a stark reminder that transfusion is not without risk and should be avoided unless clinically essential. Effective patient blood management is fundamental to transfusion safety.

Recommended resources

National Blood Transfusion Committee Indication codes for transfusion (updated 2024)
https://nationalbloodtransfusion.co.uk/recommendations

Royal College of Physicians Acute care handover toolkit
https://www.rcp.ac.uk/improving-care/resources/acute-care-toolkit-1-handover/

SHOT Bite No. 34: Switching to group-specific red blood cells in major haemorrhage
https://www.shotuk.org/resources/shot-bite-no-34-switching-to-group-specific-blood-components-during-major-haemorrhage/

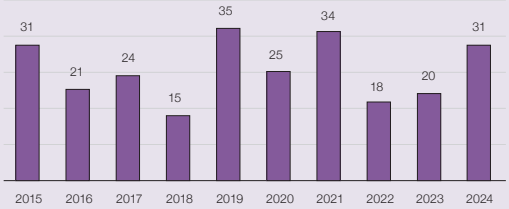
Under or Overtransfusion n=31

Authors: Paula Bolton-Maggs, Catherine Booth and Vera Rosa

Headline data 2024

Number of reports n=31
Deaths n=1
Major morbidity n=3

Under or overtransfusion reports by year



Demographic data

Male n=19
Female n=12
Adults n=11
Paediatric n=20

Blood component data

Red cells n=27
Platelets n=2
Plasma n=0
Cryoprecipitate n=2
Multiple components n=0

Key findings:

- An increase in numbers reported compared with previous 2 years
- Paediatric cases predominate (64.5%)
- Several haemoglobinopathy patients over or undertransfused

Gaps identified:

- Calculation and infusion rates for transfusion
- Communication issues and knowledge gaps

Good practice:

- Local investigations were carried out and relevant improvement actions were undertaken
- Vigilant laboratory staff querying appropriateness of requests for transfusion

Next steps:

- Patients with haemoglobinopathies should be managed under discussion with specialists and following national guidelines
- Practitioners who authorise transfusions for paediatric patients should be adequately trained to ensure calculations of volume are correct, and the correct infusion equipment is used

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

A dose inappropriate for the patient's needs, excluding those cases which result in transfusion-associated circulatory overload (TACO) and usually resulting in a haemoglobin or platelet level significantly outside the intended target range. Infusion pump errors leading to under or over transfusion with clinical consequences (if no clinical consequences, then it is reportable under handling and storage errors (HSE).

Introduction

There has been an increased number of reports received in this category in 2024, 31, compared to 20 in 2023. Most, 20/31 (64.5%), were paediatric cases. The majority were caused by wrong calculations or wrong infusion rates. Overtransfusion was reported in 13 cases, and 11 of these were paediatric patients. Undertransfusion occurred in 18 cases, and 9 of these were paediatric patients.

Eight cases occurred in patients with haemoglobinopathies, 3 with thalassaemia (all paediatric) and 5 with sickle cell disease (2 paediatric).

Most (27/31) related to red cells; 2 related to cryoprecipitate (a baby received too much and an adult with major haemorrhage was underdosed). A child received an excess of platelets due to an administration error, and an adult was undertransfused platelets due to an error with the infusion pump.

Deaths related to transfusion n=1

Case 13.1: Death from severe drug-induced haemolysis and ineffective transfusion (imputability 1 – possible)

An elderly person died from probable severe drug-induced haemolysis with haemoglobinuria and ineffective transfusion. The patient had an infected joint prosthesis and was receiving rifampicin. Over a 4-day period, red cell transfusions were provided using best-matched concessionary release red cells together with steroids and intravenous immunoglobulin. However, there was insufficient response in the haemoglobin (Hb) due to the rampant haemolysis.

Rifampicin-induced haemolysis is recognised, often severe, but rare and deaths have been reported despite best available treatment (as in this case) (Ahrens, et al., 2002; Covic, et al., 1998; Sveroni, et al., 2018). Limited details were available regarding this case and from the information provided, rampant haemolysis resulted in patient death whilst transfusion was being administered.

Major morbidity n=3

Case 13.2: Extravasation of transfusion and inadequate monitoring

An elderly patient presenting with rectal bleeding received a transfusion of red cells which extravasated extensively with bruising of his arm. The patient received no benefit from the transfusion which was also not adequately monitored. They were very unwell with fluid overload and renal dysfunction and died but unrelated to the transfusion.

Case 13.3: Undertransfusion during exchange transfusion: use of wrong giving set

A neonate underwent exchange transfusion for haemolytic disease of the fetus and newborn but was significantly undertransfused. The wrong giving set was used resulting in a lower volume transfusion than planned. The hospital's supplier produced two paediatric giving sets that looked very alike, one for transfusion and one for fluids. Exchange transfusion was very infrequently performed in this hospital. The infant developed hypovolaemic shock with cardiac arrest and required ventilation. The child recovered when appropriately transfused.

This case is also described in Chapter 25, Paediatric Cases, Case 25.7.

The 3rd case involved overtransfusion of red cells due to a calculation error in a child who was also severely thrombocytopenic.

Errors in haemoglobinopathy patients n=8

Five of 8 cases occurred in paediatric patients. A young child only received a quarter of the intended volume (101 rather than 404mL) due to a miscalculation resulting in a lower than desired Hb at the next visit. Two other patients were transfused based on a wrong calculation and 2 based on an incorrect prescription. An adult with sickle cell disease received an inadequate number of red cell units for exchange transfusions due to difficulty sourcing compatible group O D-positive units. The patient had multiple antibodies and there was a national shortage of group O.

Case 13.4: Overtransfusion of a child with thalassaemia

An infant with known beta thalassemia was prescribed 80mL red cells but was transfused 210mL in error. There were additional concerns: there were significant delays in providing the blood components due to mislabelled samples, conflicting information regarding whether irradiated units were required, how fresh the blood should be, and what component type i.e., large volume unit vs paediatric packs. The child was not harmed.

The management of this case suggests staff were not familiar with the process. Transfusion of patients with haemoglobinopathies is specialised and should follow national guidelines including standards for clinical care in thalassaemia (UK Thalassaemia Society, 2023; Trompeter, et al., 2020a; Trompeter, et al., 2020b).

Case 13.5: A patient with sickle cell disease could not complete their exchange transfusion

A young person was receiving an exchange transfusion via an implanted central venous line which stopped functioning during the procedure. Two red cell units were returned to the refrigerator but as they had been out of temperature control for 31 minutes, they were not subsequently released to finish the transfusion. The patient was not harmed.

The local review considered that concessionary release of these red cell units could have been appropriate to complete the exchange.

Learning point

- Wherever possible, patients with haemoglobin disorders should be managed by specialists with appropriate transfusion protocols

Near miss n=3

An incorrect Hb result was reported for a patient who was bleeding and in need of surgery.

This was at the time of a laboratory information technology cyber-attack which increased the laboratory workload and necessitated manual transcription of results with some delay. The surgical staff did not question why the reported Hb of 130g/L was so different to the previous day (Hb 84g/L). During surgery, repeat Hb measurement on the blood gas machine confirmed significant anaemia (Hb 59g/L) and the patient received a single unit of red cells which was all that was available. The corrected result for the original Hb was 74g/L. The patient came to no harm and was not undertransfused.

There were 2 other cases of near miss, both related to overtransfusion, which were identified when laboratory staff queried the transfusion request.

Conclusion

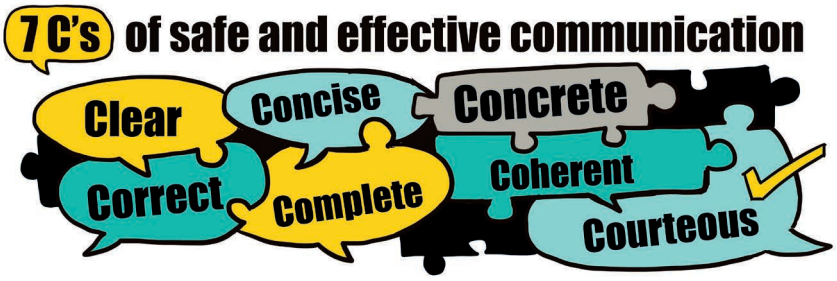
Cases of under or overtransfusion occur most commonly in paediatric patients (see additional comments in Chapter 25, Paediatric Cases). Patients with haemoglobin disorders should be managed under specialist guidance. In cases of catastrophic haemolysis, it may not be possible to keep up with the fall in Hb by transfusion.

Recommended resources

Avoidable, Delay and Under or Overtransfusion (ADU) Cumulative Data
https://www.shotuk.org/resources/avoidable-delay-and-under-or-overtransfusion-adu-cumulative-data/

Avoidable, Delayed or Under/ Overtransfusion webinar (ADU)
https://www.shotuk.org/resources/avoidable-delayed-or-under-overtransfusion-webinar-adu/

SHOT Bite No.4: Lessons in Paediatrics (including neonates)
https://www.shotuk.org/resources/shot-bite-no-4-lessons-in-paediatrics-including-neonates/



SHOT
Serious Hazards of Transfusion

Incidents Related to Prothrombin Complex Concentrates (PCC) n=35

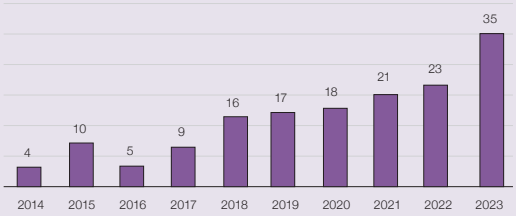
14

Authors: Paula Bolton-Maggs and Vera Rosa

Headline data 2024

Number of reports n=35
Deaths n=1
Major morbidity n=1

PCC reports by year



Demographic data

Male n=15
Female n=20
Adults n=35
Paediatric n=0

Blood product data

Prothrombin complex concentrates (PCC) n=35

Key findings:

- PCC administration in emergencies, particularly with intracranial haemorrhage (ICH), is often delayed
- Patients are often elderly with multiple pathologies
- Most patients presented in the emergency department (ED) and needed urgent treatment
- Use of trade names can cause confusion resulting in incorrect treatment

Gaps identified:

- Lack of knowledge of PCC and how it is administered
- Communication problems between clinicians and haematologists
- PCC not easily accessible near the ED resulting in delays
- Contributory human factors, particularly very busy ED

Good practice:

- PCC is used infrequently; in one hospital difficulty locating the standard operating procedure (SOP) on the computer system resulted in revision of the title making it easier to find using key words – 'PCC SOP' instead of 'Management of Bleeding and Management of Anticoagulation'

Next steps:

- Introduce fixed dose PCC in ED with audit of use
- Where possible, automated dispensing with appropriate SOP should be set up
- Instructions about using PCC should be clear and easy to locate; the product should be easily accessible

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

Hospitals are asked to report incidents related to PCC infusion where there was delay or inappropriate transfusion. Allergic reactions should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) through the Yellow Card scheme, https://yellowcard.mhra.gov.uk/.

Introduction

Delays were the most common reason for PCC case reports, occurring in 22/35 (62.9%). Avoidable use of PCC was reported in 5 cases. Problems with administration were noted in 8 cases, mostly wrong rates of infusion, and confusion over the prescription in 7. The patient age range was 32 to 97 years with the majority, 26/35 (74.3%) >70 years of age. The median age was 81 years. There were 8 cases with ICH.

Most cases, 31/35 (88.6%) originated from clinical areas, and 4 were attributed to the laboratory. In 2 laboratory cases, wrong lot numbers were allocated, and the other 2 cases reported delays in issuing PCC. In all 22 cases of delay the need was urgent and 14/22 (63.6%) patients were in the ED. Communication failure was reported in 8/22 (36.4%). Four patients experienced delays of more than 10 hours. Several reports noted lack of knowledge of PCC and how to administer it. Overall, 19/35 (54.3%) incidents were reported from the ED.

Death related to transfusion n=1

Case 14.1: Slow reversal of warfarin with PCC associated with increased ICH and death (imputability 1 – possible)

A patient who was on warfarin for a previous deep vein thrombosis suffered an assault resulting in head injury. A computed tomography (CT) scan of the head was done within an hour of admission when the patient was fully alert. This showed ICH and vitamin K was given 3 hours after the CT report. The patient sneezed just after this with a rapid deterioration in Glasgow Coma Scale. PCC was prescribed 30 minutes later and given an hour after the sneeze. This was 4 hours after the CT report. Repeat CT confirmed extension of the ICH and 9 hours after admission, the patient became unresponsive. They were transferred to a neurosurgery unit but died from the ICH. The delay in treatment with PCC was considered to have possibly led to the patient death.

PCC and vitamin K should be administered to reverse warfarin as soon as ICH is suspected or diagnosed (before imaging or transfer to another department) and certainly within an hour.

Major morbidity n=1

Case 14:2: Delayed treatment with PCC after injury resulted in a prolonged stay in the intensive care unit (ICU)

An elderly patient on warfarin attended a very busy ED after a fall in the shower sustaining a head injury. Blood tests showed a high international normalised ratio of 12.0 and vitamin K was given. Imaging showed peritoneal haematoma related to a fractured vertebra with a damaged blood vessel. Interventional radiology (IR) was planned to treat this. However, due to confusion, lack of understanding among staff and poor communication, there was a delay of at least 15 hours before PCC was requested, delaying the IR procedure. Had the PCC been given sooner, this delay may not have occurred, and it is possible that admission to ICU would not have been required. The patient was in ICU then the high dependency unit for a total of 2 weeks.

Wrong blood component or blood product n=3

Three patients failed to receive the correct blood component and/or blood product. A patient with metallic heart valves and acute-on-chronic subdural haemorrhage (SDH) was prescribed PCC for anticoagulant reversal which is contraindicated because of an increased risk of thrombosis. The haematologist was not told of the metallic valves. However, this contraindication is relative rather than absolute (Uncu, et al., 2024) and the balance of risks for the individual patient should be considered.

The 2nd patient had suspected thrombotic thrombocytopenia purpura (TTP) and received PCC (Octaplex®) instead of fresh frozen plasma (Octaplas®). These components should always be prescribed using proper names (prothrombin complex concentrate, fresh frozen plasma) and not trade names to avoid this confusion which has been reported to SHOT before. The identification and treatment of TTP is a medical emergency requiring discussion with and transfer to a specialist centre, and the patient should start plasma exchange within 4 to 8 hours of diagnosis (Scully, et al., 2023).

The 3rd patient received PCC when cryoprecipitate was required following thrombolysis for a cerebrovascular event.

Learning points

- Using similar sounding trade names leads to errors in treatment. Proper names should be used to identify blood products and components
- Providing all key information when seeking clinical input supports safe decision-making

Near miss n=1

An elderly patient had PCC issued with the wrong hospital number. The product was returned to the laboratory and reissued with the correct number.

Conclusion

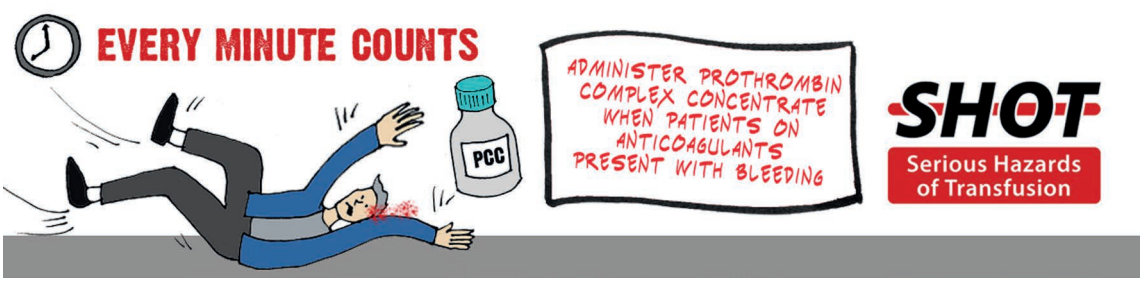
Delayed administration could be avoided by better recognition of bleeding, having a simple accessible protocol and a supply of PCC in the ED. Hospitals have variable arrangements for PCC release. Storage in the transfusion laboratory is not ideal (biomedical scientists may be unfamiliar with the indications), and it may be difficult to locate an on-call pharmacist. An optimal route might be via an automated dispensing system set up with correct governance via the pharmacy.

In the 2023 Annual SHOT Report, the evidence for using a single fixed dose for emergency administration was reviewed and this approach was recommended (Narayan, et al., 2024). In 2024, two systematic reviews also supported this approach (Alwakeal, et al., 2024; Condeni, et al., 2024). Alwakeal, et al. (2024) reported a total of 323 participants in randomised controlled trials, 161 fixed dose and 162 variable dose; there were also 1912 patients in cohort studies (858 fixed dose and 1054 variable dose). These authors concluded that using a fixed dose results in dose reduction, faster administration time, improved clinical haemostasis, reduced mortality, and reduced thromboembolic events.

Data from a United Kingdom-wide audit of reversal agents for direct acting oral anticoagulant-associated bleeding included 2477 patients, median age 80 years, 1010 with ICH (Buka, et al., 2024). PCC was used in 2037 cases and further conclusions about timing, effectiveness and side effects will be available when the full data are published.

Recommended resource

SHOT Bite No. 16: Errors with Prothrombin Complex Concentrate
https://www.shotuk.org/resources/shot-bite-no-16/



15 Near Miss (NM) Reporting n=1408

This overview page covers all NM cases – including 899 wrong blood in tube, and 509 reports in other NM categories.

Author: Vera Rosa

Key findings:

- NM events continue to be the largest category reported to SHOT even though there was a slight decrease from 2023
- A substantial increase (>25%) of NM events in the incorrect blood component transfused (IBCT) and right blood right patient (RBRP) categories
- There were 203 potential ABO-incompatible (ABOi) red cell transfusions if the error had not been identified prior to transfusion

Gaps identified:

- Failure to follow a standard operating procedure (SOP) or policy were seen in many cases
- Lack of sustained changes in practice
- Patients not identified at phlebotomy and samples labelled away from the patient continue to be the most common reasons reported for WBIT
- Interruptions during sample taking and labelling resulted in errors
- Gaps in knowledge, ineffective training, mismatch between staff and workload, high-pressured work environments, and team function issues were the most common contributory factors

Good practice:

- More than half of NM events were detected during pre-administration checks
- Evidence of increased review of cases by hospital transfusion teams
- Most WBIT (84.2%) were identified during the laboratory testing or at authorisation of results, showing the importance of a sample check for confirmation of the blood group
- Most cases were, or were planned to be, reviewed at transfusion team meetings including, hospital transfusion team meeting or equivalent (95.4%)
- In 95 WBIT cases the error was identified in the clinical area, and laboratory staff were promptly informed

Next steps:

- Ensure that documentation and policies are clear and simple to follow to avoid confusion, misinterpretation and/or incorrect practice
- Where human factors and/or systemic errors are identified, an action plan with achievable measures and deadlines should be agreed
- Sample taking and labelling should be a single continuous process carried out beside the patient

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

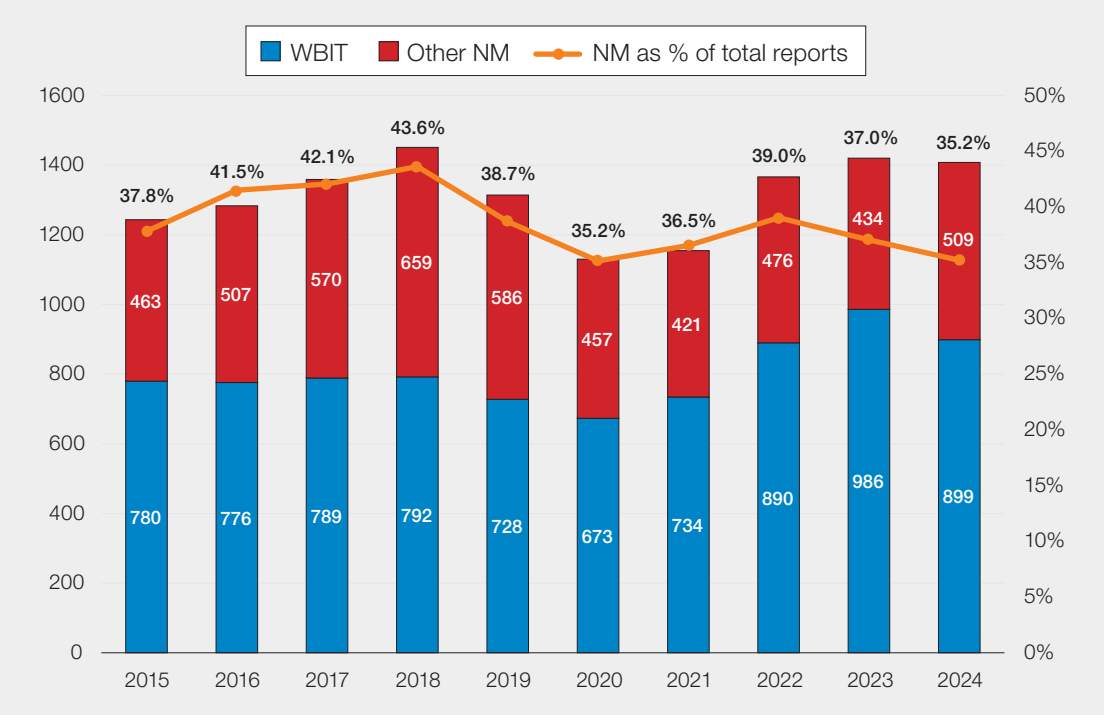
Definition:

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

Introduction

As in previous years, NM events in 2024 accounted for the largest category of cases reported to SHOT, 1408/3998 (35.2%). Although there was a small decrease in the total number of NM events compared to 2023 (n=1420), this was still the second highest number of NM events reported since 2019 (Figure 15.1).

Figure 15.1: A decade of NM (other) and WBIT reports (2015-2024)



NM=near miss; WBIT=wrong blood in tube

The largest category of NM analysed by SHOT in 2024 was WBIT (n=899), which decreased from 986 in 2023 (Figure 15.1). WBIT can lead to ABOi transfusions which can be fatal (Chapter 15a, Near Miss – Wrong Blood in Tube (WBIT)). Contrarily, there were NM events in other categories with an increase of more than 25% compared to 2023; IBCT, 152 in 2023 to 196 in 2024 (increase of 28.9%); RBRP, 99 in 2023 to 125 in 2024 (increase of 26.3%).

Table 15.1: Comparison of the NM per SHOT category reported in 2023 and 2024

SHOT category	Number of cases in 2024	Discussed in chapter
Wrong blood in tube (WBIT)	899	Chapter 15a
IBCT-wrong component transfused (IBCT-WCT)	135	Chapter 9
Handling and storage errors (HSE)	132	Chapter 10
Right blood right patient (RBRP)	125	Chapter 16
IBCT-specific requirements not met (SRNM)	61	Chapter 9
Anti-D immunoglobulin (Ig) administration errors	40	Chapter 8
Avoidable transfusion	7	Chapter 12
Delayed transfusion	4	Chapter 11
Under or overtransfusion	4	Chapter 13
Incidents related to prothrombin complex concentrates (PCC)	1	Chapter 14
Total	**1408**	

NM events are discussed in each relevant chapter of the 2024 Annual SHOT Report (Table 15.1).

Most common NM events in laboratory and clinical settings

In 2024, 268 of the NM events were laboratory errors, while 241 were clinical.

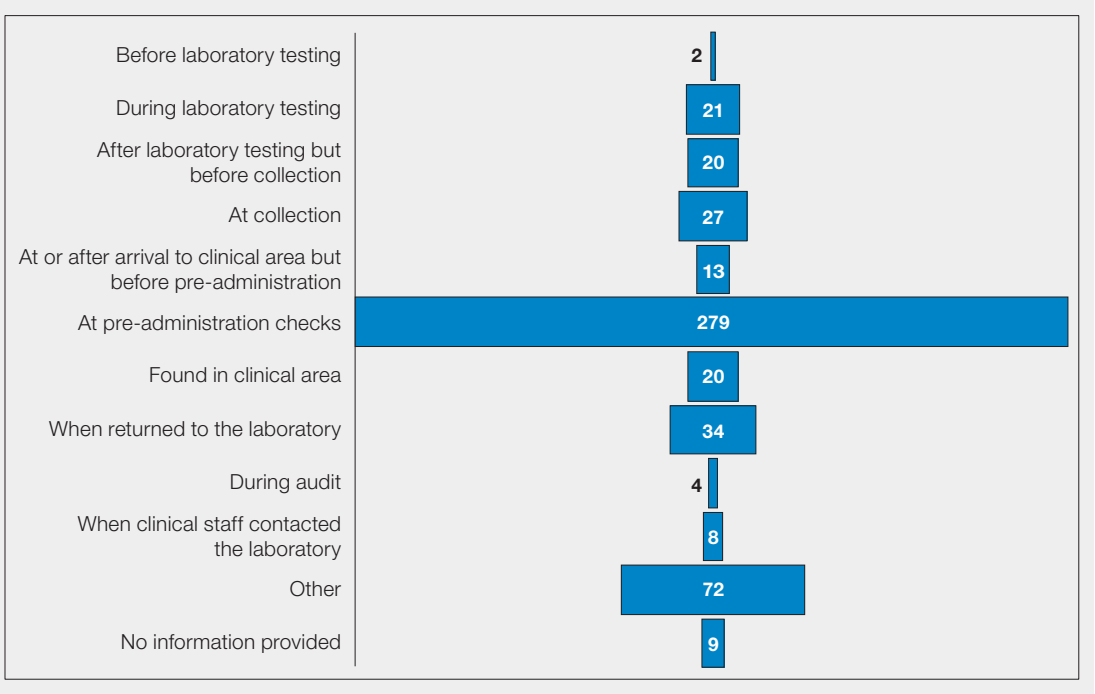
Laboratory errors were most commonly reported under RBRP, 106/268 (39.6%), IBCT-WCT, 59/268 (22.0%) and IBCT-SRNM, 44/268 (16.4%). The common errors in RBRP were labelling errors, 77/106 (72.6%) or patient identification errors, 28/106 (26.4%). In IBCT-WCT, most primary errors were either incorrect blood group provided, 25/59 (42.4%), or blood component issued for the wrong patient, 29/59 (49.2%). Not providing irradiated blood components when required was the most common error in IBCT-SRNM, 26/44 (59.1%).

Clinical errors were most commonly reported under HSE, 101/241 (41.9%) and IBCT-WCT, 76/241 (31.5%). HSE errors were mainly due to cold chain errors, 87/101 (86.1%). IBCT-WCT were mostly due to errors during blood component collection, request or about to be administered to the wrong patient, 75/76 (98.7%). Detection of these errors prevented 14 ABOi transfusions.

Point of error detection in NM events

More than half of the errors in NM events, excluding NM-WBIT, were detected during the pre-administration safety checks, 279/509 (54.8%). In 212/279 (76.0%), the error was identified by staff using a formal pre-administration checklist. There were 72 'other' responses (Figure 15.2) which included errors being detected when the laboratory staff or transfusion practitioner were either chasing traceability records, investigating an incident, or carrying out inventory and/or refrigerator checks.

Figure 15.2: Point in the process where the error was detected in NM events, excluding NM-WBIT reported in 2024 (n=509)



Local review of NM events in 2024

From 1408 NM events, 1225 were reviewed by local organisations and in 105, the review resulted in changes to transfusion procedures or policies. These changes included updating SOP or policies, improvement or changes in training, and exploring possible changes in information technology systems to improve safety. On a positive note, in the NM events that had not been reviewed, 166/1408 (11.8%), 117/166 (70.5%) stated that a review in a future (next) team meeting such as at the hospital transfusion

team, hospital transfusion committee or equivalent was scheduled. This represents 95.3% NM events either reviewed or to be reviewed.

A total of 388/509 (76.2%) reports used a human factors-based approach during investigation. Of these, 289 identified that failures in team function contributed to the event. In 107 NM, a mismatch between workload and staff available around the time of the event was reported as a contributory factor.

Conclusion

SHOT advocates and promotes learning from NM events. Investigating these helps identify potential hazards and risks before they lead to actual incidents or patient harm. NM investigations are an important tool to continuously improve systems and care provided, thus enhancing safety for all. If healthcare organisations do not have policies in place that encourage and understand the value of learning from NM events, the next patient will be at increased risk. Every report is a chance to make care safer.

Recommended resources

SHOT Bite No. 17: Learning from Near Misses (NM)
https://www.shotuk.org/resources/shot-bite-no-17/

Meet the experts – Near Miss Reporting & Wrong Blood in Tube (WBIT)
https://www.shotuk.org/resources/meet-the-experts-near-miss-reporting-wrong-blood-in-tube-wbit/

Near Miss Events and Incident Investigation Webinar 2021
https://www.shotuk.org/resources/near-miss-events-and-incident-investigation-webinar-2021/

SHOT
Serious Hazards of Transfusion

15a Near Miss - Wrong Blood in Tube (WBIT) n=899

Authors: Vera Rosa, Paula Bolton-Maggs, April Molloy and Caryn Hughes

Definition:

Blood is taken from the wrong patient and is labelled with the intended patient's details.

Blood is taken from the intended patient but labelled with another patient's details.

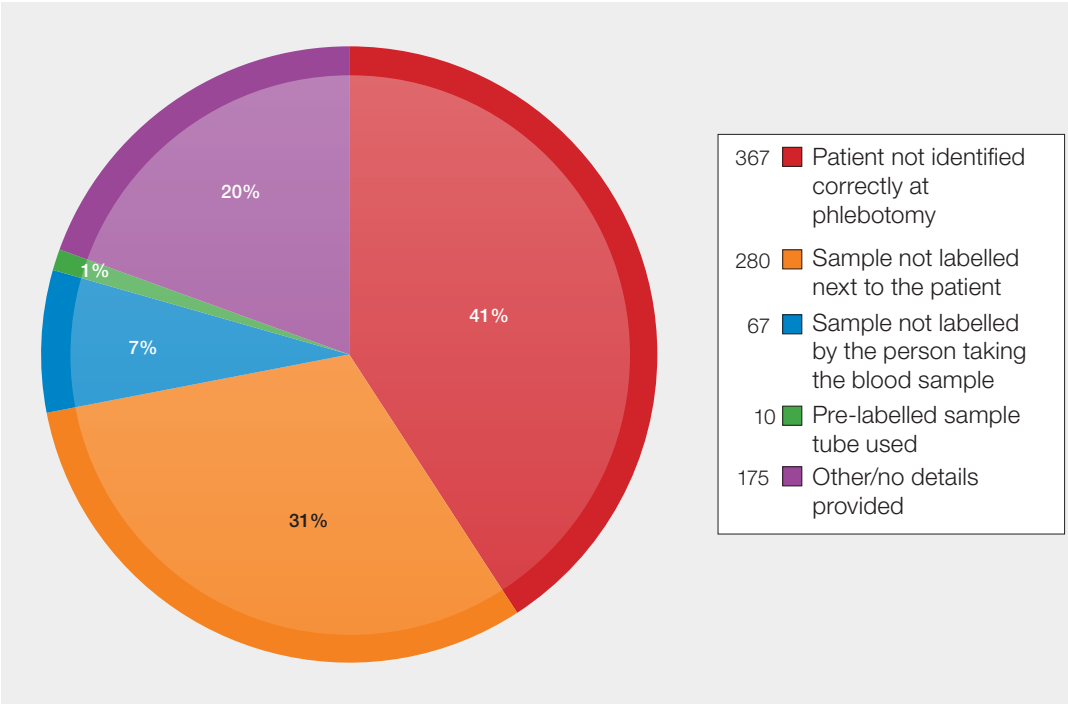
Introduction

WBIT reports continue to represent the largest proportion of near miss (NM) events reported to SHOT, 899/1408 (63.8%). However, for the first time in the last 4 years there has been a decrease in the number of WBIT events (2023 n=986, 2022 n=890, 2021 n=734).

Causes of error

As in previous years, WBIT errors resulted from the same two leading causes: failure to identify the patient correctly at phlebotomy, 367/899 (40.8%), or labelling the samples away from the patient, 280/899 (31.1%) (Figure 15a.1). Notably, both errors occurred together in 169/691 (24.5%) with or without additional errors in the same event.

Figure 15a.1: Primary errors leading to WBIT in 2024 (n=899)



Most sample labels were handwritten, 733/899 (81.5%) compared to electronic labelling, 108/899 (12.0%). There were 58 cases where this information was not provided.

Case 15a.1: Multiple errors contributed to the misidentification of a sample

Patient 1 in the emergency department (ED) required a red cell transfusion and was identified by an incorrect bed space number instead of their name. During a single venepuncture, the doctor took both a group and screen sample and a confirmatory sample from patient 2, with no positive patient identification performed. The doctor labelled the first sample away from the patient's side using patient 1's details. They then asked a nurse to label the second sample and send it to the laboratory. The error was finally detected when the blood samples were rejected by the transfusion laboratory. Patient 1

had a historical group of O D-negative with positive red cell antibodies, while the current samples grouped as AB D-positive.

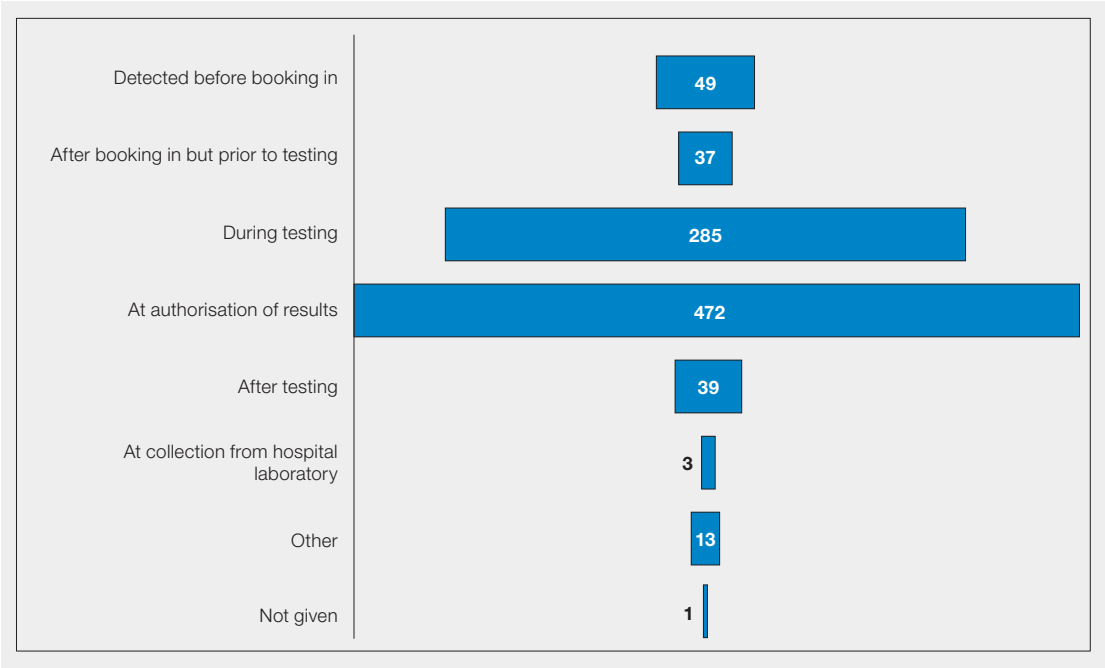
This case highlights multiple errors in positive patient identification and sample labelling procedures which could have resulted in an ABO-incompatible (ABOi) red cell transfusion. The first and the confirmatory samples for group and screen should be taken at different times, preferably by different staff. The person taking the sample should be the person that labels it, and this must be done next to the patient. In this case, all three of the most common causes of errors as shown in Figure 15a.1 were present.

Point of detection

Most errors were detected during laboratory testing or at authorisation of results, 757/899 (84.2%) (Figure 15a.2). In 95 WBIT cases, the clinical team fortuitously identified the error and contacted the laboratory team. In most of these, 73/95 (76.8%), the laboratory was informed before testing the sample.

In 2024, as in previous years, some SHOT reports identified cases where the initial error occurred some years ago (historical WBIT). These events could only be detected due to the confirmatory sample, showing the importance of this requirement in transfusion safety.

Figure 15a.2: Point in the process where the error was detected in WBIT reported in 2024 (n=899)



ABO-incompatibility

In 448/899 (49.8%) WBIT cases, details of both the blood group of the patient and of the intended blood component were provided. In 184/448 (41.1%) cases, if the WBIT had not been detected, the patient could have received an ABOi red cell transfusion with a risk of serious harm or death (Table 15a.1).

Table 15a.1: Potential for ABO-incompatible transfusion in 2024

		Group of the blood component that might have been transfused					
		A	B	AB	O	Compatible	Incompatible
Patient blood group	A	31	26	7	106	137	33
	B	26	9	3	36	45	29
	AB	8	4	2	11	25	0
	O	79	32	11	57	57	122
	Totals	**144**	**71**	**23**	**210**	**264**	**184**

Errors in maternity cases n=349

Cases from maternity departments accounted for 349/899 (38.8%) of the total of WBIT reports (a slight decrease from 388 in 2023 and 369 in 2022). A large proportion of WBIT from maternity cases were attributed to midwives, accounting for 258/349 (73.9%), followed by healthcare assistants at 26/349 (7.4%). The largest number of WBIT events related to all areas of pregnancy and childbirth (classified as 'maternity') were noted in obstetrics, comprising 205/349 (58.7%), followed by antenatal clinics, 85/349 (24.4%). Additional cases were recorded in community hospitals/clinics, 17/349 (4.9%), general practice surgeries, 5/349 (1.4%), and 6 instances occurred at the patient's home.

In maternity cases, patients not being identified correctly at phlebotomy was the primary error in 133/349 (38.1%) cases, samples not being labelled next to the patient in 118/349 (33.8%) cases and samples not being labelled by the person who took the sample in 29/349 (8.3%) cases. In 3 maternity reports the primary error was use of a pre-labelled sample tube. Handwritten labelling in maternity cases represented 302/349 (86.5%) of the WBIT reports, while electronic devices were used in 28/349 (8.0%) to label the sample.

It is crucial to exercise care and to correctly identify patients; 123/349 (35.2%) of maternity cases involved patients without an identity band in place, and 11/349 (3.2%) maternity incidents were attributed to factors such as confusion, sedation or communication barriers for individuals who were not English speakers. A further 24/349 (6.9%) cases involved patients with the same or similar name.

Errors may appear concentrated in specific staff groups simply because they are the ones commonly performing certain tasks and hence may be overrepresented in the reported cases. It is important to note that variable reporting levels with degrees of under-reporting from some areas, and the fact that SHOT is a passive haemovigilance system, means that caution must be exercised when interpreting these results. Staff are encouraged to review WBIT locally and identify areas for improvement.

Case 15a.2: Language barrier contributes to inaccurate patient identification

A patient was referred with incorrect details, which were used to update their electronic patient record. An interpreter assisted during the antenatal clinic visit, but it was unclear whether the patient confirmed their name and date of birth or if their details were checked. There was no evidence of positive patient identification at phlebotomy leading to a WBIT which was identified during testing based on discrepancies with their previous results.

Positive patient identification and timely labelling of samples next to the patient are crucial for patient safety, particularly for mother and cord samples. Numerous sample transpositions were identified during testing. These included:

- Mother and cord mix-ups (n=42), 2 identified through high-throughput non-invasive prenatal testing for fetal *RHD* genotype (cffDNA) discrepancies
- Confusion in sampling twins (n=4)
- Samples taken from the wrong placenta (n=3)

Errors in non-maternity cases n=550

Non-maternity WBIT cases represented more than half of the total of WBIT reported to SHOT, 550/899 (61.2%). In non-maternity cases, 431/550 (78.4%) sample labels were handwritten, and 80/550 (14.5%) samples were electronically labelled.

Emergency department n=160

Reports from the ED accounted for 160/550 (29.1%) in non-maternity settings and represented the largest number of WBIT events reported in a single non-maternity department. Of these, 121 samples were handwritten and 24 were labelled using electronic devices (unknown in 15).

There were 130/160 (81.3%) cases from the ED where the staff group involved in collecting WBIT transfusion samples was provided. The most frequently reported staff group were nurses accounting for 73/130 (56.2%) of the events, 71 from registered nurses and 2 from student nurses. This staff group was followed by medical staff identified in 30/130 (23.1%) events and healthcare assistants in 21/130 (16.2%).

Wards n=237

The highest proportion of errors were reported from wards, 237/550 (43.1%) likely because this includes a wide range of locations and specialities across healthcare organisations.

When assessing the staff groups who were involved in the WBIT events, 99/237 (41.8%) were samples taken by nurses, 54/237 (22.8%) by doctors, 21/237 (8.9%) by healthcare assistants, and 17/237 (7.2%) by phlebotomists.

Human factors

Review of the responses provided in the SHOT Human Factors Investigation Tool (HFIT) showed that situational factors had the biggest impact on the WBIT events.

Table 15a.2: Human factors identified as the most important contributory factors for the WBIT events in 2024

	Emergency department (n=142)	Wards (n=204)	Maternity (n=306)
Communication and culture	15 (10.6%)	29 (14.2%)	42 (13.7%)
Local working conditions	28 (19.7%)	38 (18.6%)	63 (20.6%)
Situational factors	70 (49.3%)	108 (52.9%)	161 (52.6%)
Organisational factors	29 (20.4%)	29 (14.2%)	38 (12.4%)
External factors	0 (0%)	0 (0%)	2 (0.7%)

The most commonly reported situational factor was ‘mismatch between workload and staff’, 227/899 (25.3%). Both non-maternity cases from ED and maternity cases reported that their environment hindered their work, 120/509 (23.6%). Wards cited the ‘incident was more likely to occur with the particular staff involved’, 64/237 (27.0%). More information on the human factors findings can be found in the supplementary data, which includes cases of corridor care and lack of adequate space for safe practice.

Conclusion

For the first time in 4 years, the number of reported incidents of WBIT has decreased. Data from HFIT has highlighted several challenges faced by healthcare providers, including difficulties caring for patients on trolleys in corridor settings with limited space, and the distractions of working in crowded and noisy

environments. Additionally, issues such as the lack of essential equipment or malfunctioning devices, such as printers, have been reported. Staffing pressures and inadequate training have been cited as factors leaving staff overwhelmed, which can increase the risk of oversight and error. WBIT can result in ABOi transfusions and must be prevented to enhance safety.

Recommended resources

Pre-transfusion Blood Sampling Process
https://www.youtube.com/watch?v=Vq3R3mQW-9A

Webinar on accurate and complete patient identification for safe transfusion in adults
https://www.shotuk.org/resources/webinar-on-accurate-complete-patient-identification-for-safe-transfusions-in-adults/

Webinar on accurate and complete patient identification for safe transfusion in paediatrics
https://www.shotuk.org/resources/webinar-on-accurate-and-complete-patient-identification-for-safe-transfusion-in-paediatrics/

Wrong Blood in Tube (WBIT) investigation template
https://www.shotuk.org/resources/wrong-blood-in-tube-wbit-investigation-template/

Right Blood Right Patient (RBRP) n=278

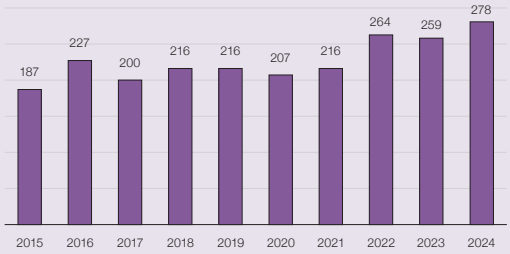
16

Authors: Caryn Hughes, Nicola Swarbrick, and Victoria Tuckley

Headline data 2024

Number of reports n=278
Deaths n=0
Major morbidity n=0

RBRP reports by year



Demographic data

Male n=144
Female n=128
Unknown n=6

Adults n=261
Paediatric n=16
Unknown n=1

Blood component data

Red cells n=237
Platelets n=14
Fresh frozen plasma (FFP) n=4
Cryoprecipitate n=2
Multiple components n=21

Key findings:

- The number of RBRP events have increased in 2024
- Errors with patient demographic details, in the laboratory and clinical settings, accounted for 62.6% of all RBRP errors
- Sample taking accounted for 46.6% of the errors in the clinical areas and component labelling errors made up 56.9% in the laboratory
- The number of laboratory near miss (NM) RBRP errors increased considerably in 2024, with the majority being component labelling errors

Gaps identified:

- Positive patient identification (PPID) processes not being undertaken at critical steps in the transfusion process
- Pre-transfusion checklists being used as a 'tick box' exercise rather that the last opportunity to detect errors
- Errors may have been detected in 97.2% of laboratory cases with the effective use of a laboratory exit check

Good practice:

- Human factors principles were applied during incident investigations in 80.9% of cases
- In NM RBRP, 73.6% errors were detected at the pre-administration checks, with 67.2% using a formal pre-administration checklist

Next steps:

- Consistent use of safety checks, such as laboratory exit checks, collection checks and the consistent use of pre-administration checklists should be embedded throughout the transfusion pathway

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

Incidents where a patient was transfused correctly despite one or more serious identification (ID) or prescription errors which in other circumstances might have led to an incorrect blood component transfused (IBCT).

Introduction

There were 278 cases reported in 2024, an increase from 2023 (n=259). Clinical cases accounted for 206/278 (74.1%) and laboratory cases 72/278 (25.9%). Although more cases were reported in 2024, the overall ratio between clinical and laboratory cases remained largely unchanged from 2023.

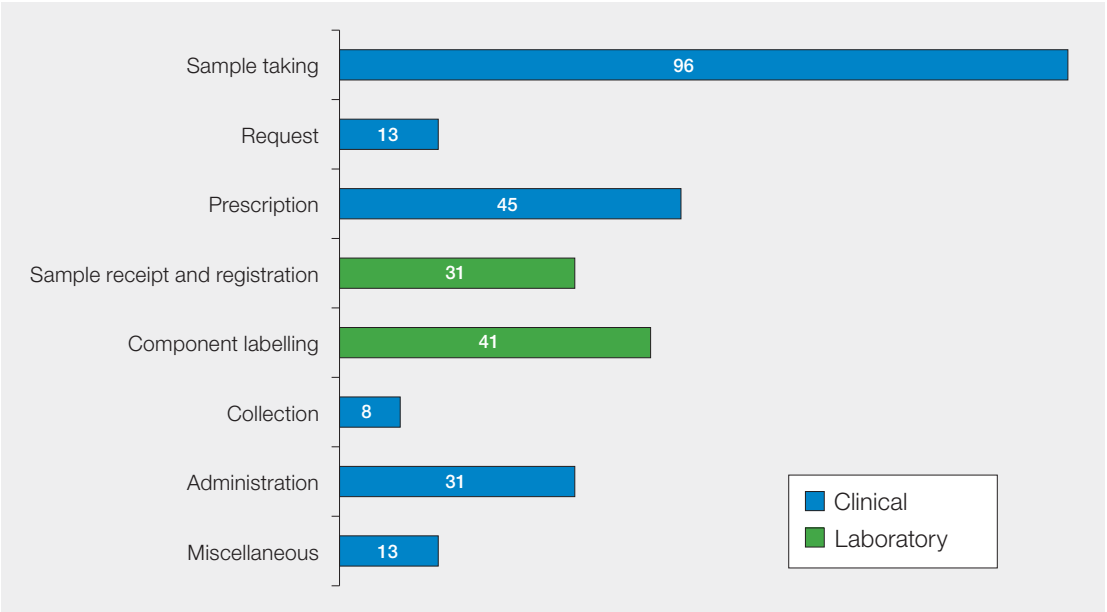
Deaths and major morbidity related to transfusion n=0

There were no deaths or major morbidity related to the transfusion because of RBRP errors.

Overview of RBRP errors

Primary RBRP errors occurred in 7 out of the 10 steps in the transfusion process. Errors with patient demographic details, in the laboratory and clinical settings, accounted for 174/278 (62.6%) of all RBRP errors. Patient identification (PID) errors occurred throughout all steps of the transfusion process, with 108/174 (62.1%) due to sample and request form transcription errors in the clinical area. Laboratory errors accounted for 39/174 (22.4%) where the patient identification information was not heeded, data was incorrectly selected and/or entered into the laboratory information management system (LIMS) or there was a failure in linking, merging or reconciling computer records.

Figure 16.1: RBRP classified by the step in the transfusion process where the primary error occurred in 2024 (n=278)



Clinical RBRP errors n=206

Clinical RBRP reports were mainly due to PID errors, 135/206 (65.5%). In addition, there were 13 patients who were transfused without a wristband and 9 cases where no pre-administration check was undertaken. The largest number of errors in clinical RBRP occurred at sampling, 96/206 (46.6%), followed by prescription errors, 45/206 (21.8%), administration errors, 31/206 (15.0%) and incorrect details on the transfusion request in 13/206 (6.3%). Collection errors accounted for 8/206 (3.9%) cases and of these 4/8 involved information technology (IT).

Case 16.1: Blood component administered on wrong date of birth (DOB)

A patient had two group and screen (G&S) samples taken for a planned transfusion. There was no ID band on the patient during sample taking as they were an outpatient. They had three entries on the electronic patient record (EPR) system with different hospital numbers, with various DOB. An incorrect DOB was recorded on the sample, which matched the request and the record in the laboratory. The chosen entry had the correct National Health Service (NHS) number but incorrect year of birth.

They were subsequently admitted for an elective transfusion. Two units of red blood cells were issued, which were labelled with an incorrect DOB. On admission, and while preparing the patient for transfusion, it was noticed that the DOB was incorrect. The EPR system was updated with the correct details and a new ID band was printed and attached to the patient. The red cells were collected and during the pre-administration check, it was noted that the DOB was incorrect on the blood component label. The staff member checking the component was the same one who had updated the DOB on the system. They felt confident that this was the right blood for the patient and, after informing the second checker of this, decided to continue with the transfusion. After starting the transfusion, they sought advice from the haematologist about how to proceed with the second unit. They were advised to repeat the G&S sample and to request that the transfusion laboratory re-issue the red cells based on the correct details.

Following local investigation, several contributory factors were noted. The LIMS also had two different entries for the same patient, with different DOB but the same NHS number. When selecting the patient on the order communications system, assumptions were made that the patient details with the NHS number were correct. There were missed opportunities to detect the PID error at phlebotomy, collection and during pre-administration checks.

Prescription errors n=45

Of the 206 clinical errors, 45/206 (21.8%) were related to errors in the prescription step of the transfusion pathway. These included 6 cases where incorrect patient identification details were recorded on the prescription and 1 prescription had the details of two different patients. In 5 cases, the prescription contained incomplete/incorrect information and in 1 case the incorrect patient had been selected from the EPR. A pre-administration checklist had been used in 28/45 (62.2%) of these cases but failed to detect the error.

Pre-administration checklists

A pre-administration checklist was used in 123/206 (59.7%) of all clinical RBRP cases but failed to detect the error. In 77/206 (37.4%) it was stated that a checklist was either not used, not available or not applicable. In 6 cases, no information was provided.

Laboratory RBRP errors n=72

Component labelling errors n=41

Transposition of compatibility labels between blood components intended for the same patient accounted for 15/41 (36.6%) of errors. In 9/41 (22.0%) cases patient demographics recorded on compatibility labels at the point of issuing were incorrect.

Sample receipt and registration errors n=31

Sample receipt and registration errors mostly occurred due to patient identification when booking in samples onto the LIMS, later leading to errors on the compatibility label, 30/31 (96.8%). These errors were largely due to demographic data entry errors, 23/31 (74.2%), available information on the sample or request form not heeded, 5/31 (16.1%) and 2 cases where the information was missed on the request.

Errors related to the use of IT occurred in 54/72 (75.0%) cases.

Case 16.2: Over 100 units transfused with incorrect patient ID due to inoperative IT caused by a cyber-attack

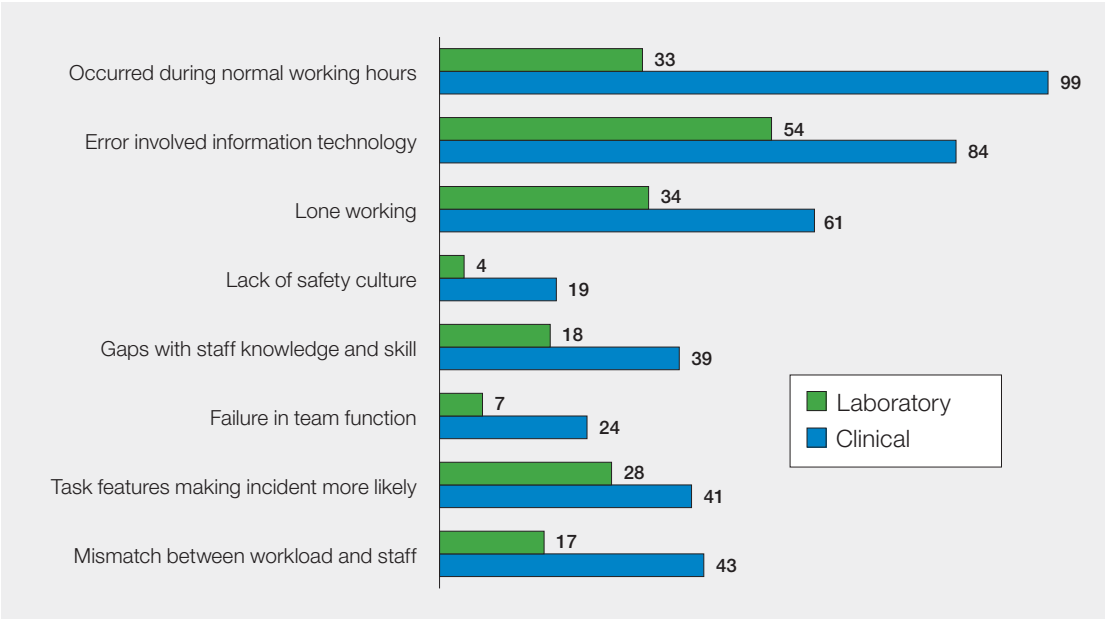
In June 2024, the blood transfusion laboratory was a victim of a ransomware cyber-attack on an unprecedented scale. The attack encrypted the entire LIMS and associated systems rendering it inoperative. The laboratory had to revert to manual processes to issue blood components. The LIMS was restored in September 2024. During this period, errors on the compatibility label were frequent due to the manual processes. A total of 540 patient records were created with incorrect details and used to issue blood components. Of these, 373/540 (69.1%) were detected by the quality management system. There were 167/540 (30.9%) patients where units were available for collection in the remote issue refrigerator with incorrect details on the compatibility label. Units for 148 patients were collected from the blood refrigerator with incorrect details. In 136 cases, the kiosk did not alert the user to the incorrect details. In 12 cases the kiosk did alert the user, but the units were still collected. In 133 cases, the unit with incorrect details arrived at the patients' side. In 16 cases, the error was detected by the pre-administration check and not transfused. In 40 cases a manual pre-administration check failed to prevent the transfusion. In 50 cases, an electronic pre-administration check alerted the user to the error, but the transfusion continued.

This case highlights the risk of manual based processes in transfusion despite rigorous double checking. The huge influence of situational and system factors, particularly the ambiguity of the first and middle name fields as displayed throughout the current EPR system contributed to the errors.

Contributory factors to RBRP errors

Investigations into errors often consider limited causes and contributing factors without fully understanding why the failure occurred in the first place. Recognising the immediate and underlying reason of the error, not only helps prevent a recurrence, but it also facilitates the design of effective control measures and improves patient safety (Brennan & Oeppen, 2022).

Figure 16.2: Contributory factors in RBRP errors reported in 2024



Near miss RBRP cases n=125

There were 125 near miss RBRP incidents, 19/125 (15.2%) originated in the clinical area and 106/125 (84.8%) in the laboratory. Component labelling errors, 86/106 (81.1%) accounted for most cases in the laboratory. In the clinical area, sampling errors, 7/19 (36.8%) were the most reported.

Learning point

- Thorough investigation of near miss RBRP incidents is vital as findings from these investigations will provide 'free' learning opportunities

Conclusion

Pre-administration safety checks, undertaken at the patients' side can detect RBRP errors, but these must be carried out correctly to be effective. The errors which resulted in RBRP incidents are the same errors which can cause patient harm in different circumstances. There is a misconception that IT solutions are the only way to prevent RBRP errors. However, some reports highlight that unless these systems are integrated and used correctly, errors are still possible. Overreliance on IT systems introduces the potential for error and staff should be aware of downtime procedures, as emphasised by the recent cyber-attacks. Organisations should ensure procedures within business continuity plans are risk assessed and cover IT downtime.

Recommended resources

SHOT Video: The Pre-administration Blood Component Transfusion Bedside Check 2020
https://www.shotuk.org/resources/pre-administration-blood-component-checking-process/

Safe Transfusion Practice: Transfusion Checklist
https://www.shotuk.org/resources/safe-transfusion-practice-transfusion-checklist/

SCRIPT Using Information Technology for Safe Transfusion
https://www.shotuk.org/resources/using-information-technology-for-safe-transfusion/

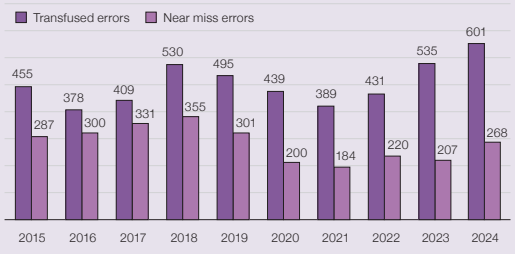
17 Laboratory Errors n=869 (601 transfused errors and 268 near miss)

Authors: Victoria Tuckley, Nicola Swarbrick, Pete Baker and Heather Clarke

Headline data 2024

Number of reports n=869
Deaths n=3
Major morbidity n=4

Laboratory reports by year



Key findings:

- Overall increase in cases (transfused errors and near miss (NM)) with a large increase in laboratory delays adversely impacting patient management
- An increase in the number of deaths, all due to laboratory delays
- ABO-incompatible (ABOi) plasma transfusions continue to be reported
- Most laboratory errors occur at the testing step

Gaps identified:

- Worsening knowledge gaps in laboratory staff were evident in many cases
- Inadequate staffing levels and skills to match workload and distribution between shifts
- Communication between the laboratory and clinical area
- Inadequate functionality or configuration in laboratory information management systems (LIMS) allowing inappropriate electronic issue
- Delays in timely provision of blood components in urgent and emergency situations including failure to use concessionary release when appropriate

Good practice:

- Fewer errors reported at the component selection and handling and storage steps
- Over half of reports stated implementation of a component exit check (54.4% in 2024, up from 47.1% in 2023)
- Please see Chapter 5, Acknowledging Continuing Excellence in Transfusion (ACE), Case 5.2 in Table 5.1 for a description of the laboratory and clinical area collaborating to ensure timely provision of blood components for a patient with complex antibodies

Next steps:

- A 'back to basics' approach should be taken when reviewing training materials to ensure staff have the essential knowledge and skills to carry out routine and non-routine tasks
- Business continuity plans (BCP) should be regularly reviewed, updated and followed. These should cover various scenarios to ensure resilience

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Introduction

There has been an increase in laboratory errors in 2024 to 601 from 535 in 2023. The largest increase has been seen in the delayed transfusion category which has more than doubled (120 from 56 in 2023). Near miss reports have also increased to 268 from 207 in 2023. There were 3 cases of ABOi transfusion caused by laboratory errors in 2024, all were related to plasma components.

Deaths related to transfusion n=3

In 2024, there were 3 deaths related to errors within the laboratory. This is an increase from previous years, as between the years 2019-2023 there were 3 deaths related to transfusion laboratory errors in total. All deaths in 2024 related to delays in blood transfusion.

One death was probably related to the transfusion (imputability 2). This case involved delayed release of blood components in a neonate with suspected disseminated intravascular coagulation (DIC). Suitable components were available but were not issued.

Case 17.1: Avoidable delays, contributing to death, whilst waiting for the most suitable component (imputability 2 – probable)

Platelets were requested for an extremely unwell neonate with a platelet count of 13x10^9/L. The laboratory had no neonatal platelets in stock and notified the clinical team that there would be a 5-hour delay in obtaining them from the local Blood Service due to geographical reasons. The patient required transfer to a specialist hospital, and this could not occur until the baby was transfused. Whilst waiting, the patient received other blood components, as DIC was suspected. The medical team queried availability of platelets once again and were notified none were available. A suitable adult therapeutic dose of platelets was available but were reserved for another patient. These were administered to the neonate after a 6-hour delay, following discussions with the neonatal consultant. This caused delay in treatment escalation (central line insertion) and transfer to the specialist hospital, resulting in the death of the patient.

The investigation found gaps in communication and misunderstanding of urgency by the laboratory staff. Communication tools were developed by the laboratory for use on the neonatal ward and standard operating procedures were updated to clarify the use of reserved components in an emergency.

Learning points

- In urgent situations where the most appropriate blood components are not available; every effort must be made to ensure a suitable alternative is provided in a timely manner
- Clear communication is a key aspect of safe patient care. Standard protocols and closed loop communication may help prevent misunderstandings

In 2 further cases, the deaths were possibly related to the transfusion (imputability 1); 1 case involved challenges in obtaining blood components for a patient having a cardiac arrest, and 1 case was due to a 2-hour delay in provision of fresh frozen plasma (FFP) during a major haemorrhage protocol (MHP) activation following a plasma thawer malfunction.

Major morbidity n=4

There were 4 cases of major morbidity caused by laboratory errors in 2024, 3 were due to laboratory delays in the availability of blood components and the 4th was due to sensitisation to the K antigen in a patient of childbearing potential. This occurred following a historical component selection error which was discovered in 2024.

Case 17.2: Delay in blood availability during LIMS downtime, with incomplete guidance in business continuity plans

A septic patient required the support of multiple blood components during an urgent invasive

procedure. The LIMS had entered unscheduled downtime 1 hour earlier due to a cyber-attack, therefore all components required manual issue and hand labelling. Labelling and second checking took around 30 minutes instead of the normal timeframe (<20 minutes) for group-specific issue. Due to haemodynamic instability and delay in receiving blood components, the patient was transferred to the intensive care unit for stabilisation. The patient's condition deteriorated, and they returned to theatre 4 hours later.

Laboratory staff were aware of the LIMS unavailability but did not know when it would be restored. There was a high level of stress in issuing blood components for the rest of the surgical list, as well as meeting the demand for top-up requests as there was a delay in cancellation of non-urgent procedures. Staff members focused their efforts on providing blood components for this bleeding patient and had good communication with the theatre team. In total, nine units of red cells, one adult therapeutic dose of platelets, one unit of FFP and two units of cryoprecipitate were administered over a 3-hour period. Emergency issue red cells were available in the satellite refrigerator but not used as both the laboratory and the clinical team were hoping the LIMS would be restored shortly, not being aware of the true cause of the downtime. Upon review, the BCP in place at the time did not consider the complete loss of information technology (IT) systems in the laboratory. The patient recovered from this procedure and survived.

ABO-incompatible (ABOi) transfusions n=3

Three laboratory errors resulted in ABOi plasma transfusions, 2 of group O FFP to group A patients, and 1 case of group O solvent detergent-FFP (SD-FFP) to a group B patient. According to manufacturer's instructions, SD-FFP should not be used across blood groups (emc, 2025). All involved IT errors, with 2 cases having a note within the LIMS to use group A FFP (as the patients had been temporarily assigned group O in an emergency). These alerts were not automatically generated and therefore not viewed or actioned. In the 3rd case there was lack of functionality with the IT system to prevent the incompatible transfusion taking place.

These cases are discussed in more detail within Chapter 9, Incorrect Blood Component Transfused (IBCT).

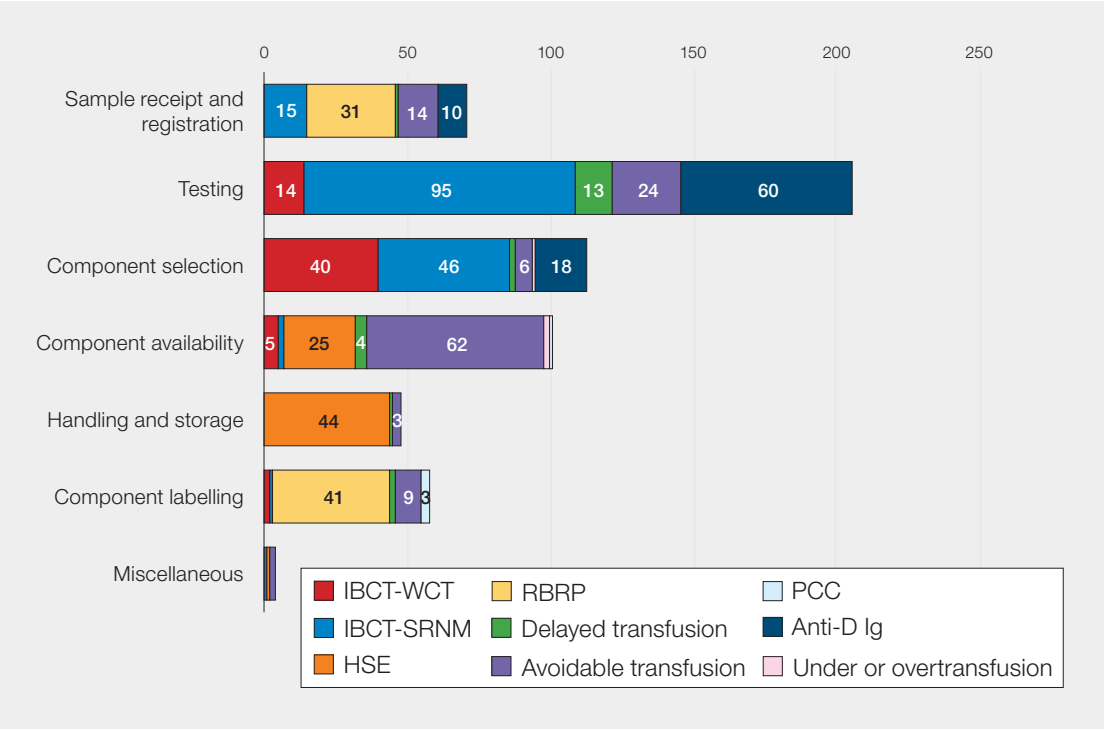
Overview of laboratory errors n=601

The largest number of laboratory error reports related to IBCT-specific requirements not met (SRNM), 160/601 (26.6%), followed by delayed transfusions, 120/601 (20.0%) (Figure 17.1). As in previous years, most errors occurred at the testing step, 206/601 (34.3%), followed by component selection, 113/601 (18.8%). Component availability, 101/601 (16.8%), was the third most common step (Figure 17.2). Further detail on laboratory errors by step is show in Table 17.1.

Figure 17.1: Laboratory errors and near misses in 2024 (n=869)

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

Figure 17.2: Laboratory errors in 2024, classified by the transfusion step where the primary error occurred (n=601)



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

Note: numbers <3 are too small to be annotated on the figure

Laboratory themes 2024

Laboratory delays

Laboratory delays have more than doubled from 56 in 2023 to 120 in 2024. This steep increase has been influenced by several factors (Figure 17.3, please note that denominators are dependent on responses received). Case 17.3 highlights how inappropriate staffing and failure to enact BCP can lead to delays in patient treatment.

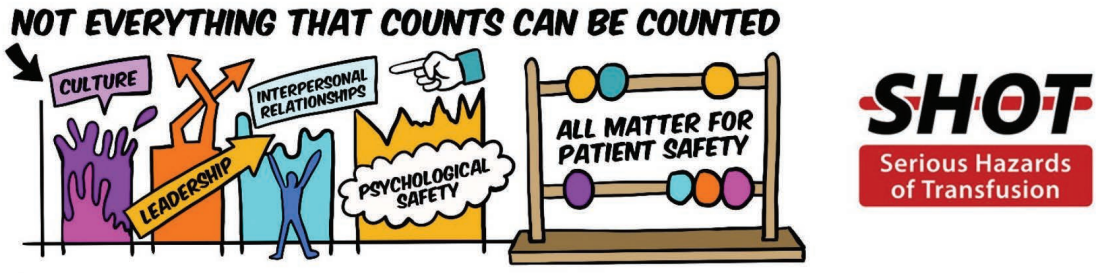
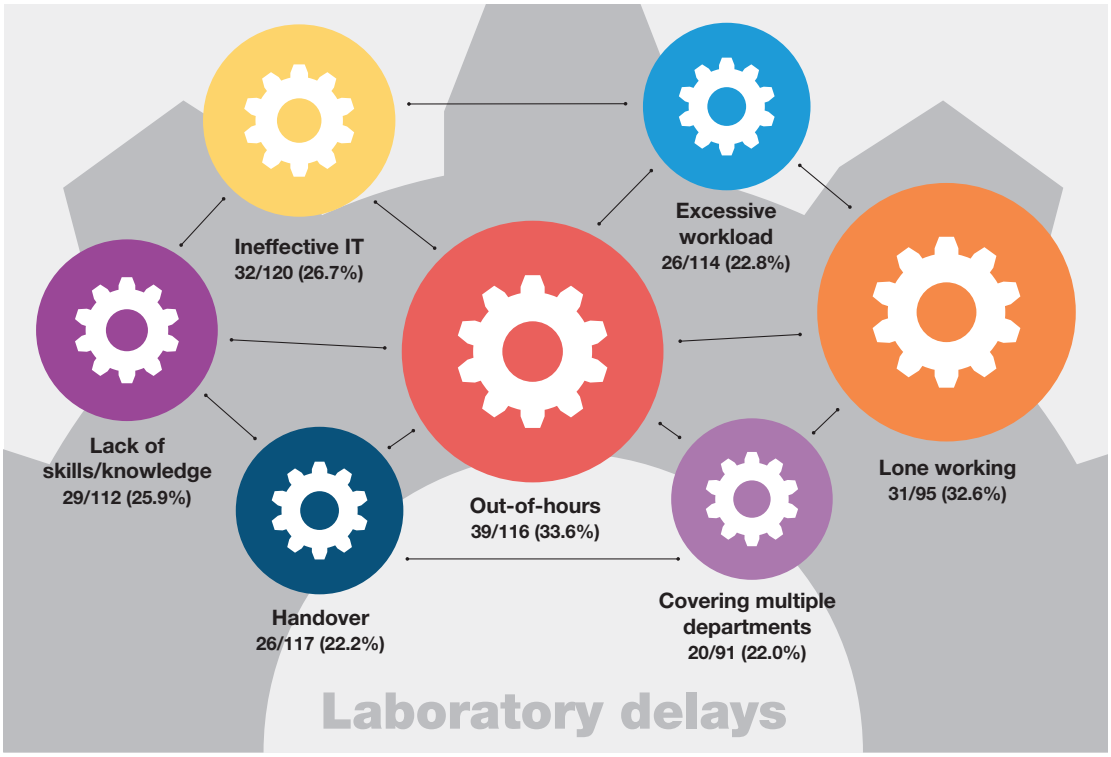


Figure 17.3: Factors interacting to contribute to laboratory delays in 2024



IT=information technology

Case 17.3: Delay in providing group specific blood components during industrial action

Red cell units were requested urgently from the emergency department resuscitation room due to a suspected ruptured ectopic pregnancy. There was a delay in processing the request and red cell units were unavailable in theatre when the haemoglobin was <70g/L. Emergency group O red cells were transfused in the patient's best interest. The patient recovered.

The transfusion delay was caused by significant staffing issues during industrial action for 12 hours overnight on two consecutive days. A single biomedical scientist (BMS) was present to maintain services of specimen reception, haematology, blood transfusion, and biochemistry (to which they had no competency assessment) 'alone, with no type of support'. Management had intended to provide a medical laboratory assistant for support, but this did not occur. Staff availability both substantive and locum/agency had been severely affected. Union representatives and participates in the industrial action had not adhered to the advised minimum safe staffing levels indicated in the BCP. In addition to maintaining critical laboratory functions, the BMS experienced 'undue pressure' to send biochemistry samples to a partner laboratory every hour. This pressure contributed to the delay in processing the request. The night BMS reported that they were not able to take a break or have any time to eat during this 12-hour night shift. When support was secured, this was not properly allocated to transfusion and instead focused on sending away biochemistry samples as this required less extensive competency assessment. Upon review, BCP were not met, and support was not adequately allocated to haematopathology and transfusion activities.

Learning points

- BCP should be regularly reviewed and cover a wide range of scenarios. If BCP cannot be met this should be escalated immediately to hospital directors
- Inability to provide group-specific blood components in a timely manner results in avoidable use of group O emergency red cells

Patient impact from transfusion delays following laboratory errors

In most cases the delay fortuitously had no adverse clinical impact on the patient. In addition to the cases of major morbidity and deaths reported earlier in this chapter, a further 8 cases recorded further bleeding or a delay in obtaining haemostatic control.

Delays in the provision of blood components may also adversely impact future treatment. In 65/120 (54.2%) reports, subsequent procedures or interventions were delayed or the patient was required to return to hospital for transfusion another day. Healthcare services interact and depend upon intricate logistical pathways; therefore, it is important to minimise any initial avoidable days. This is of particular importance in times where National Health Service (NHS) services are already stretched. Case 17.4 describes a scenario where a delay in transfusion had a significant impact on the patient.

Case 17.4: Complex situation with multiple factors resulting in delays for a patient waiting to receive a heart transplant

A patient arrived on a ward for a potential heart transplant at 13:50, and at 13:55 the transfusion laboratory was informed of the patient's transplant plan. A group and screen (G&S) sample was received in the laboratory at 15:30. The sample was tested and showed a positive antibody screen and required further antibody investigation. At 19:21 the clinician looked on the electronic patient record (EPR) system for the blood results, and everything other than the G&S result was available. In this organisation results are released upon completion of all tests; therefore, this was not viewable by the clinical area.

When contacted by the clinical team, the BMS explained they had had an issue with the blood grouping analyser, but the sample was being processed. Antibody identification was required on the sample, however due to analyser 1 downtime (which was being used for antibody investigation), analyser 2 needed to be set up and quality controlled to perform this test. It was at that point the clinician was informed that the patient had known non-specific red cell antibodies which would require additional tests, including a serological crossmatch. Information regarding previous referral to the reference laboratory was contained in the legacy LIMS but this was not accessed by the BMS at this time. The patient had been receiving a monoclonal antibody therapy at the referring hospital (which can impact blood transfusion results). This treatment plan has not been communicated to the receiving hospital or the laboratory, nor had baseline red cell phenotype been performed. The BMS informed the clinician they would contact them once the sample was processed.

The theatre availability had been scheduled for a 01:00-02:00 start time. When nothing was heard, at 20:58 the clinical team again contacted the laboratory, and spoke to a new BMS on duty, who had not received any handover regarding this patient from their colleague. The BMS stated that it would take a further 90 minutes to provide appropriate antigen-negative components. They informed the clinical team that if suitable red cell units were not available on site, the patient's sample would need to be sent to the reference laboratory. At 22:54, the sample had still not been processed and the BMS stated it would be a further 40 minutes. At 00:04, the BMS called the clinical area to inform them that they didn't have any suitable blood. At this point, the heart was declined as blood would not be available for surgery, and it was offered to another transplant centre. It was later identified that the donor heart was declined by the other transplant centre based on cardiac studies. Valves from the heart were retrieved and successfully used for two further patients.

Upon investigation, the clinical area was not aware that the patient had a history of red cell antibodies as this had never been reported to the transplant coordinators during the previous two failed transplant calls the patient had undergone. The second BMS was lone working and had a higher than usual workload due to a cyber-attack, where additional checks using alternative databases impacted the BMS's ability to carry out required tasks. Multiple improvement actions were implemented including training and education for clinical staff regarding monoclonal antibody therapy, improved visibility of results in the EPR for all clinical staff, and regular testing of antibody status for patients on solid organ transplant waiting lists.

This case demonstrates gaps in communication between the laboratory and clinical team, and a lack of handover causing delay. This could have had disastrous consequences for the patient if they had been deemed clinically fit to receive the transplant. Open lines of communication with the consultant haematologist and the reference laboratory may have been able to secure safe blood for the patient by

referring samples to the reference laboratory when the initial analyser malfunction happened.

The incident was investigated thoroughly demonstrating a clear commitment to transparency, learning and improvement. The team's efforts to share insights widely reflects true system leadership and contributes to safer care across the wider healthcare community.

SHOT and UKNEQAS performed an exercise in 2023 regarding uninterpretable groups, which contained questions regarding policies surrounding organ transplant (UKNEQAS, UKTLC and SHOT, 2024). In total, 151/254 (59.4%) of laboratories did not have a policy which covers what to do if they are contacted by an organ donor liaison team for blood grouping results. Two recommendations from this report are shown as learning points below.

Learning points

- There must be robust business continuity procedures in place which should include processes to follow during IT and equipment downtime
- There must be clear communication between all teams involved in patient care, particularly when patients receive shared care between organisations and clinical teams
- There must be processes in place to ensure adequate transfer of information during shift handover to ensure patient safety
- There should be a proactive approach to managing patients due to receive monoclonal antibody treatment in relation to baseline group, antibody screen and phenotyping (BSH, 2017)
- Findings from local investigations should be shared widely where possible to promote learning and embed safer practices throughout all aspects of patient care

Underlying causes of laboratory delays

Reports were further examined to determine the source of the error within the transfusion laboratory. Delays were mostly due to incomplete/inaccurate communication, 43/120 (35.8%), or knowledge 28/120 (23.3%), technical problems (e.g., IT downtime, non-functional equipment), 24/120 (20.0%), and excessive workload 15/120 (12.5%).

The SHOT team have developed a communication toolkit in collaboration with Royal Cornwall hospital. These include:

- A template to help clarify clinical expectations regarding product availability, storage conditions and nomenclature
- An updated handover form first provided in the supplementary material of the 2019 Annual SHOT Report
- A telephone request form which includes key questions for laboratory staff to ask to identify transfusion priorities (e.g., emergency, urgent etc.)
- SHOT Bite No. 34: Switching to group-specific red blood cells in major haemorrhage

These editable resources are available for laboratories to use if they would find them beneficial, and links can be found in the recommended resources at the end of this chapter.

Clinical groups at higher risk of laboratory delays

Reports were evaluated to determine whether the underlying clinical situation could have potentially influenced the delay. A total of 65 reports were identified, with the most common factor being patients with complex antibodies, 19/65 (29.2%), followed by a haemorrhage, 17/65 (26.2%), and pregnancy or neonatal-related conditions, 10/65 (15.4%) (Table 17.2). Knowledge gaps in staff surrounding the clinical condition or the situation or the condition itself was complex and required additional steps within laboratory processes were found in reports included in this evaluation.

Table 17.2: Clinical factors which influenced laboratory errors in 2024

Influencing factor	Number of cases
Complex antibodies	19
Haemorrhage	17
Pregnancy or neonatal	10
Regularly transfused	7
Platelet related	6
Specialist component	2
Condition requiring irradiated components	1
Granulocytes	1
Paediatric	1
Transplant	1
Total	**65**

To optimise safety and ensure timely provision of blood components, especially in an emergency, the following actions are suggested:

- Review local standard operating procedures to ensure that sufficient detail is included regarding the clinical situations listed above and the potential impact
- Guidance should be provided for escalation when staff are unaware of the correct actions to take
- Provide educational sessions on these conditions to address knowledge gaps. These could include scenario drills, specific journal-based learning topics, and these particular conditions could be included in competency assessments

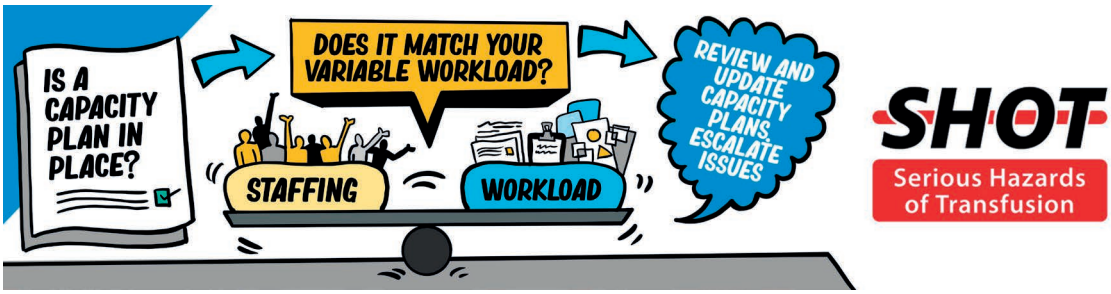
The SHOT team have developed an audit/debrief tool that laboratories can use if a delay occurs in their organisation. This document was created to help identify the source of error including contributory factors, highlight knowledge gaps within the laboratory, and suggest supporting actions that could be implemented. Furthermore, this tool may be used to update team members following an incidence of delay. It can be reviewed as part of the regular audit schedule to monitor and trend delays within laboratories. This is available in the recommended resources at the end of this chapter.

Staffing, workload and work distribution

Workload and its distribution had a notable impact upon laboratory errors in 2024. A total of 112/601 (18.6%) reports stated that there was a mismatch between workload and staff capacity at the time of the incident. This is an increase from the 72/535 (13.5%) identified in 2023. The Infected Blood Inquiry (IBI) recommendation 7C states 'Transfusion laboratories should be staffed (and resourced) adequately to meet the requirements of their functions' (IBI, 2024). Although progress has been made in many working channels, the 2024 data suggest that improvement in this area is still required. Transfusion laboratories are still struggling to obtain adequate funding for staffing provision, and to recruit and retain staff with an appropriate level of knowledge and experience.

There has been an increase in the number of reports which stated the member of staff was lone working when the error occurred, 198/601 (32.9%) in 2024 from 160/535 (29.9%) in 2023. Furthermore, in 117/601 (19.5%) reports, the staff member was covering more than one laboratory department at the time of the event (e.g., haematology). A total of 213/513 (41.5%) reports stated that the error occurred outside of normal working hours (this figure does not include data for anti-D immunoglobulin (Ig) related incidents as this question is not requested in the anti-D Ig data set).

This trend could also signify that there is an increased workload outside of routine hours, as outpatient facilities are being provided into the evenings and at the weekend more often. Considerations should be made to increasing staff outside of normal working hours if workload exceeds the amount which is acceptable for one individual during routine hours. Actions should also be taken to minimise work that needs to be undertaken outside routine hours when an individual is working by themselves. Assessing and redistributing the workload throughout the day may help reduce errors.

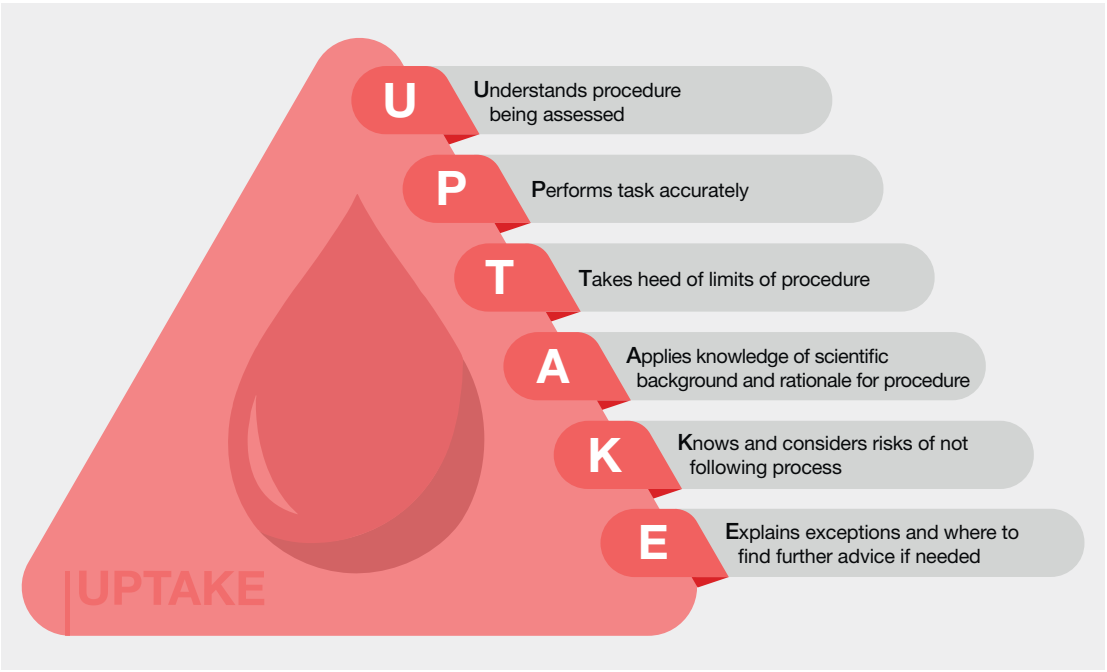


Knowledge

There has been an increase in the number of reports which stated that lack of knowledge was a contributing factor to the error, 159/601 (26.5%) compared to 124/535 (23.2%) in 2023. Gaps within transfusion knowledge were evident in errors occurring at the testing step. Within the IBCT-SRNM category there were 95 testing errors including, 44/95 (46.3%) incomplete testing errors and 33/95 (34.7%) inappropriate use of electronic issue. The second largest group of testing errors were anti-D Ig errors, of these 37/60 (61.7%) were related to incorrect interpretation of results or lack of knowledge. These types of errors can have significant clinical impact and may lead to formation of an antibody or result in transfusion reaction. Where anti-D Ig is omitted, this poses a danger to current and future pregnancies. Following incidents where gaps in knowledge are identified, appropriate action plans should be put into place to address these gaps to prevent patient harm.

Most staff involved in laboratory errors were competency assessed, 467/601 (77.7%) but the event still occurred. Analysis of SHOT laboratory data from 2017-2023 showed that 93.5% of individuals who made the primary error were competency-assessed and 91.8% of the assessments were in date (Tuckley, et al., 2023). Competency assessments should not be a tick box exercise. It is important that competency assessments are sufficiently detailed and cover essential knowledge required to perform the tasks. The content of these should be reviewed regularly. They should include non-routine scenarios in addition to frequently encountered cases. They should also contain questions regarding where to go for advice in complex situations. As competency assessments represent knowledge and skills held at one moment in time, it may be necessary to perform these more regularly when the subject is not frequently encountered in the organisation, staff are inexperienced, have limited time 'on bench' in the laboratory, or work outside of routine hours regularly. The UPTAKE model of competency assessment (first published in the 2019 Annual SHOT Report) shown in Figure 17.4 remains relevant (Narayan, et al., 2020).

Figure 17.4: UPTAKE competency assessment model



https://www.shotuk.org/resources/uptake-competency-assessment/

An example of a competency assessment aligned to the UPTAKE principles is available within the supplementary material for this chapter.

Case 9.4 in Chapter 9, Incorrect Blood Component Transfused (IBCT) describes a case of a BMS working alone, out-of-hours, in the absence of a completed competency assessment.

A decrease in quality of knowledge in newly qualified BMS staff has been noted by other organisations. In 2022, the UK Transfusion Laboratory Collaborative (UKTLC) survey noted an overall dissatisfaction with the candidates for transfusion BMS posts (UKTLC and SHOT, 2022). A repeat survey is scheduled to take place in 2025 and should reflect any changes.

In England, Transfusion 2024 (T2024) have published findings regarding the quality of transfusion education given during Institute of Biomedical Science (IBMS) accredited undergraduate degrees. Gaps and variation in the quality and quantity of transfusion education provided were found. This included one site which did not cover any transfusion in its degree programme and 11% of sites which did not offer any transfusion practical training (Caulfield, 2024). The T2024 project team are working in collaboration with the IBMS, university lecturers and practice educators to produce resources for lecturers, and other knowledge-based resources for newly qualified BMS.

Information technology (IT)

IT was identified as a contributory factor in 329/601 (54.7%) laboratory errors. The most common factor was warning flags not being actioned, 52/329 (15.8%), followed by a lack of functionality to support safe transfusion practice, 47/329 (14.3%), and systems not being used correctly, 32/329 (9.7%) (Table 17.3).

Table 17.3: IT impact on laboratory errors in 2024 (n=329)

Type of IT error	Number of reports
Warning flag in place but not heeded	52
Lack of functionality/algorithms in the system to support safe practice	47
System not used correctly	32
Computer or other IT systems failure	31
IT could have prevented the error	28
Failure to use flags and/or logic rules	26
Failure to link, merge or reconcile computer records	23
Warning flag not updated or disabled	15
Failure to consult or identify historical record	13
Other	13
Incorrect patient details selected from IT system	12
System not configured correctly	11
Lack of interfacing/interoperability	10
Incorrect results entered or accessed manually	9
Printing error	7
Total	**329**

Case 17.5: LIMS allowed electronic issue of red cells in presence of manual blood group serology

A unit of red cells was electronically issued to a child, using a sample that had a manual blood group completed due to the small volume. The LIMS had no functionality to differentiate between an automated or manual ABO blood group and inappropriately allowed red cells to be released via electronic issue when manual testing was required. The member of staff performing the test was lone working and demonstrated incomplete knowledge during the event review. Previous and subsequent blood groups were performed automatically and had no serological abnormalities. The patient had no adverse outcome.

Of note, the investigation was in depth and identified many systemic and human factors including staff fatigue, with appropriate CAPA implemented.

Learning point

- When procuring a new LIMS or reviewing existing systems, it is essential that electronic issue functions are only used if they comply with British Society for Haematology guidance (Staves, et al., 2024)

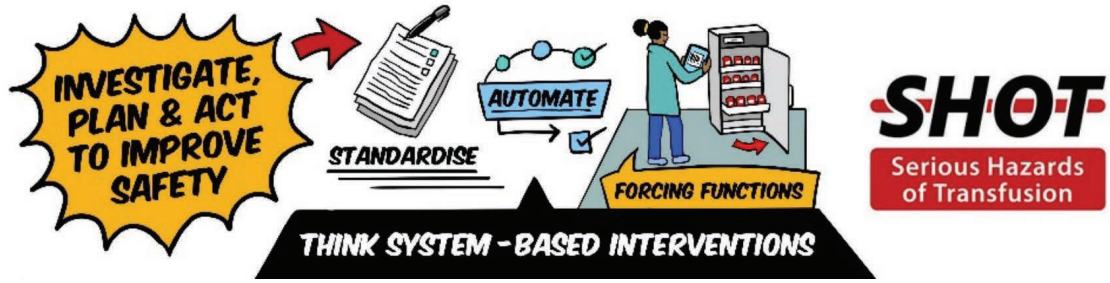
Cyber-attack impact

In June 2024, a cyber-attack impacted the transfusion IT systems of several major hospitals in London (NHSE, 2024d). In total, 43 transfusion incidents reported to SHOT in 2024 were identified as being related to this cyber-attack. Some of these reports are known to have impacted multiple patients and further reports may still be received. Of these reports 36/43 (83.7%) were laboratory errors. These are summarised in Table 17.4.

Table 17.4: Laboratory errors with cyber-attack impact on 2024 (n=36)

SHOT category	Number of reports	Percentage
IBCT-WCT	3	8.3%
IBCT-SRNM	3	8.3%
Delayed transfusion	4	11.1%
RBRP	7	19.5%
Anti-D Ig	1	2.8%
NM-other	18	50.0%
Total	**36**	**100%**

Of note, 1 case of major morbidity was impacted by the cyber-attacks (Case 17.2). This resulted in a delay providing blood components for a patient who started bleeding during surgery, as described under major morbidity section.



Errors by step in the laboratory process

Table 17.1: Laboratory errors by step in the transfusion process for 2024 (n=869)

Transfusion step	Transfused errors	Near miss	Pressure points
Sample receipt and registration n=104	**n=71↑↑**	**n=33↑**	• Data entry during sample registration which is not detected later in the process • Incorrect recording of request communicated verbally, or information not noticed on transfusion request forms causing delays
Testing n=221	**n=206↑**	**n=15↓**	• Incomplete or inappropriate testing which should have been prevented by IT systems • Limitations of technology • Misinterpretation of results or knowledge gaps regarding testing procedure
Component selection n=172	**n=113↓**	**n=59↓**	• Selection of specific antigen-negative components (particularly in multi-transfused patients) • Selection of inappropriate ABO/D group components for transplant patients • Lack of provision of D-negative components when required
Component labelling n=174	**n=58↑**	**n=116↑↑**	• Manual entry of patient details, handwriting or transcription into electronic blood management systems • Transposition of labels between components
Component availability n=117	**n=101↑↑↑**	**n=16↑**	• Components not available in the expected timeframe • Lack of knowledge of when alternative components may be suitable and timely actions needed • Components being available to collect after expiry (components and sample validity)
Component handling and storage n=76	**n=48↓**	**n=28↑**	• Response to equipment deficiencies and temperature monitoring alarms • Suboptimal inventory management resulting in the collection of expired blood components

Arrows denote increase or decrease relative to 2023. There were an additional 4 errors and 1 NM classed as 'miscellaneous' which are discussed in the supplementary material for this chapter

Laboratory near misses (NM) n=268

Laboratory NM reports have increased to 268 in 2024 from 207 in 2023. There has been a large increase in the number of NM RBRP, 106/268 (39.6%) in 2024 from 80/207 (38.6%) in 2023. Of the NM RBRP incidents, 86/106 (81.1%) occurred at the component labelling step. NM IBCT-WCT have increased to 59/268 (22.0%) from 33/207 (15.9%) in 2023, and NM IBCT-SRNM to 44/268 (16.4%) from 32/207 (15.5%).

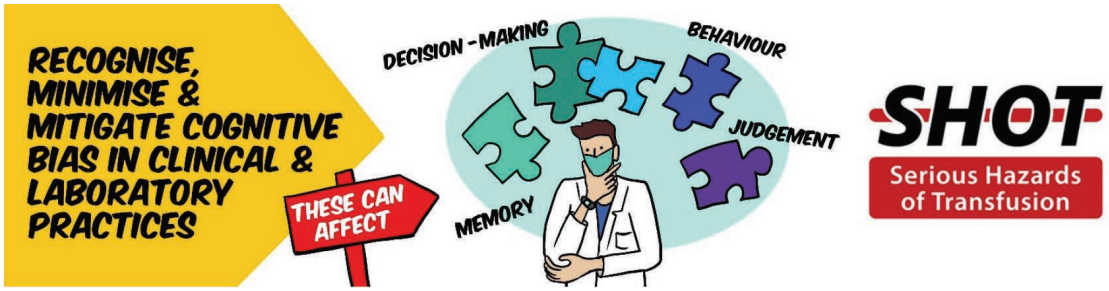
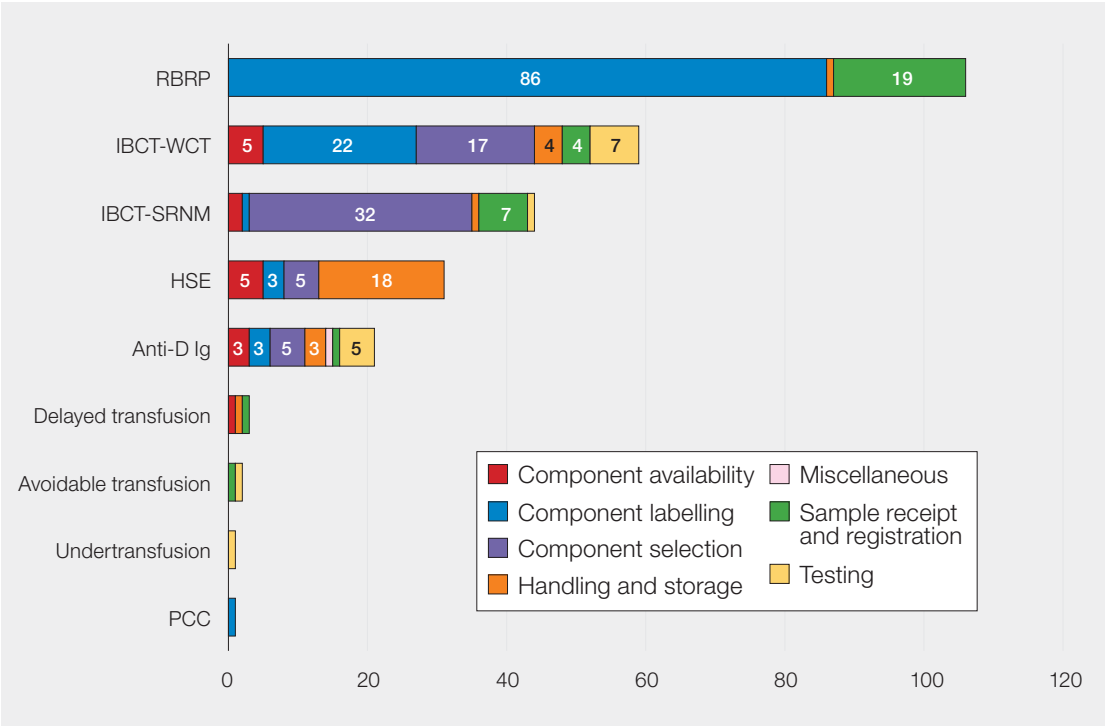


Figure 17.5: Laboratory NM classified by the transfusion step where the primary error occurred in 2024 (n=268)



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

Note: numbers <3 are too small to be annotated on the figure

A more detailed analysis of NM data can be found within the supplementary material for this chapter.

Conclusion

The 2024 data reflects a particularly challenging year for staff working in transfusion laboratories. Factors which have been previously highlighted such as staffing, knowledge and culture, persist and seem to be worsening. These have been compounded by issues such as cyber-attacks, industrial action, and an overall increase in organisational pressures within the NHS. Worsening patient impact is now evident and is reflected in the steep rise in laboratory delays. Patient harm has occured as a result of these delays.

In these challenging times, it is vital that laboratories maintain strong links and relationships with clinical areas. Non-technical skills such as empathy are needed more than ever by all staff. SHOT would once again like to extend its gratitude to transfusion staff for their tireless work and commitment to patient care, which has been clearly demonstrated within investigations, and is shown in Case 17.3. This commitment is also demonstrated within Chapter 5, Acknowledging Continuing Excellence in Transfusion (ACE).

Meaningful intervention is needed from senior hospital management, leadership teams and political leaders to improve working conditions within laboratories and to retain staff within this vital profession. The IBMS (2025), in their response to NHS England's 2025 priorities and operational planning guidance stated a need for:

- Expansion of training pathways and career progression opportunities to address workforce shortages
- Increased investment in pathology networks and community diagnostic centres
- Greater recognition of BMS' expertise in strategic NHS workforce planning
- Clear career progression pathways that enable BMS to take on advanced clinical roles, ensuring their skills are fully utilised in decision-making and service development

Without such intervention it may be possible that this caring workforce may feel more de-valued, lose momentum and the few occurrences of slips and gaps in care may ultimately turn into a landslide. SHOT

has observed and highlighted that breaking point was being approached, it may now have been passed, and the service seems to now be struggling and broken, hopefully not beyond repair.

UKTLC update

Author: Kerry Dowling, UKTLC chair

Laboratory errors continue to rise, and the same themes remain key in the root cause analyses (staffing levels, education, workload, IT).

The Infected Blood Inquiry recommendations and Transfusion Transformation are aiming to address some of these huge challenges that transfusion laboratories are facing. During the past year the UKTLC have represented on a variety of these groups using data and learning from UKTLC surveys to inform change. The UKTLC has also presented on the challenges that transfusion laboratories are facing and the findings of the culture survey at several supplier meetings and BBTS.

The UKTLC page on the SHOT website continues to be updated with useful links and useful examples such as capacity plans. Previous UKTLC surveys and the culture survey recommendations are also available on the UKTLC page (https://www.shotuk.org/transfusion-laboratory-collaborative-uktlc/).

There are also many valuable resources on the SCRIPT page to support with IT challenges https://www.shotuk.org/script/.

During 2025 the UKTLC will be repeating our survey, we would appreciate as much feedback from the transfusion community as possible. This data will continue to inform Transfusion Transformation and IBI working groups.

We are keen to continue listening and sharing learning from laboratories and welcome suggestions for resources, questions and feedback.

UKNEQAS update

Authors: Claire Witham and Richard Haggas, UK National External Quality Assurance Scheme Blood Transfusion Laboratory Practice (NEQAS BTLP)

Participation in external quality assessment (EQA) offers the chance to learn from errors. The errors made in EQA exercises can be viewed as 'free lessons', as appropriate corrective action can be taken before the error occurs with a clinical sample. The aims of all UK NEQAS Schemes are primarily educational. Provision of identical samples to all participating laboratories allows inter-laboratory comparison and identifies the overall level of performance within the UK. Learning from others through reports of exercises, leads to an improvement within the UK as a whole; specific strengths and weaknesses can be identified, driving change. National guidelines are reinforced and the need for new guidelines identified.

The aim of the UK NEQAS pre-transfusion testing (PTT) programme is to assess performance in undertaking standard pre-transfusion serological testing, and decision-making with respect to selection of red cells for crossmatching or issue. Additional educational elements are sometimes included with PTT exercises, e.g., testing in an emergency situation, or selection of components for a range of patient types.

One of the main aims of exercise 24E9 was to assess the limit of detection of anti-D. The exercise included two samples, made from material provided by the European Organisation of External Quality Assurance Providers in Laboratory Medicine (EQALM), Patients 2 and 3, contained anti-D at low concentrations (approximately 0.05 and 0.025 IU/mL respectively). These levels are at a lower concentration than typically required in anti-D control antisera. All participating UK and Republic of Ireland (RoI) laboratories detected the anti-D (0.05IU/mL) in Patient 2, with the majority of participants reporting a 2+ reaction strength. Three laboratories recorded an additional specificity in Patient 2 which was not present (two anti-C^w and one anti-C). The anti-D (0.025IU/mL) in Patient 3 was not detected in the indirect antiglobulin test (IAT) antibody screen by 36% of participating laboratories worldwide (35% in UK and RoI), and this was not linked to any particular technology.

In exercise 24R10, two samples were included to assess the ability to interpret 'unusual' ABO typing results. Patient 1 was group O D-positive with a missing reverse group reaction vs B cells, and Patient

2 was D-negative with a positive direct antiglobulin test (DAT), which can occasionally produce false positive reactions vs. the anti-D and inert control wells in some column agglutination grouping cards. In this exercise there were no errors in interpretation of D group for the positive DAT (Patient 2). For Patient 1, the majority stated either 'uninterpretable' for the ABO group alone or for both the ABO and D group. Seventy-six (20.9%) laboratories made an interpretation of O D-positive and one laboratory, recording a forward group of O and a reverse group of B, made an interpretation of B D-Positive for Patient 1. Reverse groups in ABO grouping are intended to show the presence of anti-A and / or anti-B in a patient's plasma and this provides confirmation of the forward (cell) group obtained. Reverse groups can be weak or absent in babies, elderly patients, or in patients with some clinical conditions, especially post stem cell transplant. Had this been a clinical sample requiring blood for transfusion, the selection of group B red cells may not have produced an incompatible crossmatch reaction and an ABO-mismatched transfusion given. Laboratories should have policies for dealing with absent reverse groups which consider all of these factors and should suggest further steps, including testing a reverse group at lower temperatures or using a greater plasma to red cell ratio.

These exercises represent similar clinical samples being tested for the first time, i.e., there is no previous transfusion history available, and under such circumstances, the BSH guidelines recommend the level of testing that should be performed (Milkins, et al., 2013). In 2024, an additional 'emergency scenario' was sent with exercise 24R5. This comprised of a whole blood sample for grouping and an accompanying questionnaire. The aims were to explore testing undertaken within 10 minutes where blood is required in an emergency situation, and the provision of red cells and components (where the major haemorrhage protocol is not triggered). The BSH criteria for issue of group specific red cells is that following the initial group, a further test to detect ABO-incompatibility should be performed, i.e., a second group on a new aliquot of the primary sample, or an immediate spin crossmatch (ISXM) (Milkins, et al., 2013). In 27% of laboratories performing a group within 10 minutes BSH criteria for issuing group specific blood were met, whilst 73% did not include a second test to detect ABO-incompatibility. 9/111 (8%) laboratories, completing a blood group within 10 minutes, issued group specific red cells based on testing that did not meet the BSH criteria. Conversely, 21/111 (19%) met the criteria for issue of group specific red cells but issued group O at 10 minutes.

Recommended resources

Laboratory communications toolkit (phone log, handover log & guidance for clinical areas)
https://www.shotuk.org/resources/laboratory-communications-toolkit/

Transfusion delays investigation tool
https://www.shotuk.org/resources/transfusion-delays-investigation-tool/

Laboratory competency UPTAKE model
https://www.shotuk.org/resources/uptake-competency-assessment/

SHOT Safety Notice 01: Emergency preparedness in the transfusion laboratory in case of total power outage
https://www.shotuk.org/resources/safety-alerts-and-safety-notices/safety-notices/

RCI Assist - Referral Support Tool
https://nationalbloodtransfusion.co.uk/transfusion-2024/deliverable/b3/documents-and-resources

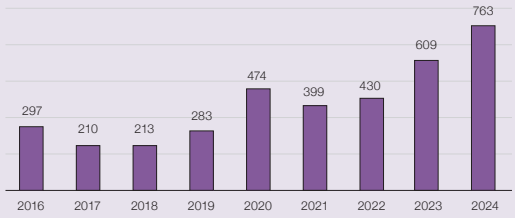
Errors Related to Information Technology (IT) n=763

Authors: Jennifer Davies and Megan Rowley

Headline data 2024

Number of reports n=763
Deaths n=2
Major morbidity n=7

IT-related cases by year



Key findings:

- Reports of IT-related errors to SHOT are rising each year
- This trend reflects both the increased use of IT systems and growing awareness of their role in supporting safe clinical practice
- There is a growing dependence on IT in both clinical and laboratory environments to enhance safety and efficiency

Gaps identified:

- IT systems not configured correctly and/or lack of algorithms in IT to support safe practice
- Ineffective training for staff using new IT systems leads to errors
- Alerts and warnings not heeded
- Manual downtime processes may not be effective in preventing error
- Failure to consider human factors and ergonomics when implementing IT systems

Good practice:

- Near misses (NM) detected by electronic systems used as part of pre-administration checks
- IT identified as an improvement action in incident investigations
- Laboratory information management systems (LIMS) being upgraded and networked to meet changing delivery of healthcare

Next steps:

- There is a need for critical function standards for IT systems, including LIMS, electronic blood management systems (EBMS) and electronic patient records (EPR)/order communications to reflect available national guidelines
- Consideration of human factors and ergonomics principles during all stages of implementation to ensure optimal use of the IT systems

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

This chapter includes transfusion adverse events that relate to laboratory information management systems, other IT systems, and related equipment used in the delivery of hospital transfusion services.

Cases include events where IT systems may have caused or contributed to reported errors, as well as instances where IT systems were used incorrectly. When hospitals recommended IT-based solutions for corrective or preventive actions in response to these errors, those cases have also been included.

Introduction

There is increasing recognition that information technology can support safe practice and provide a barrier to error. IT systems and automation are well established in healthcare and are increasingly being adopted in transfusion practice. SHOT continues to promote vein-to-vein IT systems (clinical and laboratory) for patient safety and the United Kingdom Transfusion Laboratory Collaborative (UKTLC) standards reiterate this (Dowling, et al., 2024). There is evidence that IT supports safe transfusion practice in the clinical setting (Murphy, et al., 2019; Staples, et al., 2019). This facilitates accurate sample labelling, collection of the correct blood component from storage devices, and electronic patient identification (ID) checks at the administration of components. In the UKTLC survey, only 21.6% respondents had IT systems that covered the full vein-to-vein transfusion process, from sample labelling to administration and 31.1% had no clinical EBMS at all (UKTLC and SHOT, 2022).

The cases for this chapter are identified by the reporters in answer to the question – '*Did IT contribute to this error?*' and further reports are included following analysis by the SHOT incident specialists. Gaps in IT provision as well as corrective and preventive action in response to errors have been identified in response to the question – *'Could the error have been prevented by using IT?'*. To avoid duplication, examples related to IT included in other chapters are not covered in this chapter, including reference to the impact of various cyber-attacks experienced during this reporting year.

Overview of cases

The number of IT-related cases in 2024 has increased compared to the 2023 data. The rising proportion of IT errors could potentially reflect improved visibility, reliance on digital systems and increased staff awareness. A total of 763 cases are reviewed for 2024; 623 related to blood components, and a further 140 that involved anti-D immunoglobulin (Ig) (Table 18.1). The main increase in reports related to right blood right patient (RBRP) errors and delayed transfusions. The errors attributed to the laboratory accounted for 329/763 (43.1%) of the total IT errors.

Table 18.1: Primary reporting categories containing errors related to information technology in 2024

Primary reporting category for IT cases	Laboratory errors	Clinical errors	Number of cases 2024	Number of cases 2023
Incorrect blood component transfused-wrong component transfused (IBCT-WCT)	48	17	**65**	78
IBCT- specific requirements not met (IBCT-SRNM)	102	63	**165**	163
Right blood right patient (RBRP)	54	84	**138**	86
Delayed transfusion	32	33	**65**	37
Avoidable transfusion	5	28	**33**	22
Under or overtransfusion	0	3	**3**	4
Prothrombin complex concentrates (PCC)	3	8	**11**	6
Handling and storage errors (HSE)	49	94	**143**	145
Anti-D Ig administration errors	36	104	**140**	68
Total	**329**	**434**	**763**	**609**

Incorrect blood component transfused-wrong component transfused (IBCT-WCT) n=65

Errors mainly resulted in transfusion of a blood component of an incorrect ABO/D group for the patient, 47/65 (72.3%) or transfusion to the wrong patient, 10/65 (15.4%). IT errors were evident in all 4 cases of ABO-incompatible transfusions with LIMS alerts either overridden or a lack of optimal functionality in the IT systems. Errors in transplant patients (haemopoietic stem cell transplant (HSCT) or solid organ transplant (SOT)) accounted for 19/65 (29.2%) cases, D-positive components were inadvertently transfused to D-negative patients in 15/65 (23.1%) cases and in 14/65 (21.5%) cases incorrect, but ABO-compatible components were transfused. The involvement of IT in the error was varied (full details in the supplementary information) but mainly related to warning flags not being heeded, lack of algorithms for safe practice, and reporters noting that IT could have prevented the error had it been available or used.

Incorrect blood component transfused-specific requirements not met (IBCT-SRNM) n=165

IT was noted to be involved in transfusion of blood components that did not match the specific requirements in 165 cases. These mainly related to transfusion of non-irradiated components, 54/165 (32.7%), inappropriate electronic issue of red cells, 36/165 (21.8%), red cells that did not meet antigen-matching criteria, 29/165 (17.6%) and incomplete testing performed, 15/165 (9.1%). The majority of these errors occurred in the laboratory, 102/165 (61.8%). Further details on the involvement of IT can be seen in the supplementary material.

Case 18.1: Antigen-positive red cells transfused to a patient with red cell antibodies

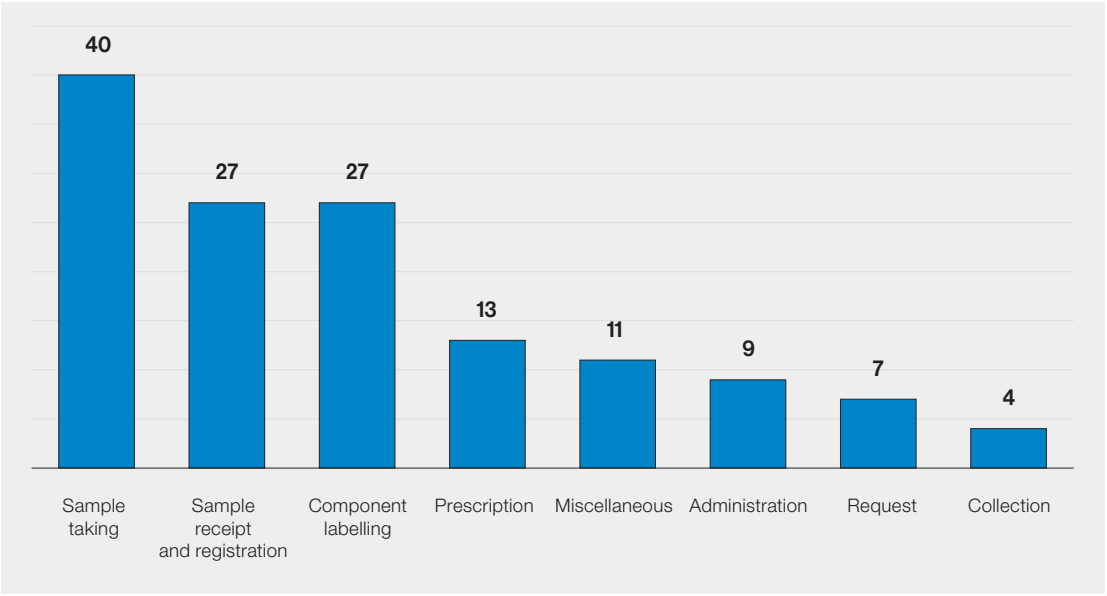
A patient with historic red cell antibodies required a transfusion. Recent antibody screens were negative. The current LIMS contained a 'critical note' that the legacy LIMS should be interrogated for details of the antibody. This note was missed by the biomedical scientist (BMS) and the sample for crossmatch was the first to be tested in the new LIMS. Antigen-positive red cell units were selected, crossmatched and transfused to the patient.

The investigation noted that antibody specificities had not been migrated to the new LIMS from the original legacy LIMS. Correct selection of blood components was reliant on staff reading a note and reviewing the legacy LIMS. Data migration is a critical part of implementation of a new LIMS. Specific transfusion requirements should be migrated to the correct data fields in the new LIMS to drive algorithms for safe practice. Data cleansing may be required prior to migration (Staves, et al., 2024).

Right blood right patient (RBRP) n=138

The majority of RBRP events involving IT occurred in the clinical setting, 84/138 (60.9%). IT-related errors were noted across a range of transfusion process steps (Figure 18.1). In 40/138 (29.0%) cases, sample labelling errors were not noted in the laboratory and blood components were released with incorrect patient details. These may have been prevented by electronic sample labelling. Sample receipt and registration and blood component labelling steps each accounted for 27/138 (19.6%) cases. Of the sample receipt and registration errors, 17/27 (63.0%) could have been prevented had interoperability between the patient administration system (PAS) and LIMS been in place. In 10/27 (37.0%) component labelling errors, the error could have been prevented by an electronic label verification system. Eleven errors occurred at patient registration, incorrect patient details at this stage in the process affect all downstream steps. These are included as 'miscellaneous' in Figure 18.1.

Figure 18.1: RBRP IT-related errors according to the step in the transfusion process in 2024 (n=138)



In many cases, it was noted that IT could have identified or prevented the error prior to administration, 59/138 (42.8%), most notably the potential use of electronic patient identification systems at administration. These would provide an alert to the user when incorrect patient details are present on blood component labels. In 15/138 (10.9%) cases, an electronic patient identification system was used, and provided an alert, but this was ignored. IT downtime accounted for 10/138 (7.2%) cases, including cyber-attack events. Ineffective downtimes processes failed to identify errors. Further details on the contribution of IT can be found in the supplementary information.

Handling and storage errors (HSE) n=143

IT involvement was noted in 143 HSE errors (Table 18.2) resulting from IT systems not being used correctly, 60/143 (42.0%), warning flags not heeded, 21/143 (14.7%) and IT failures, 17/143 (11.9%). In 17/143 (11.9%) cases, it was noted that IT could have prevented the error had it been available and used appropriately.

Table 18.2: HSE errors with IT involvement in 2024 (n=143)

HSE error	Number of cases
Administration error	51
Cold chain error	46
Excessive time to transfuse	25
Reservation period excursion	11
Expired blood component transfused	9
Miscellaneous	1
Total	**143**

Case 18.2: Ineffective alarm escalation leads to transfusion of red cell units subjected to temperature excursion

Laboratory support staff doing daily blood refrigerator checks found that there was water on the floor and the refrigerator door was slightly open. There was a unit of red cells in the refrigerator that was due to be returned to stock. The staff member removed the red cell unit and took it back to the laboratory without checking the cold chain. The support staff informed the BMS about the situation, but lack of clear communication meant that the BMS determined the red cell unit was acceptable and returned it to stock. This blood component was subsequently reissued to another patient and transfused. The temperature-monitoring alarm system had previously alerted the hospital

switchboard and two attempts were made to notify the laboratory staff with no response. The temperature-monitoring system then sent an email informing laboratory staff of the situation, but this had not been actioned. Hence the BMS returning the unit to stock was unaware of a temperature excursion.

Although an IT system was in place for monitoring and escalating temperature excursions, the escalation process was ineffective in ensuring that this information was passed to appropriate staff. Alarm escalations should not culminate in emails to inboxes that may not be monitored or actioned in an appropriate and timely manner. This also highlights the importance of clear and concise communication to support safe decisions in transfusion practice.

Delayed transfusion n=65

IT involvement in delayed transfusions mainly related to the system not being used or configured correctly, 23/65 (35.4%), IT failures, 10/65 (15.4%) and lack of functionality to support safe practice, 6/65 (9.2%). IT could have prevented the error in 11/65 (16.9%) cases.

Case 18.3: Incorrect use of electronic blood 'prescribing' system leading to procedure delay

There was a delay to the availability of blood components for a procedure in a patient with known red cell antibodies. A midwife who was not trained in blood authorisation accessed the EPR prescribing system with an intention to request blood components. Completing the EPR prescription did not order the blood components from the laboratory and therefore they were not available. This resulted in a delay to planned surgery whilst suitable red cells were sourced. The procedure went ahead when all blood components were available. The training on the new EPR had not made it clear how to order blood components and who was eligible to prescribe/authorise blood components.

This case demonstrates the importance of staff training and understanding of the functionality and use of new IT systems. Lack of understanding of new systems was a common theme in transfusion delays, suggestive of ineffective training and inadequate support during the implementation phase.

Near miss events n=181

There were 181 near miss events involving IT (see supplementary information), mainly relating to RBRP, 65/181 (35.9%) and IBCT-WCT, 49/181 (27.1%). It was noted that in 42/181 (23.2%) cases, IT could have prevented the error had it been in place and used appropriately. Label verification systems are available and should be utilised to identify label transposition errors prior to release of blood components and blood products. Errors in data entry accounted for 30/181 (16.6%) cases which were noted later in the process.

Improved interfacing from patient administration systems could reduce risk of error. Computer downtimes accounted for 22/181 (12.2%) cases, many related to cyber-attacks. Organisations should ensure that contingency plans are effective at preventing errors in manual processes. In 21 cases, IT alerted the user and error was prevented, mainly as part of the pre-administration checks. Failure to heed alerts, lack of functionality within systems and failure to use systems correctly continue to be a source of error relating to IT (see supplementary information).

Gaps in staff training to use new systems, using ID bands not attached to patients and EPRs allowing override of scanning patient ID bands contributed to errors. It is encouraging to note that IT is being seen as a preventive measure for wrong blood in tube events. It should however be noted that for new IT systems to be effective, they need to be validated, configured and used correctly, with staff appropriately trained in their use. Failure to consider human factors and ergonomics in the design and implementation can lead to unsafe workarounds.

Case 18.4: Ineffective checks during IT downtime

Two units of fresh frozen plasma (FFP) were issued for a patient. One unit was collected and delivered to the clinical area where it was noted that the unit number on the compatibility label did not match the unit number on the component. The FFP unit was returned to the laboratory where transposition of labels between these two units was noted. A label verification step was available within the EBMS,

but this had been disabled, because of a cyber-attack on the LIMS, to allow other functions to work. During this period, label verification became manual but high workload and interruptions increased the risk of human factors leading to error.

Near miss - wrong blood in tube (NM-WBIT) n=220

In the majority of NM-WBIT, it was noted that IT could have prevented the error had it been in place or used, 142/220 (64.5%). In 34/220 cases IT was not used correctly, predominantly using ID bands not attached to the patient. Themes include challenges with using IT systems in outpatient and antenatal clinics where ID bands cannot be printed, issues with labelling cord blood samples due to the delays in registration in electronic patient record systems, connectivity issues and equipment failures.

Case 18.5: Implementation of a new EPR system introduced unsafe workarounds

A group and screen sample grouped as B D-positive, but the patient was known to be O D-positive. The sample was labelled away from the patient. The organisation implemented an EPR system using workstations on wheels that were too large to be moved to near the patient. There was no other mobile equipment that could be used for sample labelling. Prior to the introduction of the new EPR system, transfusion sample labels were generated using a different system (mobile handset and mobile printer) which allowed easy use at the patient's side. The introduction of the new EPR resulted in an increase in 'workarounds' by staff such as using ID bands not attached to the patient.

Learning point

- IT is an integral part of healthcare provision. It is essential that it is configured, validated, and implemented correctly to reduce risk of error. Training for new and current IT systems must be effective and systems must be designed with consideration of human factors and ergonomics

Conclusion

It is important that IT works for healthcare workers and for patient safety needs and that those needs should not be compromised because the system cannot support them. This requires clear standards for safe functionality. These must be met by the systems and suppliers; collaborative working between healthcare organisations and IT suppliers will improve systems for future users and patients. Sharing learning and good practice via SHOT and SHOT UK Collaborative Reviewing and reforming IT Processes in Transfusion (SCRIPT) enables improvement in transfusion safety.

The Infected Blood Inquiry (IBI) report (2024) recommended IT to support safe transfusion practices. Progress with implementation of the IBI recommendations and the National Health Service Blood and Transplant (NHSBT)/National Blood Transfusion Committee (NBTC) Transfusion Transformation program should increase the availability of IT to support transfusion practice in England. The Blood Services in Scotland and Northern Ireland have paved the way for fully interoperable systems, with bi-directional traceability and monitoring of component usage. Similar work to improve transfusion IT systems are ongoing in Wales.

Across the UK, transfusion laboratories are replacing and upgrading LIMS, requiring formal change control and validation. Organisations should review systems to ensure that interoperability is optimised, and manual entry of data minimised or removed. SHOT near miss cases demonstrate how IT is actively preventing errors, particularly as part of the pre-administration checklist. IT has also been noted as effective in prevention of ABOi (Mirrione-Savin, et al., 2025). SHOT data shows that errors may be introduced because of lack of understanding of the functionality, failures in data migration from legacy systems, interoperability challenges and poor training of staff in use of the new IT systems.

EPR systems, which are being increasingly used across the UK to digitise patient records and replace paper systems, provide more than just a repository of patient data. They can support requesting and timely access to results from transfusion tests, prescription/authorisation of blood components and provide decision-support to promote patient blood management. Interoperability between clinical systems as well as links to laboratory systems is vital if all the benefits are to be realised. Equally, failure

to interface systems, or failure to map data to appropriate fields, leads to error and unsafe practice. Concerns around EPR systems were raised in Australia and New Zealand where they were sometimes perceived as suboptimal, being mostly sourced from the United States with variable adaptation to local healthcare systems (Verral, et al., 2019, cited in Crispin, et al., 2022). Lack of regulation and standards for EPR systems has been noted even within the United States (Crispin, et al., 2022).

The challenge for organisations is in the selection, procurement, validation and implementation of IT systems to support safe transfusion practice. Hospital management should ensure that transfusion subject matter experts are included in the selection process for relevant new systems across laboratory and clinical settings. Consideration of human factors and ergonomics should be applied across the life cycle of the system. Transfusion IT must be designed and implemented using a system-thinking approach to reduce the risk of unsafe practices and workarounds (Kushniruk and Borycki, 2023). Staff training must cover all aspects of the transfusion IT system and be supported by functionality that is intuitive to use, with clear flags and warning where patient safety may be compromised.

The use of artificial intelligence (AI) introduces a range of possibilities in the healthcare setting. International Society of Blood Transfusion (ISBT) surveys are evaluating the global current and potential future use of AI in both clinical transfusion and haemovigilance activities. A lack of national or international standards governing the functionality and use of AI in transfusion could translate into ineffective or unsafe practices. SHOT is uniquely poised to gather signals from new technology and inform recommendations and standards for safe practice.

SHOT data continue to demonstrate our reliance on IT and that contingency plans for planned or unplanned downtimes need to be effective in reducing risk of error. The cyber-attacks in 2024 provided a sobering warning of the vulnerability of IT, impact on the local patient population and on the blood supply chain. Organisations should ensure that systems are protected from cyber-attack.

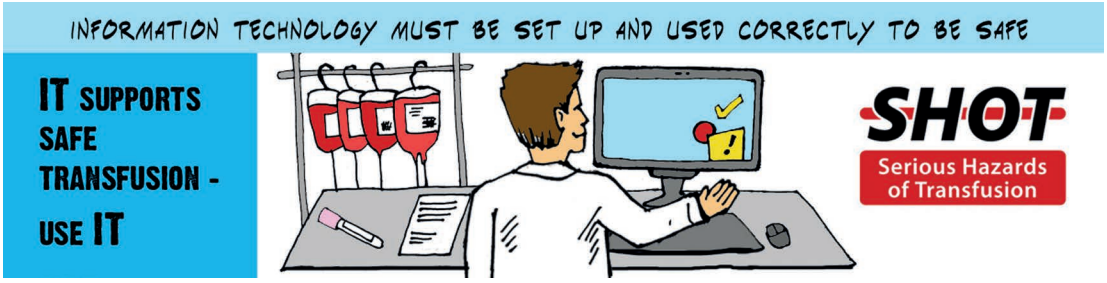
It is acknowledged that IT requires investment, but this can be offset by savings, including staff efficiencies (Health Technology Wales, 2023). A recent publication reviewing implementation of electronic blood transfusion safety systems in three organisations highlights the importance of involving the end users at an early stage in the process, ensuring training is effective, flexibility in system design and provides an overview of the common challenges and solutions to address them (Horck, et al., 2025). This study also identified a lack of inter-organisational platform for shared learning, at national and international level.

The SCRIPT group have created templates and guidance for using IT, including planned and unplanned downtimes. Organisations are encouraged to access these resources to support their own planned or current use of IT. IT supports safe practice, but only if configured, implemented and used correctly. There is a clear need for agreed standards in the UK for transfusion IT systems.

Recommended resources

SHOT UK Collaborative Reviewing and reforming IT Processes in Transfusion (SCRIPT)
https://www.shotuk.org/script/about-script/

SCRIPT Resources
https://www.shotuk.org/script/script-resources/



REACTIONS IN PATIENTS

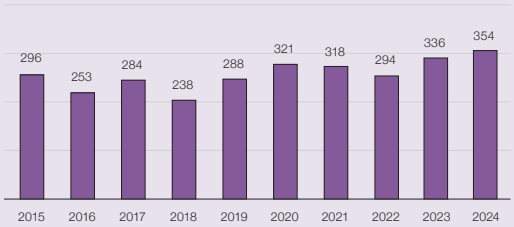
19 Febrile, Allergic, and Hypotensive Reactions (FAHR) n=354

Author: Catherine Booth

Headline data 2024

Number of reports n=354
Deaths n=0
Major morbidity n=113

FAHR reports by year



Demographic data

Male n=158
Female n=196
Adults n=308
Paediatric n=46

Blood component data

Red cells n=192
Platelets n=121
Fresh frozen plasma (FFP) n=20*
Solvent-detergent FFP n=1
Granullocytes n=4
Cryoprecipitate n=2
Multiple components n=14

1 FFP case also involved SD-FFP

Key findings:

- An increase in reports in 2024 – the highest number in 10 years
- Particular increase in reactions to pooled platelets (febrile and allergic)
- One third of patients with febrile reactions were treated inappropriately with antihistamine and/or steroid
- Red cell serological investigations were commonly performed unnecessarily (for allergic reactions or reactions to platelets/plasma)

Gaps identified:

- Lack of knowledge amongst clinicians about appropriate classification and targeted management and investigation of FAHR reactions
- Laboratory staff not empowered to challenge inappropriate requests for investigation

Good practice:

- Inappropriate use of antihistamine and/or steroid for febrile reactions reduced in both 2023 and 2024

Next steps:

- Check out the new SHOT Bite on appropriate investigation of febrile, allergic, and hypotensive reactions

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

The reactions assessed are isolated febrile type (not associated with other specific reaction categories), allergic and hypotensive reactions occurring up to 24 hours following a transfusion of blood or components, for which no other obvious cause is evident.

Introduction

Reactions are classified according to the International Society of Blood Transfusion (ISBT)/International Haemovigilance Network (IHN) definitions, which are summarised in Table 19.1 and have been adopted by the British Society for Haematology (BSH) (Soutar, et al., 2023). Mild reactions are not reportable to SHOT.

Table 19.1: Classification of reactions

CURRENT IHN/SHOT/B(C)SH CLASSIFICATION OF ACUTE TRANSFUSION REACTIONS				SABRE classification
	1=Mild	**2=Moderate**	**3=Severe**	
Febrile type reaction	A temperature ≥ 38°C and a rise between 1°C and 2°C from pre-transfusion values, but no other symptoms/ signs	A rise in temperature of 2°C or more, or fever 39°C or over and/or rigors, chills, other inflammatory symptoms/signs such as myalgia or nausea which precipitate stopping the transfusion	A rise in temperature of 2°C or more, and/or rigors, chills, or fever 39°C or over, or other inflammatory symptoms/signs such as myalgia or nausea which precipitate stopping the transfusion, prompt medical review AND/ OR directly results in, or prolongs hospital stay	**Other/febrile FAHR**
Allergic type reaction	Transient flushing urticaria or rash	Wheeze or angioedema with or without flushing/urticaria/ rash but without respiratory compromise or hypotension	Bronchospasm, stridor, angioedema or circulatory problems which require urgent medical intervention AND/ OR, directly result in or prolong hospital stay, or **Anaphylaxis** (severe, life-threatening, generalised or systemic hypersensitivity reaction with rapidly developing airway AND/ OR breathing AND/OR circulation problems, usually associated with skin and mucosal changes)	**Anaphylaxis/ hypersensitivity/ allergic/FAHR**
Reaction with both allergic and febrile features	Features of mild febrile **and** mild allergic reactions	Features of both allergic and febrile reactions, at least one of which is in the moderate category	Features of both allergic and febrile reactions, at least one of which is in the severe category.	***Other/mixed febrile/allergic FAHR**
Hypotensive reaction		Isolated fall in systolic blood pressure of 30 mm Hg or more occurring during or within one hour of completing transfusion **and** a systolic blood pressure 80 mm or less in the absence of allergic or anaphylactic systems. No/minor intervention required	Hypotension, as previously defined, leading to shock (e.g., acidaemia, impairment of vital organ function) without allergic or inflammatory symptoms. Urgent medical intervention required	**Other/ hypotensive FAHR**

**This category may include mild symptoms/signs of one reaction type providing the other category is either moderate or severe*

The 354 reports submitted in 2024 represents an increase from the 336 in 2023, which itself was the highest number for 10 years. There was a particular increase in reports related to platelets (121 in 2024 compared to 99 in 2023), which included both febrile and moderate allergic reactions.

There were 192 reports related to red cells, 21 fresh frozen plasma (FFP), 2 cryoprecipitate, 4 granulocytes and 14 involving multiple components.

Deaths related to transfusion n=0

There were no FAHR reports in 2024 that resulted in a transfusion-related death.

Major morbidity n=113

The ISBT/IHN classification of a severe reaction has been used to define major morbidity.

Reactions are categorised in Table 19.2.

Table 19.2: Classification of reactions in 2024 (n=354)

	Moderate	Severe	Total
Febrile	155	28	**183**
Allergic	58	64	**122**
Mixed allergic/febrile	25	15	**40**
Hypotensive	3	6	**9**
Total	**241**	**113**	**354**

All patients with major morbidity recovered with no sequelae. In 25 of the 113 reactions classified as severe, this was primarily because the patient was admitted, or hospital stay was prolonged.

Reactions in IgA deficient patients n=6

There were 6 reports of reactions in patients who were later identified to have severe IgA deficiency (IgA <0.07g/L). Four were confirmed to have anti-IgA antibodies; results were not available for the other cases. Two of the reactions were febrile-type reactions and 3 were mixed febrile/allergic. All of these involved marked systemic upset. One of the patients reported a history of a similar reaction in 2023, while another experienced recurrence of identical symptoms when transfusion was attempted again in the same admission. One patient had a purely allergic reaction with rash, wheezing and hypoxia, but recovered without needing adrenaline.

It is recommended that these patients receive washed components for future red cell or platelet transfusions, provided this does not risk delaying an urgent transfusion (Latham, 2019).

Anaphylaxis n=33

There were 33 severe allergic reactions requiring treatment with adrenaline. The components most often responsible were platelets (n=15) and FFP (n=18). Children were disproportionately represented: ten of these reports (30.3%) involved people under 18. This compares to 46/354 (13.0%) reports related to children in the whole FAHR category. Two reactions occurred in outpatient departments, 16 on wards, 1 in the emergency department and 3 on the medical assessment unit. Ten involved transfusions outside of normal working hours.

Type of reaction by component

Types of reaction by component reported in 2024 remain consistent with previous Annual SHOT Reports; see Figure 19.1. Red cells were most often associated with febrile-type reactions, 147/192 (76.6%), whereas plasma components and platelets more commonly cause allergic reactions, 21/23 (91.3%) and 70/121 (57.9%) respectively.

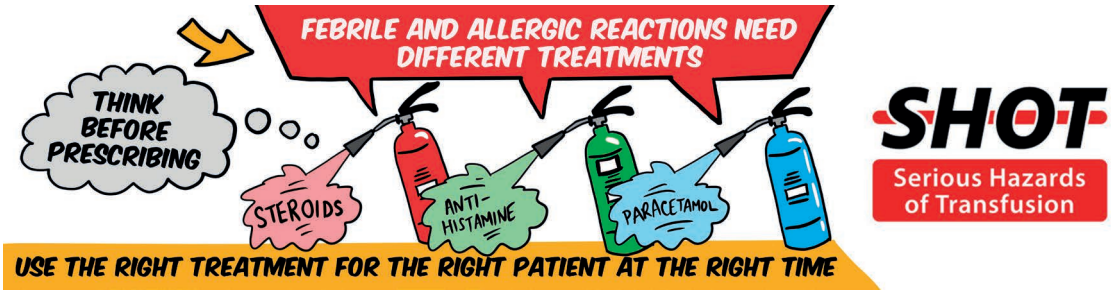
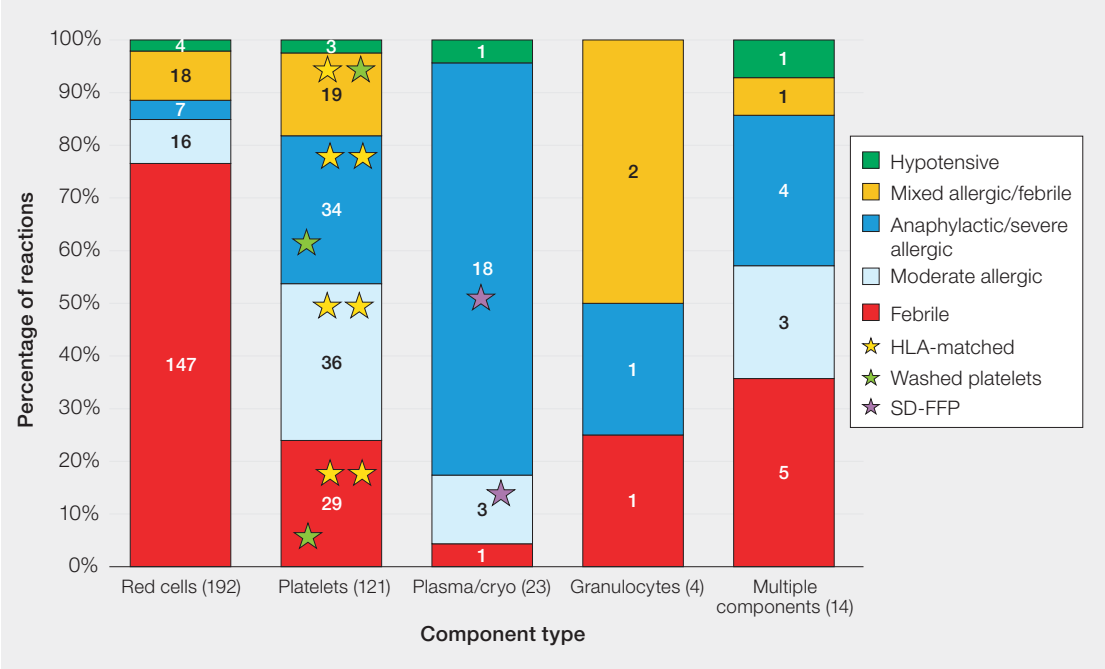


Figure 19.1: FAHR reactions by component type in 2024 (n=354)

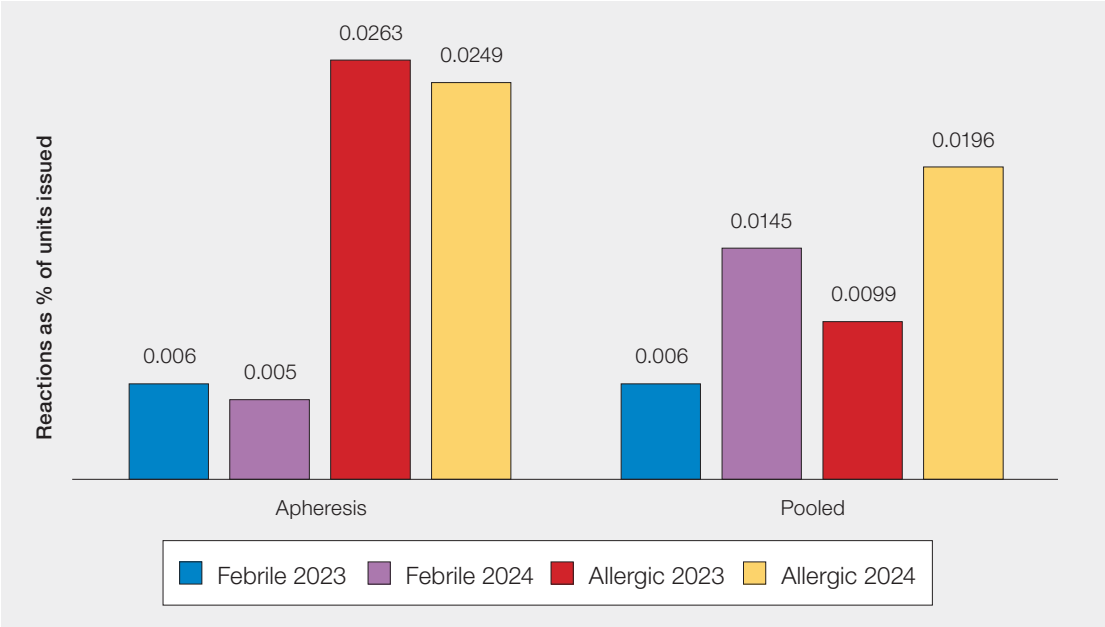


HLA=human leucocyte antigen; cryo=cryoprecipitate; SD-FFP=solvent detergent-treated fresh frozen plasma

In comparison to 2023 data, the incidence of reactions to apheresis platelets remains similar, for both allergic and febrile reactions. The overall increase in platelet reactions was related to pooled platelet components. The incidence of both febrile and allergic reactions roughly doubled in comparison to 2023 (Figure 19.2). SHOT will continue to monitor this.

The incidence of allergic reactions remains higher in apheresis platelets compared to pooled platelets, which relates to their higher plasma content (Estcourt, et al., 2017). The first step for subsequent transfusions for a patient experiencing a mild to moderate allergic reaction to apheresis platelets should be to switch to a pooled component.

Figure 19.2: Incidence of platelet reactions as a percentage of units issued 2023-2024



Management of reactions

Of the 179 reactions with only febrile features where treatment was stated, 63/179 (35.2%) were managed inappropriately with an antihistamine and/or steroid. This represented a further small improvement on previous years (Table 19.3).

Table 19.3: Inappropriate management of febrile reactions 2020-2024

Year	Number of febrile reactions	Medication stated	Antihistamine and/or steroid
2024	183	179/183 (97.8%)	63/179 (35.2%)
2023	163	163/163 (100%)	61/163 (37.4%)
2022	132	130/132 (98.5%)	61/130 (46.9%)
2021	174	155/174 (89.1%)	61/155 (39.4%)
2020	166	140/166 (84.3%)	58/140 (41.4%)

Table 19.4 summarises appropriate treatment targeted to the reaction type, and preventive cover for future transfusion, if needed (Soutar, et al., 2023).

Table 19.4: Targeted treatment for febrile and allergic reactions

Reaction	Treatment	Prevention of recurrent reactions
Febrile	Paracetamol	Paracetamol 60 minutes before anticipated time of reaction
Allergic	Antihistamine (steroid should not be used routinely) If anaphylaxis, adrenaline is essential	If previous reaction with apheresis platelets try pooled platelets (suspended in platelet additive solution) If reactions continue, give pre-transfusion antihistamine; If reactions continue, consider washed platelets/red cells; for FFP try a pooled component e.g., solvent-detergent treated plasma

Laboratory investigation of reactions

There were continued high rates of investigations, many of which were not tailored to the clinical situation. In 78 cases, repeat group and screen was sent inappropriately. This included serological testing in:

- 49/121 (40.5%) of the reactions to platelets
- 10/23 (43.5%) of the reactions to FFP/cryoprecipitate
- 51/122 (41.8%) of the reactions with only allergic features

In 1 report, samples were sent to the Blood Service reference laboratory following a febrile platelet reaction. This constitutes an avoidable burden on laboratories and could have led to unnecessary delays in providing further components to the patient.

Mast cell tryptase was sent unnecessarily in 6 patients with febrile reactions. In 29 allergic reactions, patient blood cultures were sent, and in 11 cases the unit was cultured. All cultures were negative.

A new SHOT Bite is available to support appropriate use of investigations in FAHR (see 'Recommended resources').

Case 19.1: Mismanagement of a febrile reaction to a platelet transfusion given outside of guidelines

A patient with pancytopenia, receiving an adult therapeutic dose of platelets to cover a bone marrow biopsy on the haematology ward, developed rigors and a temperature rise to 38°C after completion of transfusion. They were treated with an antihistamine and hydrocortisone and repeat group and screen was sent. No blood cultures were performed. The patient recovered completely within 4 hours.

It is concerning to see inappropriate treatment and investigation of this febrile platelet reaction, particularly as the patient was under the care of haematology. Giving paracetamol and taking blood cultures would

have been more appropriate. As prophylactic platelet transfusion is not recommended prior to bone marrow biopsy, the transfusion itself was outside of guidelines (Estcourt, et al., 2017).

Case 19.2: Mixed febrile/allergic reaction to granulocytes in a patient with an allergic predisposition

A patient post allogeneic bone marrow transplant for aplastic anaemia received granulocytes in the evening for neutropenic sepsis. The patient developed facial oedema, urticaria and dyspnoea. Temperature increased from 37 to 38.5°C. There was a mild blood pressure drop from 136/81 to 114/57mmHg. The patient had known allergy to banana and peanuts and carried an EpiPen. They were treated with their own EpiPen 300µg intramuscular (IM) whilst waiting for the emergency drug bag and then received a further 500µg IM dose of adrenaline after 5 minutes. They were transferred to intensive care for overnight observations but made a full recovery.

Learning points

- Treatment of febrile and allergic reactions should be targeted to the patient's symptoms and signs (Soutar, et al., 2023)
- Antihistamines are of no benefit in the absence of allergic features, and even in allergic reactions, steroids should not be used routinely
- Red cell serological investigations are only required for febrile or hypotensive reactions to red cells, and where the reaction is severe enough to warrant discontinuing transfusion
- All clinical areas giving transfusion must be equipped and staff trained to manage anaphylaxis, and transfusion should only be given overnight when clinically necessary

Conclusion

Febrile, allergic, and hypotensive reactions to transfusion are unpredictable and largely unpreventable. This emphasises the importance of avoiding transfusion where it is not clinically essential and discussing the possibility of these reactions with patients when taking their consent. Harm can be minimised by ensuring that treatment given, and investigations performed are correctly targeted to the type of reaction. This means using the patient's symptoms and signs to distinguish febrile from allergic reactions. This should be covered in clinical education and training, but also supported by resources within hospitals which are readily accessible and user-friendly.

Recommended resources

SHOT Bite No. 05(a): Febrile, Allergic, and Hypotensive Reactions (FAHR) – getting the diagnosis right
https://www.shotuk.org/resources/shot-bite-no-5/

SHOT Bite No. 05(b): Investigating FAHR
https://www.shotuk.org/resources/shot-bite-no-05b/

SHOT Video: FAHR – Febrile, Allergic, and Hypotensive Reactions
https://www.shotuk.org/resources/fahr-febrile-allergic-and-hypotensive-reactions/

JPAC Consent for Blood Transfusion - Guidance for Healthcare Practitioners in the UK
https://www.transfusionguidelines.org/transfusion-practice/consent-for-blood-transfusion/guidance-for-healthcare-practitioners-involved-in-this-role

20 Pulmonary Complications

Author: Tom Latham

With contributions from the SHOT Pulmonary Working Expert Group members

Pulmonary complications remain the largest category contributing to transfusion-associated deaths reported to SHOT and the second most common category of transfusion reactions. Patients with respiratory complications are often elderly with multiple co-morbidities which could all contribute to issues post transfusion. These complications present diagnostic and therapeutic challenges with mainly supportive measures available and specific therapies are lacking.

At least some of these pulmonary complications are potentially preventable and early recognition with prompt treatment is vital. Patient education and awareness are also important, especially if transfused as day cases or in the community.

Blood components should only be administered after careful consideration of the patient's unique risk of a transfusion complication versus the physiologic benefit of the planned transfused blood component. Less is often more with regards to transfusion.

A significant intervention in 2024 involved the issuing of a National Patient Safety Alert (NatPSA) in the UK to address the rising numbers of pulmonary complications (MHRA and SHOT, 2024). To our knowledge this is the first systematic attempt to address the prevention of pulmonary complications on a national scale. NatPSA/2024/004/MHRA was issued on 4 April 2024 via the NatPSA system, following extensive review. A target date of October 2024 was given to complete the comprehensive set of recommendations. The recommendations have all been existing SHOT recommendations for several years. The alert did appear to achieve a high level of engagement within the transfusion community, given the good attendance at webinars conducted by SHOT and constructive queries received from transfusion teams.

The total number of pulmonary complications continues to increase: The existing trend of increasing reports of transfusion-associated circulatory overload (TACO) continues, with a marked increase in reports received in 2024. A greater proportion of the reported TACO cases in 2024 were thought to be of imputability 2 or higher, than in previous years. The number of non-TACO complications has also increased; the majority of these were also thought to be predominantly due to fluid overload based on a compelling clinical scenario, although they did not meet TACO criteria. It is unclear whether any effect of the NatPSA on prevention may have been offset by an increase in reporting because of improved awareness. However, the hallmark signal of an effective safety system (increased reporting but decreasing severity of outcomes) is not seen here yet, as deaths have also increased.

Data from cases reported to SHOT this year provide early indicators of the uptake and effectiveness of the NatPSA recommendations: Use of the TACO pre-transfusion risk assessment is the most explicitly measurable intervention, as this is an existing question in the dataset collected for all suspected pulmonary complication reports to SHOT.

There appeared to be better use of the TACO pre-transfusion risk assessment in 2024 compared to previous years: Where data was supplied, the TACO pre-transfusion risk assessment was completed in 29/49 (59.2%) reports, where the incident occurred after the October completion date. This is an improvement on the historical rate, which had plateaued at around a third of cases (Narayan, et al., 2024) but not significantly different to the completion date for incidents occurring prior to the April issue date of the alert, 29/50 (58.0%). It is too early to determine the long-term effects of the NatPSA.

Fluid risks were common, but suboptimal application of the tool may have limited its effectiveness in identifying the risk: A fluid risk was retrospectively identified in 112/122 (91.8%) evaluable cases submitted, using the criteria in the SHOT risk assessment. There was a statistically significant association (p=0.02 using Fisher exact test) between a risk factor being identified during risk assessment and a fluid overload risk factor being identified retrospectively, but only 60/112 (53.6%) cases where a fluid risk was present were identified on prospective risk assessment.

Excessive and unnecessary transfusion occurred in many TACO cases: Evidence of excessive or unnecessary transfusion was present in 46/188 (24.5%) TACO cases. Excessive transfusion is an avoidable factor both for TACO and non-TACO complications. There should be a systematic approach to the decision to transfuse, considering the cause of anaemia and risks/benefits of transfusion which then informs the appropriate dose of red cells.

Appropriate use of the pre-transfusion risk assessment tool appears effective at prompting recommendations for mitigating actions, but there is variability in the range of actions proposed: Reported data indicates that at least one mitigating action was recommended in 85/95 (89.5%) cases where a fluid risk was identified on risk assessment. Where mitigating actions were recommended, this included a diuretic in 32/60 (53.3%) evaluable cases. These appear to show improvement compared to the 2017 National Comparative Audit, where diuretic was prescribed in only 11% of patients at risk of fluid overload (TACO Audit Working Group on behalf of the NCABT, 2018). The available data is not able to demonstrate how practices such as 'close monitoring' would have differed from practice if the risk assessment had not been performed.

Substantial numbers of reactions due to fluid overload occurred despite mitigating actions: Including both TACO cases and non-TACO cases where the working group considered fluid overload was likely to have contributed to the reaction, 57/193 (29.5%) had at least one mitigating action recommended, and 29 had received prophylactic diuretic (15.0%). In other words, about 1/3 of TACO cases occurred despite full use of the preventive measures recommended

There is a high rate of suspicion of fluid overload post reaction: Diuretics were given at the time of reaction in 178/193 (92.2%) evaluable cases considered to be due to fluid overload. This does appear to suggest improvement compared to the National Comparative Audit in 2017, where diuretic use was 76% (TACO Audit Working Group on behalf of the NCABT, 2018). The SHOT TACO investigation guidance tool was reported as being used retrospectively in 121/222 (54.5%) evaluable cases overall.

In summary, it has not been possible to demonstrate any early and measurable effect of the NatPSA on pulmonary complications following transfusion: There is some evidence of gradual improvements in the use of TACO prevention measures and the recognition and treatment of TACO, but this has not translated into a reduction in cases or deaths. A UK-wide survey is being planned at the end of 2025 to understand challenges in implementation of the recommendations from the NatPSA. Monitoring will continue and there will be further scope for implementation to gain ground with completion of local audit and improvement cycles, even after the target completion date.

Incomplete implementation and incomplete effectiveness of interventions may both contribute to residual risk: Interpretation of the reasons for a lack of response to the intervention are constrained by a lack of control data; we do not know whether the increase in cases is due to increasing numbers of cases at risk or increased reporting. It is also not clear as to how many cases might have occurred were it not for the intervention. The data does show that the use of the TACO pre-transfusion risk assessment is still far from universal. What more could be done to improve usage rates? Managerial approaches to improving transfusion safety practices, such as benchmarking performance indicators between hospitals, have been proposed and are indeed likely to improve uptake. Without addressing the root causes of why it appears difficult in practice to perform and document risk assessments, there is a danger that simply enforcing compliance may not actually improve the quality of risk identification.

Investigating why risks of fluid overload are not always identified when applying the TACO risk assessment tool will also help improve effectiveness of the tool. There is an unmet need to identify the most appropriate interventions when the risk of fluid overload is present, since many cases of TACO occur despite mitigation actions being performed. Improvements might include more specific guidance on the use of diuretics and monitoring of the response to diuretics. However, there is almost no clinical trial evidence to inform these recommendations. Clinical trials of TACO-prevention interventions must be considered a priority for transfusion medicine, but previous attempts to conduct trials have proved problematic (Pendergrast, et al., 2019). Data from haemovigilance systems should inform clinical research priorities. Haemovigilance organisations could perhaps have a stronger role in influencing these priorities so that research questions address the most common causes of clinical harm.

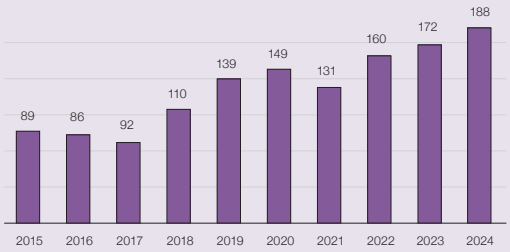
20a Transfusion-Associated Circulatory Overload (TACO) n=188

Author: Sharran Grey

Headline data 2024

Number of reports n=188
Deaths n=31
Major morbidity n=32

TACO reports by year



Demographic data

Male n=91
Female n=97
Adults n=184
Paediatric n=4

Blood component data

Red cells n=162
Platelets n=4
Plasma n=3
Granulocytes n=1
Cryoprecipitate n=2
Multiple components n=16

Key findings:

- TACO-related mortality has doubled for the second consecutive year
- TACO-related major morbidity has increased by more than 50% compared to 2023
- Unnecessary/avoidable and overtransfusion is a factor in around 25% of reported TACO cases in 2024
- The release of the TACO National Patient Safety Alert (NatPSA) may have contributed to the increase in the numbers reported

Gaps identified:

- The cause of anaemia not identified and hence unable to establish the indication for transfusion which informs the appropriate dose of red cells
- Cases continue to be reported where the TACO pre-transfusion risk assessment was not used, or risk mitigation measures were not instituted appropriately despite the identification of risks

Good practice:

- Evidence of structured investigation following TACO
- Continued implementation of the TACO pre-transfusion risk assessment into paper and electronic systems

Next steps:

- Promotion of the updated TACO pre-transfusion risk assessment (Figure 20a.1) and associated supporting tools (Figures 20a.3)
- Addressing unnecessary/avoidable and overtransfusion is a key element of TACO risk reduction and has been added to the TACO pre-transfusion risk assessment as a mitigation measure

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

TACO is defined as acute or worsening respiratory compromise and/or acute or worsening pulmonary oedema during or up to 12 hours† after transfusion, with additional features including cardiovascular system changes not explained by the patient's underlying medical condition; evidence of fluid overload and a relevant biomarker¥.

† SHOT accepts cases up to 24 hours

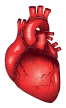
¥ see Table 20a.1 for details of required and additional criteria for the surveillance definition

Introduction

The TACO pre-transfusion risk assessment infographic (Figure 20a.1) was updated in the 2020 Annual SHOT Report to make it suitable for incorporation into clinical documents (Narayan, et al., 2021). Following feedback from reporters, a clarification has been added regarding the use of a prophylactic diuretic. The word 'checklist' has also been standardised to 'risk assessment'. Overtransfusion and unnecessary/avoidable transfusion remain significant avoidable causes of TACO. The TACO pre-transfusion risk assessment has been further updated this year to ensure the appropriate indication and volume of red cell transfusion is a key consideration as a mitigation for TACO. It reflects the recently updated National Blood Transfusion Committee (NBTC) indication codes which includes code R7 (transfusion for severe chronic anaemia) which emphasises a minimal/single unit transfusion strategy for those patients who are at additional risk of TACO (NBTC, 2024). Other changes include inclusion of all heart valve disease, and simplification of 'hypoalbuminaemia' to 'a low serum albumin level'.

SHOT recognise that, following the release of the National Patient Safety Alert (MHRA and SHOT, 2024) in April 2024 to reduce the risks of TACO, staff have invested time and resources in aligning processes with the earlier version of the TACO risk assessment. SHOT acknowledge that the new update may mean additional work for hospital teams to reflect the new version. The new version incorporates the changes described above with the aim of improving clarity, consistency, and effectiveness of application. Specifically, the 2024 data provide a clear signal that inappropriate and excessive volume of transfusion are significant risks in cases of TACO, which was the main driver for this update. It is also important to note that this risk assessment is based on real-life haemovigilance data and not traditional research studies. TACO reports are received from a wide range of clinical contexts and patients. These signals offer powerful insights to risk patterns and patient vulnerabilities. Acting on haemovigilance data allows us to adapt our practice, refine risk assessments and implement preventive strategies to improve patient safety. It is a key part of learning from experience and making transfusion practice safer for everyone.

Figure 20a.1: Updated TACO pre-transfusion risk assessment

TACO Risk Assessment		YES	NO
	Does the patient have any of the following?: diagnosis of 'heart failure', congestive cardiac failure (CCF), left ventricular dysfunction, aortic stenosis, or any other heart valve disease		
	Is the patient on a regular diuretic?		
	Does the patient have severe anaemia?		
	Is the patient known to have pulmonary oedema?		
	Does the patient have respiratory symptoms of undiagnosed cause?		
	Is the fluid balance clinically significantly positive?		
	Is the patient receiving intravenous fluids (or received them in the previous 24 hours)?		
	Is there any peripheral oedema?		
	Does the patient have a low serum albumin level?		
	Does the patient have significant renal impairment?		

If risks identified	YES	NO
Review the need for transfusion (do the benefits outweigh the risks)?		
Can the transfusion be safely deferred until the issue is investigated, treated or resolved?		

If proceeding with red cell transfusion: ensure appropriate indication and volume is prescribed (adults)

Indication code for transfusion	Target Hb	Dosing advice
Acute anaemia (R2)	Post-transfusion target Hb 70 - 90g/L	Body weight dosing (max 2 units)
Acute anaemia (R3: with acute MI/ACS)	Post-transfusion target Hb 80 - 100g/L	Body weight dosing (max 2 units)
Severe symptomatic chronic anaemia (R7)	No target Hb - minimum transfusion	Usually single unit only
Regular transfusion programme (R4)	Individualised target Hb	Body weight dosing (max 2 units)

Other measures to mitigate TACO: ASSIGN ACTION AS APPROPRIATE	TICK
Review patient after each unit (red cells) and review symptoms of anaemia. Is further transfusion necessary?	
Measure the fluid balance	
Consider a prophylactic diuretic (where appropriate/not contraindicated)	
Monitor the vital signs closely, including oxygen saturation	

Name (PRINT):	**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.**
Role:	
Date: **Time (24hr):**	
Signature:	

TACO=transfusion-associated circulatory overload; MI=myocardial infarction; ACS=acute coronary syndrome; Hb=haemoglobin

Table 20a.1: TACO surveillance definition (adapted from Wiersum-Osselton, et al., 2019)

TACO surveillance definition
Patients classified with TACO (surveillance diagnosis) should exhibit at least one required criterion* with onset during or up to 12 hours after transfusion (SHOT continues to accept cases up to 24 hours), and a total of 3 or more criteria i.e., *A and/or B, and total of at least 3 (A to E)
*** Required criteria (A and/or B)**
A. Acute or worsening respiratory compromise and/or
B. Evidence of acute or worsening pulmonary oedema based on: • clinical physical examination, and/or • radiographic chest imaging and/or other non-invasive assessment of cardiac function
Additional criteria
C. Evidence for cardiovascular system changes not explained by the patient's underlying medical condition, including development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral oedema
D. Evidence of fluid overload including any of the following: a positive fluid balance; clinical improvement following diuresis
E. Supportive result of a relevant biomarker, e.g., an increase of BNP levels or NT-pro BNP to greater than 1.5 times the pre-transfusion value

The number of cases reported in 2024 (n=188) is the highest to date and is an increase of 16 cases from 2023 (n=172). Although the pathophysiology of the pulmonary complications of transfusion is not fully understood, the evolving understanding of risk factors for TACO and the development of tools to mitigate risks has advanced significantly in recent years. This chapter describes the demographics of patients reported to have TACO, the adoption of risk-reduction strategies, and highlights areas for further focus based on signals from the data and ongoing trends.

Deaths related to transfusion n=31

Figure 20a.2 shows peaks in TACO deaths in 2016 and 2020, with the latter possibly related to COVID-19. There were 15 deaths related to TACO in 2023 which was almost double the number in 2022 (n=8), and this was a concerning signal in the data that was highlighted in the 2023 Annual SHOT Report (Narayan, et al., 2024). The trend led to the TACO NatPSA which was issued in April 2024 (MHRA and SHOT, 2024). This has again doubled in 2024 with 31 deaths where TACO was implicated (imputability 1 and 2). The cause of this is not clear and is likely multifactorial. Analysis of the 2024 data shows that 6/31 (19.4%) deaths, and 46/188 (24.5%) of all reported TACO cases had evidence of unnecessary/avoidable, or excessive volume of transfusion, suggesting some cases may have been mitigated or avoidable.

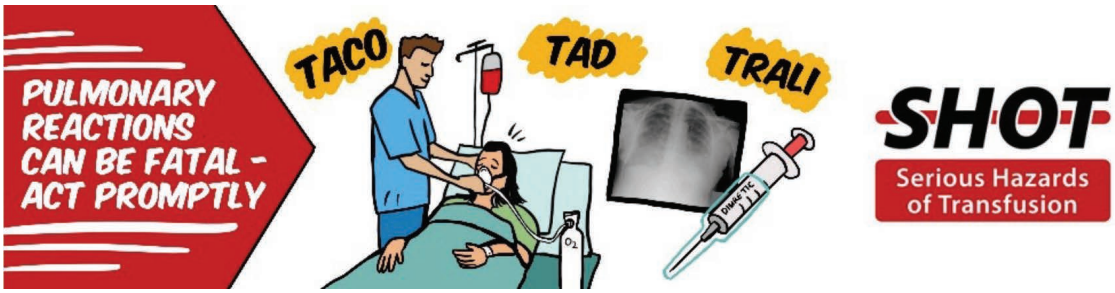
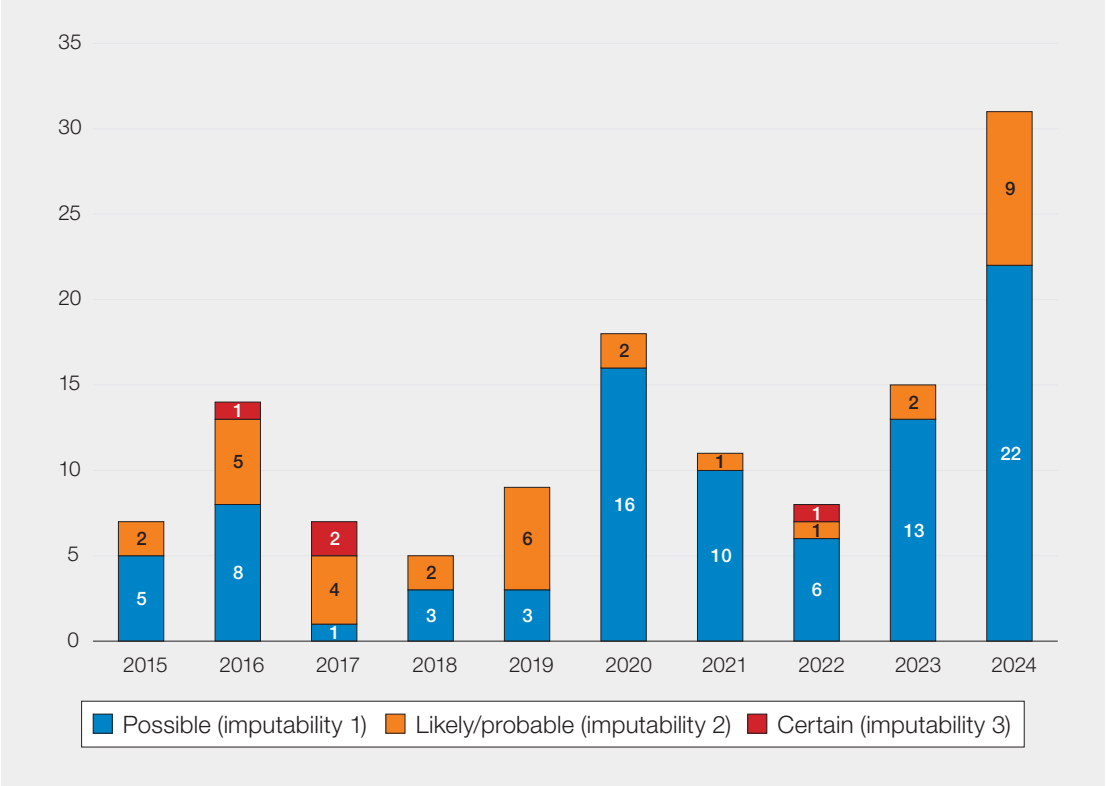


Figure 20a.2: TACO-related deaths with imputability, 2015 to 2024 (n=125)



Major morbidity n=32

There was a significant increase in major morbidity in the 2024 data (n=32) which was more than a 50% increase compared to 2023 (n=20).

Table 20a.2: Demographic overview of TACO cases in 2024

Demographic	Number of reports
Deaths (imputability 3)	0
Deaths (imputability 2)	9
Deaths (imputability 1)	22
Major morbidity	32
Age	Range: 2 months – 97 years (4 paediatric patients < 18 years) Median: 75 years
Sex	Female=97, male=91
Body weight (adults)*	Female (n=73): mean 69.5kg (range 42-125kg) Male (n=72): mean 78.1kg (range 39-130kg)
Top 4 medical specialties*	1st Haematology (n=36); 2nd acute medicine (n=26); 3rd general medicine (n=22); 4th emergency medicine (n=16)
Intensive care or high dependency units	12
Day case including community transfusion	13
Bleeding patients (NBTC indication code R1 or 'massive bleeding' indicated) * (NBTC, 2024)	34
Non-bleeding patients (other NBTC indication codes or 'not stated')	154

** Where data was provided - small numbers do not imply infrequent events*

Unnecessary transfusion and excessive volume of transfusion: a major contributory factor for TACO

Analysis of the 2024 data shows that 46/188 (24.5%) of TACO cases had evidence of unnecessary/

avoidable, or excessive volume of transfusion. It should be noted that the volume of transfusion, body weight, and pre- and post-transfusion haemoglobin levels are not universally reported and therefore these figures can be regarded as an under-estimate of TACO cases where unnecessary and excessive transfusion is a significant contributory factor.

- Unnecessary/avoidable transfusions = 10/188 (5.3%)
- Evidence of excessive volume (red cells) = 34/188 (18.1%)
- Evidence of excessive volume (red cells) and possibly unnecessary/avoidable = 2/188 (1.1%)

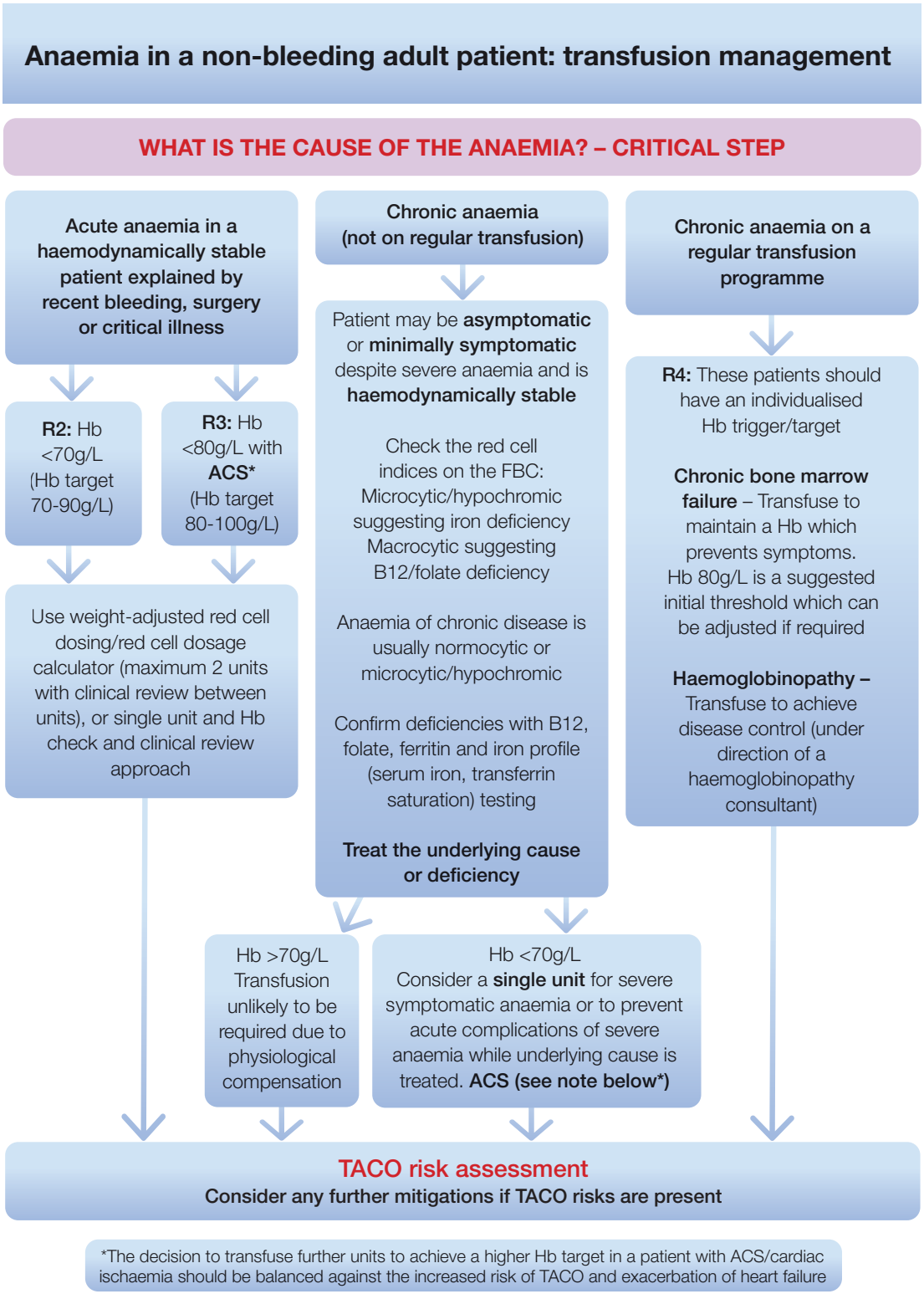
Case 20a.1: Excessive transfusion for chronic anaemia contributed to a patient's death (imputability 1 – possible)

A patient on palliative care for colorectal carcinoma with heart failure, renal impairment and other comorbidities was admitted with a 2-week history of shortness of breath. They were transfused two units of red cells for chronic anaemia (haemoglobin (Hb)68g/L, mean corpuscular volume (MCV)81fl). They had a relatively low body weight (59kg). The clinician decided to aim for a target Hb of >90g/L due to 'cardiac disease'. Acute coronary syndrome was not cited in the report, and it is likely this was chronic cardiac disease. The patient was on a regular diuretic, and they also had a low serum albumin level. There was no current fluid balance recorded, and the patient had peripheral oedema. The pre-transfusion chest X-ray showed a small pleural effusion and atelectasis in the base of the right lung. A TACO pre-transfusion risk assessment was not performed and therefore the multiple risks for TACO were not identified, and mitigations were not implemented. The patient developed a worsening respiratory status with tachypnoea (26 breaths per minute), oxygen desaturation to 87%, and an increased oxygen requirement (3L oxygen to maintain an oxygen saturation of 96%). The heart rate increased to 101 beats per minute, and the blood pressure had also increased from the baseline to 144/78mmHg. The post-transfusion Hb was 95g/L. The post-transfusion chest X-ray showed progression of the pleural effusion and new interstitial oedema. The patient was treated with a steroid, bronchodilator, and multiple doses of diuretic, however the patient deteriorated and died.

TACO was thought to have contributed to the patient's death but was not entirely causal. An internal investigation took place which recognised that administering a second unit of red cells was the cause of the TACO and therefore could have been avoided. The organisational transfusion authorisation card was reviewed and updated. The TACO pre-transfusion risk assessment was also made more detailed and prominent to include TACO mitigation measures. Additionally, TACO education was incorporated into the transfusion face-to-face training. Nurses administering blood components were empowered to challenge prescribers if the TACO pre-transfusion risk assessment was not correctly completed. Single unit transfusions were also promoted.

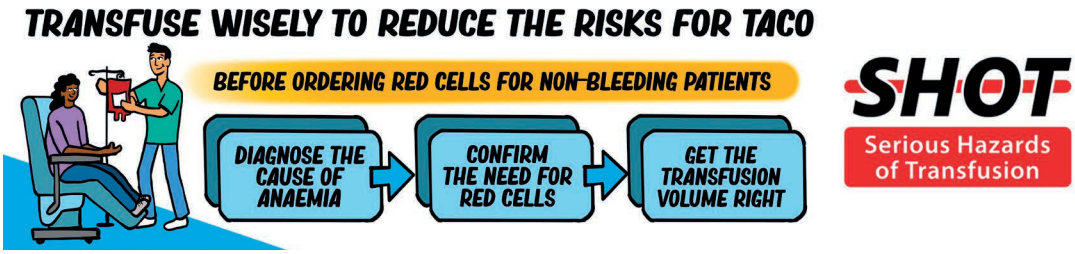
Overtransfusion and unnecessary transfusion remain major contributory factors in TACO and TACO-related deaths. This case highlights the risk of excessive transfusion in a patient with severe chronic anaemia where a minimal transfusion strategy could have been more appropriately adopted. Decision-making regarding the Hb target and volume to transfuse in the context of acute coronary syndrome is complex. The risk of ongoing cardiac ischaemia must be balanced by the risk of exacerbating heart failure and overload due to transfusion. However, in this case there was no evidence of acute coronary syndrome and the Hb target appeared to be based upon the patient having chronic cardiac disease. There is no specific Hb target for patients with severe chronic anaemia. Transfusion is not usually required if the Hb is >70g/L. Below this level a single unit of red cells with appropriate pharmacological treatment (e.g., intravenous iron) is usually indicated to relieve any severe symptoms of anaemia. The TACO pre-transfusion risk assessment has been updated to reflect this and the updated NBTC indication codes (NBTC, 2024). The 2023 Annual SHOT Report also highlighted the critical step of identifying the cause of anaemia as this is fundamental in informing appropriate transfusion strategy (Figure 20a.3) (Narayan, et al., 2024).

Figure 20a.3: Transfusion management of a non-bleeding adult patient – identification of the cause of anaemia



ACS=acute coronary syndrome; FBC=full blood count; Hb=haemoglobin; TACO=transfusion-associated circulatory overload

Unnecessary and excessive transfusion are significant contributors to TACO. Determining the correct dose of red cells in a non-bleeding adult patient is a key mitigation for TACO. This is important for all causes of anaemia. The cause of anaemia should be identified to establish the indication for transfusion which then informs the appropriate dose of red cells. A systematic approach should be taken.



Learning points

- Severe chronic anaemia (asymptomatic or minimally symptomatic) requires only minimal transfusion (usually a single unit) followed by pharmacological treatment where appropriate. Non-bleeding adult patients with severe chronic anaemia are particularly vulnerable to TACO even in the absence of comorbidities that predispose to TACO
- In all cases there should be a systematic approach to the decision to transfuse. The **cause** of anaemia should be identified to establish the **indication** for transfusion which then informs the appropriate **dose** of red cells. These are key factors in mitigating the risk of TACO

Conclusion

The most concerning signal from the 2024 data is the continued increase in mortality and major morbidity in reported cases of TACO. Unnecessary, avoidable and overtransfusion, particularly of red cells persist along with suboptimal management of severe chronic anaemia. This prompted the TACO NatPSA alert in 2024 which was intended to support organisations in implementing best practice to minimise the risk of TACO. The pathophysiology and aetiology of pulmonary complications of transfusion is complex and incompletely understood which limits mitigation strategies. However, there are well known risks associated with transfusions which can be mitigated by best practice measures. These include appropriate use of blood, alternatives to transfusion, and correct dose of blood components. The TACO pre-transfusion risk assessment (Figure 20a.1) has been updated to promote a systematic approach to red cell transfusion to address modifiable risks for TACO which include avoidable, inappropriate and excessive volume/dose. Organisations are encouraged to adopt the updated TACO pre-transfusion risk assessment (Figure 20a.1) and associated guidance (Figures 20a.3 and 20a.4) in this chapter.

Recommended resources

Example of weight-adjusted red cell dosing implemented in clinical practice
MHRA and UKCA marked blood transfusion Red Cell Dosage Calculator Web App
www.rcdcalculator.co.uk

TACO Incident Investigation Guidance Tool
https://www.shotuk.org/resources/transfusion-associated-circulatory-overload-taco-cumulative-data-2/

TACO pre-transfusion risk assessment (alternative format for incorporation into clinical documents)
https://www.shotuk.org/resources/taco-pre-administration-risk-assessment-transfusion-associated-circulatory-overload/

SHOT Bite No. 11: Respiratory symptoms during transfusion
https://www.shotuk.org/resources/shot-bite-no-11/

SHOT Video: TACO – Transfusion-Associated Circulatory Overload
https://www.shotuk.org/resources/taco-transfusion-associated-circulatory-overload/

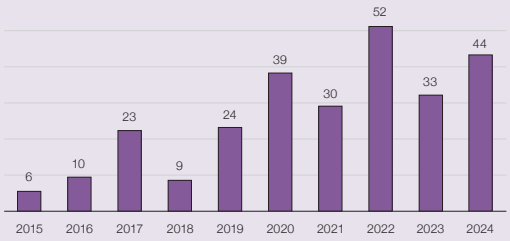
20b Pulmonary Complications of Transfusion: Non-TACO n=44

Author: Tom Latham

Headline data 2024

Number of reports n=44
Deaths n=4
Major morbidity n=9

Non-TACO reports by year



Demographic data

Male	Female	Adults	Paediatric
n=21	n=23	n=44	n=0

Blood component data

Red cells n=33
Platelets n=3
Fresh frozen plasma (FFP) n=1
Granulocytes n=1
Multiple components n=6

Key findings:

- Excessive fluid contributed to 48% of cases but did not meet transfusion-associated circulatory overload (TACO) criteria
- There was 1 case of antibody-mediated transfusion-related acute lung injury (TRALI)
- At least three comorbidities were identified to have contributed to the reaction in almost 50% of the cases. Hypoxia or raised respiratory rate were identified prior to transfusion in 64% of the cases
- There was 1 case of TRALI following granulocyte transfusion

Gaps identified:

- Insufficient information available to apply international criteria meant that 38% of cases were classified as transfusion-associated dyspnoea (TAD)
- No significant concordance between identification of TACO risk and presence of fluid risks

Good practice:

- Improved rate of TACO pre-transfusion risk assessment completion (66% vs 33% in 2023)
- Diuretic was given in response to reaction in 81% of cases where fluid overload was thought to be likely
- Structured TACO investigation was used in 40% of reports and identified areas for improvement in 71% of cases

Next steps:

- Ensure recommendations from the National Patient Safety Alert: Reducing risks for transfusion-associated circulatory overload (NatPSA/2024/004/MHRA) are fully implemented

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

Cases where there is a respiratory deterioration within 24 hours of transfusion which does not meet International Society of Blood Transfusion (ISBT) TACO criteria, and which is not explained by the recipient's underlying condition.

Introduction

There were 59 cases submitted or transferred from other categories. Thirteen were withdrawn as they were either of insufficient severity or the respiratory deterioration was deemed to be due to the underlying condition, and 2 cases were transferred to TACO.

Cases were classified using the International Revised Consensus (IRC) definitions of TRALI (Table 20b.1). Cases satisfying both TRALI (Vlaar, et al., 2019) and TACO (Wiersum-Osselton, et al., 2018) criteria were categorised as 'TRALI-TACO' and cases satisfying neither as 'TAD'. The TAD category is subclassified into TAD-IC (cases which could not be classified because of incomplete information reported) and TAD-C (cases where there was sufficient information to judge that the case did not meet either TACO or TRALI criteria).

The final classification of cases with imputability is presented in Table 20b.2.

Table 20b.1 International Revised Consensus classification of TRALI (Vlaar, et al., 2019)

TRALI type I - Patients who have no risk factors for ARDS and meet the following criteria:	
a.	i. Acute onset
	ii. Hypoxemia (P/F ≤300 or SpO2 < 90% on room air)
	iii. Clear evidence of bilateral pulmonary edema on imaging (e.g. chest radiograph, chest CT, or ultrasound)
	iv. No evidence of left atrial hypertension (LAH), or, if LAH is present, it if judged to not be the main contributor to the hypoxemia
b.	Onset during or within 6 hours of transfusion
c.	No temporal relationship to an alternative risk factor for ARDS
TRALI type II - Patients who have risk factors for ARDS (but who have not been diagnosed with ARDS) or who have existing mild ARDS (P/F of 200-300), but whose respiratory status deteriorates and is judged to be due to transfusion based on:	
a.	Findings as described in categories a and b of TRALI type I and
b.	Stable respiratory status in the 12 hours before transfusion

Table 20b.2: Final classification of non-TACO cases in 2024

		Imputability			
		1-possible	**2-probable**	**3-definite**	**Total**
Category	TAD-C	13	7	0	**20**
	TAD-IC	9	8	0	**17**
	TRALI-TACO	0	1	0	**1**
	TRALI type II	2	4	0	**6**
Total		**24**	**20**	**0**	**44**

Deaths related to transfusion n=4

There were 4 transfusion-related deaths due to non-TACO pulmonary complications. Of these, 3 were classified as TAD-C (2 with imputability 2, and 1 with imputability 1) and 1 case which was TAD-IC (imputability 2). Additional narrative detail on deaths is available in the supplementary information on the SHOT website.

Major morbidity n=9

There were 9 cases of major morbidity, classified as TRALI type II (n=3), TAD-C (n=4), TAD-IC (n=1) and TRALI-TACO (n=1).

TRALI cases and leucocyte antibody cases n=7

There was 1 case associated with leucocyte antibodies. In 4 other cases, donors were recalled for antibody testing. Testing was negative in 2 cases and donors failed to respond in 2 cases.

Case 20b.1: TRALI type II associated with granulocyte antibody of undetermined specificity in a donor

A patient with history of ischaemic heart disease and pulmonary embolus underwent laparotomy 2 days after caesarean section because of bleeding. Low albumin and raised C-reactive protein were present prior to surgery. The patient became haemodynamically unstable with a haemoglobin of 55g/L and was transfused four units of red cells, four units of plasma and 4L of crystalloid. The patient developed respiratory deterioration 2 hours after transfusion, and despite a 4L diuresis, continued to deteriorate. Non-invasive ventilation was required, and the patient improved after 48 hours. Chest X-ray showed progressive bilateral pulmonary oedema.

Donor antibody testing showed one donor with IgG reactivity against 4/5 granulocyte panels but negative human leucocyte antigen (HLA) antibodies and reactivity against lymphocytes. A human neutrophil antigen (HNA) specificity could not be determined, and monoclonal antibody immobilisation of granulocyte antigens assay (MAIGA) testing was also negative.

This case met the criteria for TRALI type II. The history and subsequent clinical course were fairly classical for an antibody-mediated TRALI although the haemorrhagic shock is itself a sufficient explanation for acute respiratory distress syndrome. Inflammation, intravenous fluids, and low albumin are other contributory insults.

The donor serology indicates antibody to a granulocyte-specific antigen outside of the recognised HNA systems. A causative relationship could not be proven and a granulocyte crossmatch to prove that the antibody was reactive with recipient cells was impractical.

Case 20b.2: TRALI type II - therapeutic effect of granulocytes

A patient with neutropenic sepsis already on antifungals and broad-spectrum antibiotic developed fever, rigors and respiratory deterioration following a first granulocyte transfusion. The chest X-ray showed patchy bilateral consolidation which was not present before transfusion. The patient required mechanical ventilation for 1 day but then improved.

Respiratory and febrile deteriorations following granulocytes are common. In many cases this represents the intentional immune response of the transfused granulocytes. This case was classified as 'TRALI type II' given the temporal response to transfusion and bilateral imaging changes although it could be argued that the respiratory state was not 'stable' prior to transfusion. Leucocyte antibody testing of donors was not performed and would be unlikely to be informative due to the large number of donors contributing to the granulocyte pools.

Conclusion

As in previous Annual SHOT Reports, many patients included in the non-TACO category were unwell prior to transfusion. Most cases had signs of cardiorespiratory stress prior to transfusion: where appropriate data was supplied, 15/38 (39.5%) were tachycardic and 18/28 (64.3%) were hypoxic or had a raised respiratory rate prior to transfusion.

The median number of pathophysiological factors which could have contributed to the reaction was 3. Inflammatory factors were common, present in 33/44 (75.0%) of cases. As in previous years, many cases had features of fluid overload; 30/44 (68.2%) of cases were considered at risk of fluid overload and 21/44 (47.7%) of reports were considered likely to be caused by fluid overload but did not meet full TACO criteria.

Providing data necessary for classification remains challenging, resulting in the high proportion of cases classified as TAD-IC. There does appear to have been a higher use of the TACO pre-transfusion risk assessment in 2024. A risk assessment was performed in 31/47 (66.0%) cases where data was provided, compared to approximately a third in 2023. However, the risk assessment only identified a fluid risk in 3/11 cases where data was provided, and the data reported to SHOT indicated that a risk of fluid overload was present.

Haemolytic Transfusion Reactions (HTR) n=51

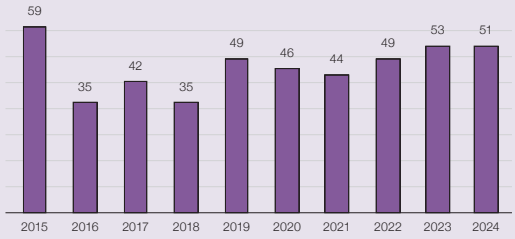
21

Authors: Tracey Tomlinson and Anicee Danaee

Headline data 2024

Number of reports n=51
Deaths n=3
Major morbidity n=14

HTR reports by year



Demographic data

Male n=24
Female n=27
Adults n=45
Paediatric n=6

Blood component data

Red cells n=51
Platelets n=0
Plasma n=0
Multiple components n=0

Key findings:

- The number of HTR cases reported to SHOT each year remain stable
- Antibodies to the Kidd blood group system (anti-Jk^{a} and anti-Jk^{b}) are most commonly implicated in causing delayed HTR
- Most cases of hyperhaemolysis were reported in patients with sickle cell anaemia

Gaps identified:

- Incomplete investigations in patients with suspected HTR
- Direct antiglobulin tests (DAT) and elution studies on the post-transfusion sample are inconsistently performed making it difficult to distinguish between a HTR and haemolysis due to other causes
- Partial information submitted to SHOT makes it difficult to assess the effectiveness of the various treatment options available to manage hyperhaemolysis

Good practice:

- Lifesaving transfusions were provided even in the absence of suitable antigen-negative blood. In urgent clinical situations where suitable components are not available it may be necessary to transfuse red cell units which are positive for a confirmed antibody. Where this occurs the patient must be closely monitored for signs of a HTR

Next steps:

- Adequate and thorough laboratory investigations should be carried out in patients with suspected HTR
- Relevant information should be provided to SHOT to facilitate effective analysis

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

Acute haemolytic transfusion reactions (AHTR) are characterised by fever, a fall in haemoglobin (Hb), rise in bilirubin and lactate dehydrogenase (LDH) and a positive direct antiglobulin test (DAT). They generally present within 24 hours of transfusion.

Delayed haemolytic transfusion reactions (DHTR), occur more than 24 hours following a transfusion and are associated with a fall in Hb or failure to increment, rise in bilirubin and LDH and an incompatible crossmatch not detectable pre transfusion.

Hyperhaemolysis is characterised by more severe haemolysis than DHTR, with haemolysis affecting the transfused red cells and the patient's own red cells; there is a decrease in Hb to below pre-transfusion levels, which is often associated with a reticulocytopenia. It may be triggered by a new red cell alloantibody, but frequently no new red cell antibody is identified. Hyperhaemolysis can be divided into acute and delayed hyperhaemolysis.

Introduction

A total of 51 cases have been included: 16 acute reactions, 21 delayed reactions and 14 cases of hyperhaemolysis. The total number of reactions reported is comparable to previous years.

All reported cases occurred following red cell transfusions.

The age range of the patients affected was 3 to 83, with a median age of 40. This is shown in Figure 21.1, broken down further by gender. HTR were reported in 6 paediatric patients, which is a slight increase from previous years (2 in 2023 and 5 in 2022). Reactions in female patients accounted for 27/51 (52.9%) of the reactions.

Figure 21.1: Age range in males and females experiencing a HTR in 2024

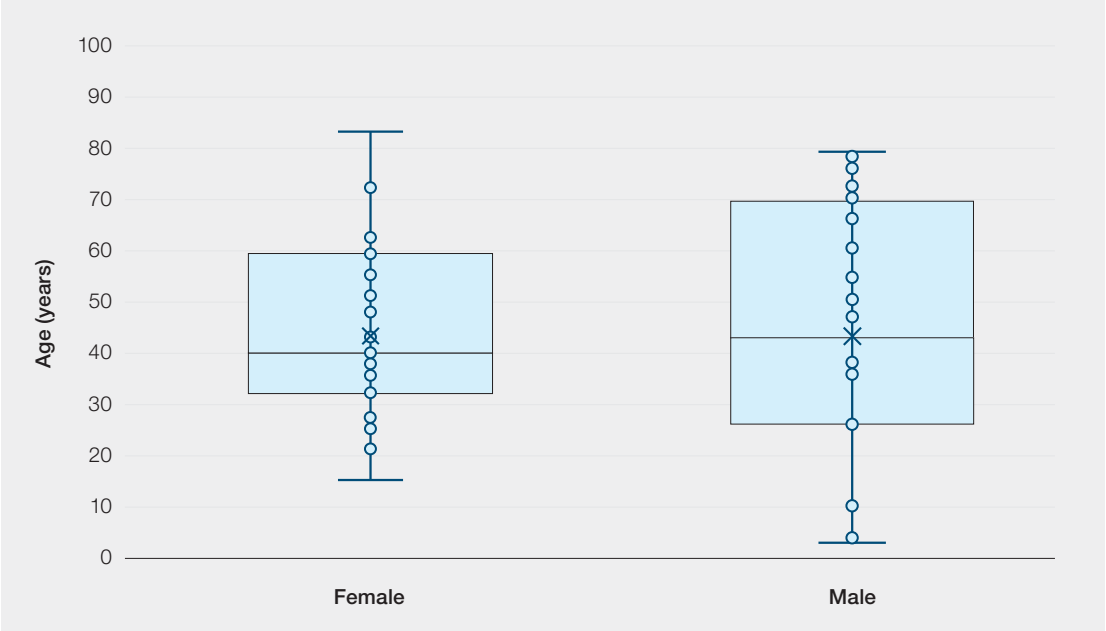


Figure 21.1 is a box and whisker diagram showing the median age and the age range of patients experiencing a HTR reported to SHOT separated by gender. The middle bar in the shaded box indicates the median age, the outer bars of the box represent the upper and lower quartiles. The lines extending from the boxes (whiskers) indicate the lowest and highest values.

Deaths related to transfusion n=3

There were 3 deaths in which the transfusion reaction contributed to the patient death, all in patients with sickle cell anaemia.

Case 21.1: Patient death following an AHTR (imputability 1 – possible)

A patient with a history of multiple red cell antibodies (anti-Co^{b}, -E, -S, -Le^{a} plus an auto and non-specific antibody), reacted to the first unit transfused as part of a routine red cell exchange transfusion to manage the symptoms associated with sickle cell anaemia. During the transfusion, the patient reported feeling unwell with lumbar pain. The transfusion was stopped, and the patient was treated for a suspected transfusion reaction. Serological investigation of the implicated unit demonstrated a positive crossmatch with both the pre- and post-transfusion samples and anti-Co^{b} was identified in the eluate prepared from the patient's red cells. Despite supportive measures, and management in the intensive care unit (ICU), the patient deteriorated and died 5 days later.

Case 21.2: Patient death following hyperhaemolysis (imputability 2 – probable)

A patient presented in hospital with a suspected sickle crisis. They were transfused two units of red cells and discharged home the following day. The patient re-presented 6 days later reporting general weakness and continued pain. The patient's Hb had fallen to below the pre-transfusion level and they exhibited multiple markers of haemolysis. The patient was admitted to the ICU and died 2 days later.

The 3rd case was a death following hyperhaemolysis and is discussed in detail in Chapter 26, Haemoglobin Disorders (Case 26.1).

Major morbidity n=14

SHOT considers that all reported cases of probable hyperhaemolysis, where there is a significant fall in Hb level, should be considered as major morbidity. Following application of this criterion 12 cases of hyperhaemolysis were upgraded from a reported 'minor morbidity' to major morbidity. The remaining 2 cases of major morbidity occurred following DHTR. In both cases the patient had received clinically indicated urgent transfusions and required additional clinical interventions to manage the transfusion reaction.

Hyperhaemolysis n=14

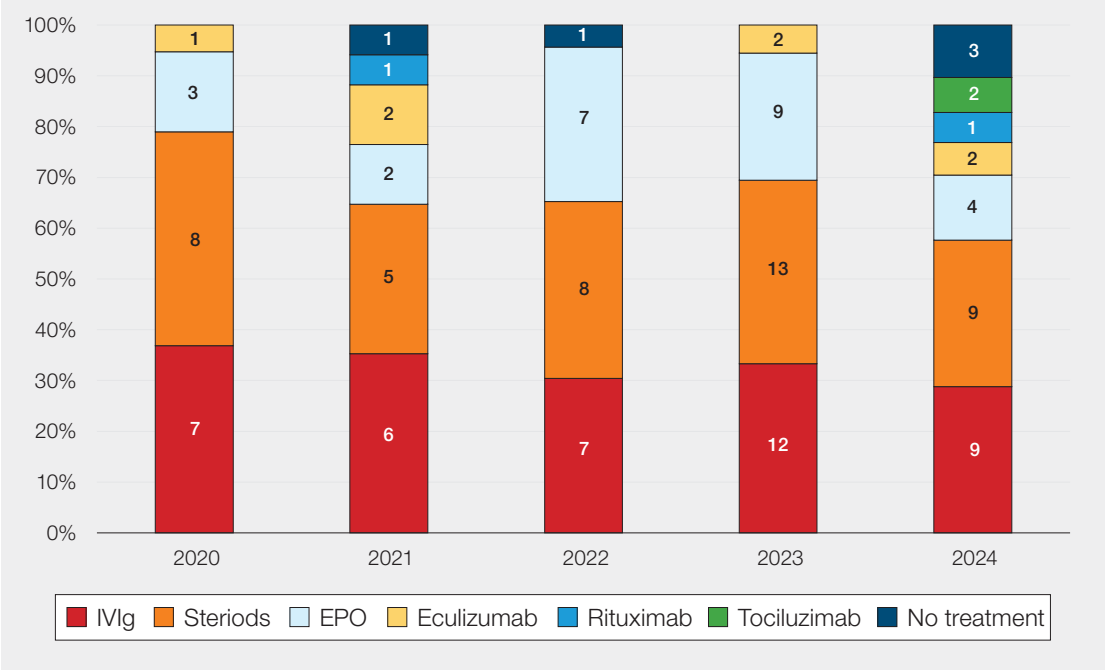
Eleven hyperhaemolysis cases reported occurred in patients with sickle cell anaemia. The remaining 3 cases occurred in a single patient with severe immunodeficiency who experienced multiple reactions over a 10-day period (see Case 25.9 in Chapter 25, Paediatric Cases).

Hyperhaemolysis can be divided into acute and delayed hyperhaemolysis. Acute hyperhaemolysis occurs within 7 days of transfusion and the DAT is usually negative. Delayed hyperhaemolysis occurs more than 7 days post transfusion and the DAT is often positive. In contrast to a classical DHTR, in delayed hyperhaemolysis both patient and transfused red cells are haemolysed (Danaee, et al., 2015). Seven cases reported the reactions occurred within the first 7 days post transfusion.

Treatment in hyperhaemolysis

SHOT has been requesting information on treatment modalities used to manage hyperhaemolysis since 2020. The aim is to provide a better understanding of practice nationally, improve and share knowledge. Eculizumab has been licensed to treat ongoing brisk haemolysis (NHSE, 2020) and was reported as being used in 2 cases in 2024. There was 1 additional case in which rituximab was given to treat the hyperhaemolysis. SHOT data shows that patients are generally treated with a combination of intravenous immunoglobulin (IVIg), steroids and erythropoietin (EPO). Figure 21.2 illustrates the treatments used in the management of hyperhaemolysis cases reported to SHOT 2020-2024. In 2 cases, tocilizumab was used to treat hyperhaemolysis and has been included in the figure. It is important to note that combinations of different treatments are often used to manage hyperhaemolysis, with no clear trends. Further details can be found in the supplementary material of this chapter.

Figure 21.2: Treatments used to manage hyperhaemolysis (2020-2024)



Clinical and laboratory signs and symptoms

Acute haemolytic transfusion reactions n=16

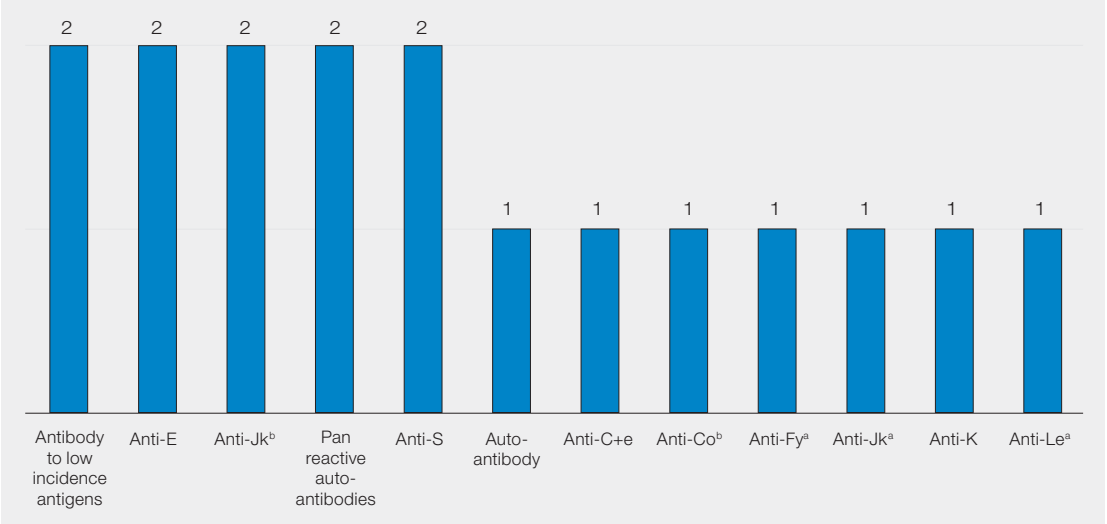
Clinical symptoms of a transfusion reaction were observed in 15/16 reports. Alloantibodies to red cell antigens were identified in 12 of the 16 AHTR cases reported. The alloantibodies implicated are shown in Figure 21.3.

In 2 cases where no alloantibodies were detected, a strongly active pan-reactive warm autoantibody was detected. A further case had an auto anti-D and auto anti-C.

In 3 AHTR cases, the patients received urgent transfusion of antigen-positive red cell components with input from consultants with transfusion expertise. It is important that lifesaving transfusion is not withheld due to a history of alloantibodies. In urgent clinical situations where suitable antigen-negative blood is not available it may be necessary to transfuse blood which is positive for a confirmed antibody (SHOT, 2025c).

There were 3 reactions attributed to antibodies to low incidence antigens (1 anti-Wr^{a} and 2 unidentified). However, reactions to these antibodies remain rare.

Figure 21.3: Antibodies implicated in AHTR in 2024



Delayed haemolytic transfusion reactions n=21

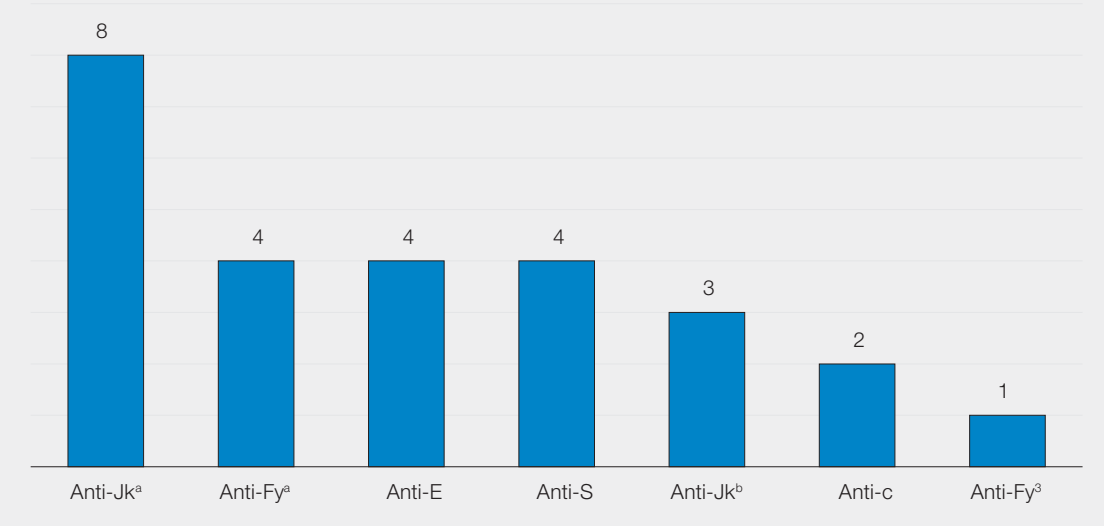
No clinical symptoms of a transfusion reaction were reported in 10/21 DHTR cases submitted to SHOT but in all cases a lack of sustained Hb increment following transfusion was described.

Antibodies to the Kidd blood group system remain the most frequently implicated antibodies in DHTR (Figure 21.4).

Case 21.3: DHTR due to anti-Jk^a

A positive antibody screen was detected prior to transfusion. Antibody identification was performed by the reference laboratory but the antibody was mistakenly identified as anti-K. K-negative units were crossmatched and transfused, however the patient later showed symptoms of a delayed transfusion reaction. On investigation of the cause of the reaction, it was identified that the antibody detected pre transfusion was actually an anti-Jk^a.

Figure 21.4: Antibodies implicated in DHTR in 2024



In 8/21 DHTR cases, the patient had multiple red cell antibodies detected post transfusion. In cases where an eluate was performed, detection of an antibody in the eluate was considered as evidence of that specificity being the cause of the reaction. Elution studies and DAT tests are considered a key test in the diagnosis of a HTR. This can help distinguish between a true HTR and cases in which the observed clinical features and laboratory results are indicative of the patient's underlying condition. DAT was performed on the post-transfusion sample in all cases, however an eluate was not reported in 6/21 DHTR and 5/16 AHTR. Relevant diagnostic workup is vital to correctly diagnose and report transfusion reactions.

Mitigating the risk of HTR

HTR, when they occur, can be very distressing to both patients and the treating clinical teams. Whilst it is impossible to prevent all HTR, the risk can be mitigated by robust pre-transfusion procedures which includes determining if the patient has a history of red cell antibodies. This is especially true for DHTR, which are often caused by previously identified red cell antibodies dropping to undetectable levels in the pre-transfusion antibody screen. Issuing antibody cards to patients with red cell antibodies has been used to inform patients and alert clinical teams. The effectiveness of these depends on the patient showing the card to their healthcare professional prior to transfusion testing and for this information to be relayed to the blood transfusion laboratory. Another method is the use of national antibody databases, such as Specialist Services Integrated Clinical Environment (Sp-ICE), however these are not interfaced with laboratory computer systems and therefore add an additional step to the pre-transfusion process, which is often omitted. Further work is therefore required to address this issue. Alternative methods to share important safety information including the presence of red cell antibodies need to be investigated, for example, by including it on the electronic patient record.

Conclusion

Diagnosis of a HTR can be difficult as many of the classically associated clinical symptoms can also be seen in a number of clinical conditions for which a transfusion is prescribed. In these cases, changes in the results of laboratory tests can be instrumental in providing evidence to confirm a suspected transfusion reaction. Examples include the Hb falling below pre-transfusion levels, the development of a positive DAT in HTR and reticulocyte levels falling in hyperhaemolysis. It is therefore vital that robust laboratory testing is performed when a HTR is suspected.

Providing all relevant details in incident reports submitted to SHOT including results from laboratory investigations supports better understanding, effective analysis and meaningful learning to improve transfusion safety. The SHOT team contacts the reporter to request this information when this is not provided. Over recent years, SHOT has seen a gradual decline in this information being provided within reports. This makes it increasingly difficult for SHOT working experts to distinguish the true reactions and has a negative impact on the quality of the haemovigilance data available for analysis.

Preventing, identifying, treating and reporting HTR requires careful co-ordination, collaboration and communication between multiple clinical and laboratory teams.

Recommended resources

SHOT Bite No. 8: Massive haemorrhage – delayed transfusion
https://www.shotuk.org/resources/shot-bite-no-8/

SHOT Bite No. 15: Hyperhaemolysis
https://www.shotuk.org/resources/shot-bite-no-15/

SHOT Bite No. 31: The role of Sp-ICE in preventing Haemolytic Transfusion Reactions (HTR)
https://www.shotuk.org/resources/shot-bite-no-31/

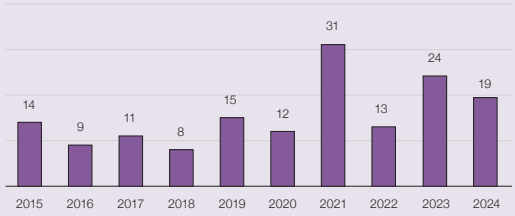
Uncommon Complications of Transfusion (UCT) n=19

Authors: Caryn Hughes and Shruthi Narayan

Headline data 2024

Number of reports n=19
Deaths n=1
Major morbidity n=1

UCT reports by year



Demographic data

Male n=11
Female n=8
Adults n=13
Paediatric n=6

Blood component data

Red cells n=12
Platelets n=4
Plasma n=0
Granulocytes n=1
Multiple components n=2

Key findings:

- Fewer cases reported compared to 2023
- Incomplete details provided in reports impact on analysis and inferences

Gaps identified:

- Lack of early recognition of symptoms suggestive of possible transfusion reactions and prompt reporting and communication to the transfusion laboratory
- Poor vital sign monitoring of patients receiving transfusions
- Organisations lacked defined processes for reporting, reviewing, and trending uncommon complications of transfusion
- Learning from these events is not always evident from reports

Good practice:

- In some cases, there were clear actions taken by hospital transfusion committees to address poor practice
- An unusual cluster of reactions was identified and escalated appropriately by the organisation

Next steps

- Reporters are encouraged to continue to report cases with atypical reactions to transfusion. This will help gain a better understanding of these complications, identify risk factors, and develop risk-reduction strategies

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

Pathological reaction or adverse effect in temporal association with transfusion which cannot be attributed to already defined side effects and with no risk factor other than transfusion and do not fit under any of the other reportable categories, including cases of transfusion-associated hyperkalaemia.

Serious reactions in this category are reportable to the European Union (EU) as 'uncategorised unintended responses'.

Introduction

This category includes cases with uncommon reactions reported in patients with a temporal relation to transfusions but cannot be classified into other categories. Patients often have multiple comorbidities which may contribute to the complication noted. Reporting and reviewing these cases helps to facilitate the ever-evolving understanding of transfusion complications and improve the safety of transfused patients through the implementation of appropriate risk-reduction measures. Occasionally, uncategorisable error reports are included in UCT to ensure learning is captured and shared.

Deaths related to transfusion n=1

There was 1 death reported in this category assessed as possibly related to the transfusion (imputability 1).

Case 22.1: Patient not monitored during platelet transfusion (imputability 1 – possible)

An elderly patient with acute myeloid leukaemia was admitted to the emergency department with a history of a fall, hypothermia, confusion, and suspected septicaemia. The patient was not actively bleeding but did have thrombocytopenia (platelet count <10x10^9/L). They were prescribed an adult therapeutic dose of platelets which was commenced at 16:50. At 18:19 the patient was found in cardiac arrest and subsequently died. On investigation it was noted that baseline observations were performed at 15:20 after which no vital signs had been taken. At the time of the arrest call, the platelets were not considered as a contributory factor and the transfusion laboratory were not informed until 2 days after. This delayed a precautionary recall. The cause of death was determined to be hypothermia and sepsis, with an underlying diagnosis of acute myeloid leukaemia.

Reviewing local policy and practices highlighted that although patients receiving platelet transfusions had to have their vital signs taken, in this clinical area, this wasn't being done. It is unclear whether the staff were trained or competent in blood transfusion. This highlighted the risk of a lack of timely identification, escalation and obtaining advice pertaining to patients with suspected transfusion reactions. The hospital transfusion committee agreed to include this information in the form of a flowchart to provide guidance to clinical staff. This information would be accessible at the nursing station of those areas where transfusion was a frequent occurrence.

Major morbidity n=1

Case 22.2: Patient diagnosed with subdural haematoma following red cell transfusion

A patient with acute coronary syndrome, chest pain and suspected pernicious anaemia was admitted with a haemoglobin (Hb) of 44g/L and chest pain. They were transfused with three units of red cells over approximately 18 hours. Following completion of the third unit, the patient experienced headaches, blurring of vision and other symptoms. A computed tomography head scan revealed a large subdural haematoma. The patient was admitted to intensive care and made a full recovery. The investigation noted that the patient received one dose of aspirin and ticagrelor the day before the bleed. It was later revealed that the patient had fallen and hit their head three days prior to admission resulting in loss of consciousness for 20-30 seconds.

No further details on the reason for the low Hb or the platelet count were available to SHOT. While underlying factors could be contributory, the case has been included here in view of the temporal relationship of the reaction with transfusion.

Other cases n=17

There were 6 paediatric cases, including 4 neonatal cases all from the same centre who presented with 'red urine' following a red cell transfusion from the same donor. There was no laboratory evidence of haemolysis. Their post-transfusion direct antiglobulin test and antibody screen were negative and retrospective crossmatch confirmed compatibility locally. The relevant Blood Service invited the donor back and performed extensive tests to identify any cause for the haemolysis and nothing significant was identified.

A variety of cases with nonspecific symptoms, for example tachycardia, dizziness and facial numbness have been reported in the other cases included in this category. These cases can be viewed in the supplementary information on the SHOT website.

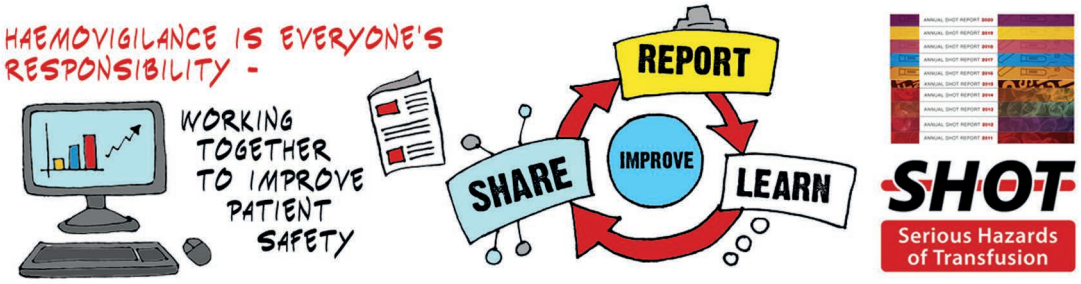
Learning points

- Clear protocols must be in place for clinical staff to access guidance and advice when monitoring transfused patients who present with unusual signs and symptoms
- Investigations into suspected reactions should follow British Society for Haematology guidelines (Soutar, et al., 2023)
- Trending, reporting, and escalating unusual clusters of incidents help organisations identify and mitigate risk and improve patient safety

Conclusion

All staff involved in the transfusion process have an integral part to play in recognising transfusion reactions through the regular monitoring of patients. This ensures the timely detection, escalation, and treatment of these to minimise the impact of the reaction and optimise transfusion safety.

Education and knowledge, including the early recognition of transfusion reactions, as well as learning from these events, should be included in transfusion training and competency assessment. The importance of providing all the relevant details associated with the transfusion reaction is essential to ensure accurate analysis and interpretation.



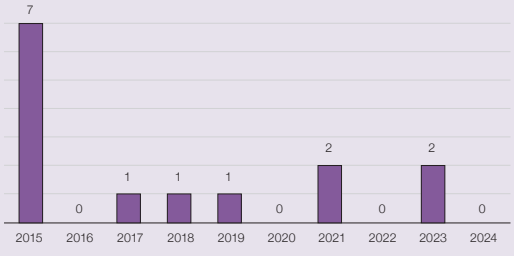
23 Transfusion-Transmitted Infections (TTI) n=0

Authors: Tali Yawitch, Katy Davison and Su Brailsford

Headline data 2024

Number of reports n=0
Deaths n=0
Major morbidity n=0

Confirmed TTI recipients by year



Key findings:

- No confirmed TTI were reported in 2024
- Two bacterial near miss cases were reported in 2024

Gaps identified:

- Bacterial transfusion transmitted infections are rare due to the mitigations in place such as bacterial screening of platelets however, colleagues are encouraged to check for visually abnormal units and remain alert for transfusion reactions

Good practice:

- Visual inspection of blood component packs by vigilant staff at various steps in the transfusion pathway have helped to reduce TTI
- The United Kingdom (UK) Blood Services store a sample from every blood donation for at least 3 years, allowing testing of these samples if a TTI is suspected
- Use of SHOT data to inform policy and prompts necessary changes to improve safety
- The UK Blood Services continuously monitor infection rates in donors to maintain a safe supply of blood components

Next steps:

- All suspected TTI should be reported for investigation, even though confirmed or probable TTI are rare
- Hospitals are encouraged to report suspected TTI when there are no other obvious risks
- The consultant microbiologist, virologist, and/or other infectious disease experts should be consulted to confirm the diagnosis of a suspected TTI
- Once confirmed, the suspected TTI should be reported to the appropriate UK Blood Service for further investigation

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

Included as a TTI if, following investigation, the recipient had evidence of infection post transfusion, there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection.

AND

Either at least one component received by the infected recipient was donated by a donor who had evidence of the same infection.

Or at least one component received by the infected recipient was shown to contain the agent of infection. These may be identified because of infection in the recipient where transfusion is the suspected source, and a post-transfusion infection reported to the Blood Services.

Alternatively, an infection in a recipient may be identified from lookback investigations which are initiated when a donation from a repeat donor is identified as having markers of infection. Archive samples are retrieved for retrospective testing, which may find a previous donation to also be positive but with markers of infection below the detection level of routine screening. In this case further work will be carried out to identify recipients.

Note that for the purposes of the European Union legislation, serious adverse reactions (SAR) are defined as any reactions in patients that are 'life-threatening, disabling or incapacitating, or which result in, or prolongs, hospitalisation or morbidity'. These must be reported to the Medicines and Healthcare products Regulatory Agency (a legal requirement). This includes all confirmed transfusion-transmitted infections.

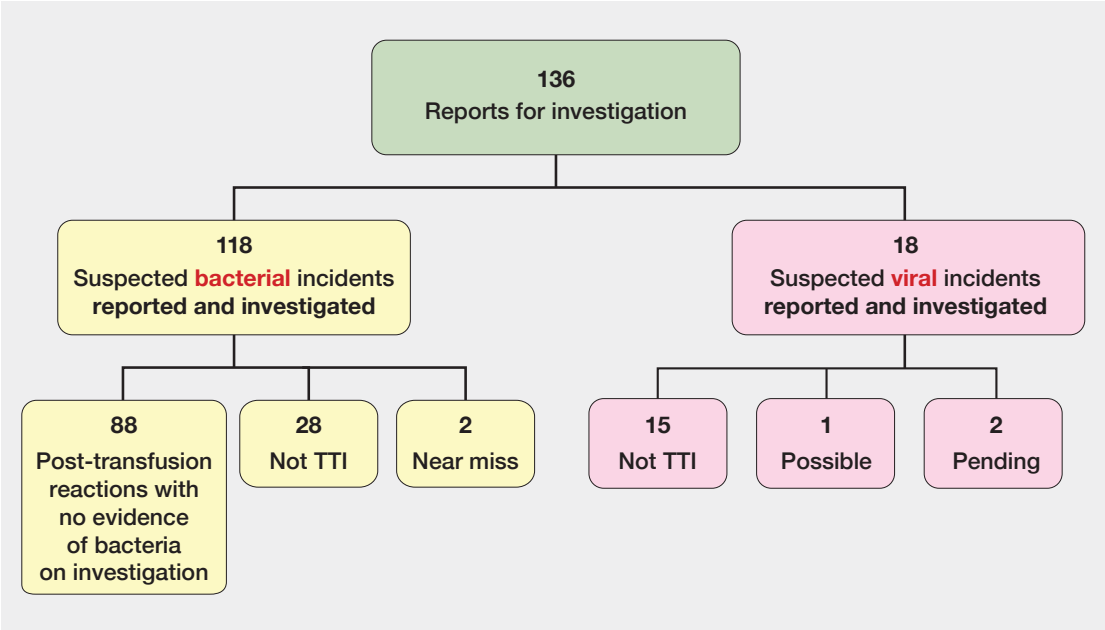
Introduction

This chapter describes suspected TTI incidents investigated by the UK Blood Services and reported to the UK Health Security Agency (UKHSA) and National Health Service Blood and Transplant (NHSBT) joint Epidemiology Unit's surveillance scheme in 2024. Additionally, investigations where the UK Blood Services newly identify infection in a repeat donor and lookback to their previous donation(s) for evidence to exclude transmissions to recipients are reported on.

Summary of investigations in 2024

During 2024, the UK Blood Services investigated 118 suspected bacterial incidents and 18 suspected viral incidents (Figure 23.1).

Figure 23.1: Outcomes of suspected TTI investigated in 2024 and reported to NHSBT/UKHSA Epidemiology Unit for England, Northern Ireland, Scotland, and Wales



Please note:

- *Hepatitis C virus (HCV), hepatitis E virus (HEV), human immunodeficiency virus (HIV) or human T-cell lymphotropic virus (HTLV) identified either before routine screening or through national lookbacks following the implementation of screening are recorded separately and do not form part of the main SHOT numbers*
- *A confirmed TTI is as per the definition with evidence that the virus/bacterium is indistinguishable on molecular typing between patient and donor/donation*
- *A probable TTI is as per the definition, but where molecular typing cannot be carried out to confirm this*
- *A possible TTI is as per the definition, but where prior infection or an alternative source could not be completely excluded*
- *Not a TTI is defined as an investigation that concluded the infection in the recipient was NOT caused by transfusion, either as all indicated donors were traced and none of them were shown to be infected; or there was no evidence of infection in the recipient; or they were shown to be infected already prior to transfusion*
- *A near miss is defined as either an infection that was identified in the unit due to be transfused however the unit was NOT transfused (e.g., bacterial growth seen in the unit and returned to the bacteriology laboratory prior to transfusion for investigation) or an infected donor calls post donation, and the unit is recalled, and infection found in the unit before it is transfused*
- *An undetermined conclusion is when the investigation has been completed as far as possible, however it is not possible to confirm or refute blood transfusion as the cause of infection in recipient*

Deaths and major morbidity related to transfusion n=0

There were no reported deaths or major morbidity cases associated with TTI in 2024.

Near miss n=2

There were two near miss reports in 2024.

Bacterial TTI reports in 2024

In 2024, no reported suspected bacterial TTI investigations were concluded to be confirmed, probable or possible. Two investigations were concluded to be near misses, with *Staphylococcus aureus* identified in both cases as described below.

Case 23.1: Near miss (*Staphylococcus aureus*)

A platelet pack was returned to the Blood Service following the hospital transfusion laboratory noticing a large clump in the pack. The affected pack was a day six apheresis pack, the associated pack was recalled but had already been transfused. Routine bacterial screening remained negative at day seven. Gram staining of the returned pack indicated Gram-positive cocci, organisms were cultured and were identified using matrix-assisted laser desorption/ionisation time-of-flight (MALDI-ToF) as S. aureus. The donor was followed up and no reason was identified that should have prevented them from donating, they volunteered to have nasal swabs taken. S. aureus was isolated from the nasal swabs which were indistinguishable from the pack isolate. Multi-locus sequence typing (MLST) and single nucleotide polymorphism (SNP) analysis using whole genome sequencing showed a single staphylococcus lineage (MLST 5) that is genetically closely related and belonged to the 10 SNP cluster.

The associated platelet pack had been transfused to a patient undergoing regular transfusion. The clinical team followed up the patient who had not experienced any transfusion reaction and remained well seven days post transfusion. The donor has been removed from the donor panel.

Case 23.2: Near miss (*Staphylococcus aureus*)

During quality checking prior to issue, the Blood Service hospital services department noticed a visible clump of approximately 1cm in a pooled platelet pack. This had not been detected by bacterial screening. A sample from the pack was inoculated and Staphylococcus aureus flagged as positive on the BacT/ALERT Virtuo within 5 hours of loading. The original day two sample remained negative on the BacT/ALERT at seven days and was terminally cultured with no growth observed. The four associated red cell units were cultured but there was no growth so the bacteria could not be linked to a single donor.

Since 2011, all four UK Blood Services have used the BacT/ALERT system for bacterial screening, in addition to diversion and arm cleansing. These have been successful in reducing the risk of bacterial TTI (McDonald, et al., 2017). The details are described in Table 23.1.

Table 23.1: Bacterial screening methods used by the UK Blood Services

Blood Service	Time of sampling (hour)	Volume sampled (mL)	Apheresis sample	Time at release (hour)	Length of screening
NHSBT	≥36	2 x 8	Post-split	6	Day 7
NIBTS	≥36	16	Pre-split	6	Day 7
SNBTS	≥36	2 x 8	Pre-split	6	Day 7
WBS	≥36	2 x 8	Post-split	12	Day 7

NHSBT=National Health Service Blood and Transplant; NIBTS=Northern Ireland Blood Transfusion Service; SNBTS=Scottish National Blood Transfusion Service; WBS=Welsh Blood Service

Bacterial TTI 1996-2024

The introduction of bacterial screening of platelets, most recently by England in 2011, has had a significant impact in the numbers of bacterial TTI. However, screening of platelet components cannot guarantee the absence of bacterial contamination. Packs are released for issue as 'negative-to-date' which on rare occasions can be before bacteria have multiplied sufficiently to trigger detection on screening, and growth is seen in the unit before transmission. There have been 19 such near misses, all but two in platelet components, reported between 2011 and 2024. Since reporting began in 1996 there have been 40 bacterial transfusion-transmissions to individual recipients. Of these, 33 were caused by the transfusion of platelets, and 7 by red cells. One red cell case in 1998 also involved fresh frozen plasma (FFP) (Table 23.6). The last confirmed case of bacterial TTI in the UK was in 2015.

Current British Society for Haematology guidance recommends that patients are advised to report any symptoms that occur within 24 hours of transfusion although patients with confirmed bacterial TTI generally become unwell very rapidly, often during transfusion (Soutar, et al., 2023). Clinical teams are reminded that any suspected bacterial TTI should be discussed with the relevant Blood Service so that, if appropriate, packs can be returned for culture and any other associated packs recalled.

Viral TTI reports in 2024

In 2024, there were 18 suspected viral TTI investigated. This included 4 incidents where blood that hadn't been tested for cytomegalovirus (CMV) was used in an emergency, when under ideal circumstances, CMV-negative blood components should have been requested. CMV testing was completed retrospectively in these instances. Such investigations are not further explored in this chapter as they do not fulfil the definition of a TTI. These are included in the figures described in Chapter 9, Incorrect Blood Component Transfused (IBCT), of this Annual SHOT Report.

One possible HCV transmission was identified from a transfusion in 1993; a window period donation could not be completely excluded since the donor tested negative for anti-HCV antibodies, but HCV nucleic acid testing (NAT) was not available at the time of testing. This donor has not donated since the implicated donation and the donor was not traceable in the UK to arrange further testing.

In addition, 2 HCV TTI were reported in recipients transfused before routine HCV screening by SNBTS. These related to HCV lookbacks and have therefore not been included in the data below or in the tables as they had been previously reported.

Revision to the data

In very recent years prior to this Annual SHOT Report, the total annual number of investigations reported in this chapter included some SNBTS cases involving recipients transfused many years in the past, most often before the introduction of screening. These were reported in the body of the Annual SHOT Reports alongside Figure 1, but since the transfusion date was prior to screening and none were confirmed TTI, they were not reported in the tables, as per the definition.

Confirmed viral TTI 1996-2024

The transfusion may have occurred several years before the suspected infection is investigated and/or reported to SHOT due to the chronic nature, and possible late recognition, of some viral infections. Since 1996, 33 confirmed transfusion-transmitted viral infections have been documented in the UK. Among these, HBV (n=11) and HEV (n=12) were the most reported proven viral TTI. For HBV, this is partly because the 'window period' is longer than for HCV or HIV, despite NAT screening of blood donations. A 'window period' is where an infectious donation from a recently infected donor cannot be detected by the screening tests. Since 2022, hepatitis B core antibody (anti-HBc) screening has been undertaken to reduce the risk of HBV transmission from donors with occult HBV.

All except 2 of the 12 HEV transmissions were reported before the HEV ribonucleic acid (RNA) testing was introduced in April 2017 in the UK (Harvala, et al., 2022). This has identified and removed 3344 HEV RNA positive blood donations from the UK blood supply to end of 2024. The rate of HEV RNA detected among donors is greater than other viral infections because it is generally acquired through food, and there is no specific donor selection criteria to minimise donations from those infected.

Lookback investigations

Lookback investigations are initiated by the Blood Service in England when repeat donors are found to be newly positive for a marker of infection. This can be either due to donor seroconversion, post-donation information or introduction of new test. These investigations may involve contacting hospital and primary care teams. Anti-HBc testing was rolled out for UK blood donations from April 2022. All anti-HBc repeat reactive donations are discarded and confirmatory HBV deoxyribonucleic acid (DNA) testing is done on individual donation samples. The implementation strategy varied by country: Scotland began screening all current donors from 05/04/2022, and subsequently tested donations from new and returning donors; Northern Ireland started screening all donations from 30/05/2022; Wales started screening all donations from 27/05/2022; England from 31/05/2022. England's capacity to screen all donations increased with time; donations with repeat reactive anti-HBc and anti-HBs over 100IU/L on screening were discarded without additional confirmatory testing; all screen anti-HBc reactives had confirmatory tests from March 2023; and functionality to allow screening of all donors once only rather than testing at every donation started from May 2023 in England.

During 2024, NHSBT initiated investigations prompted by 11 donors with newly detected markers of infection known to have previously donated (Table 23.2). Fourteen archive samples were available for testing from nine of these donors. Investigations involved 17 previous donations, with 22 of 29 components issued known to be transfused. Of the 22 recipients identified, seven were alive and tested, with four found to have no evidence of transmission, three recipient test results are pending. In lookback investigations, test results confirming negative recipient status include anti-HBc negativity six months post transfusion for HBV, no treponemal antibodies detected for syphilis or no RNA and IgG/IgM antibodies at six months post transfusion for HEV.

Table 23.2: Summary of lookback investigations in England, 2024

	B19	HAV	HCV	HEV	HIV	OBI	Syphilis	Total
Donors with a previous donation identified as positive in retrospective testing	1	1	1	1	1	4	2	11
Archive samples available for testing	1	1	0	0	1	8	3	14
Donations by these donors considered here	1	1	1	1	1	10	2	17
Total components from these donations	**1**	**1**	**2**	**3**	**2**	**16**	**4**	**29**
Cryoprecipitate	0	0	0	0	1	4	1	6
FFP	0	0	0	1	0	1	0	2
Plasma for medicine	0	0	0	2	0	0	1	3
Platelets	0	0	1	0	0	1	1	3
Red cells	0	1	1	0	1	10	1	14
Not known	1	0	0	0	0	0	0	1
Components reported as transfused (recipients transfused)	**0**	**1**	**2**	**3**	**1**	**14**	**1**	**22**
Recipient identified but deceased	0	0	1	2	1	10	1	15
Recipient identified and alive	0	1	1	1	0	4	0	7
Recipient status unknown	0	0	0	0	0	0	0	0
Recipients tested	**0**	**1**	**1**	**1**	**0**	**4**	**0**	**7**
Recipient tested positive	0	0	0	0	0	0	0	0
Recipients tested negative	0	1	0	0	0	3	0	4
Recipient test pending	0	0	1	1	0	1	0	3

Lookback investigations that were reported as pending in the 2023 Annual SHOT Report included two malaria and one HIV investigations (Narayan, et al., 2024), and have been since concluded with no transmisison.

Other reports

Not all reports proceed to a full investigation if transmission can be ruled out, as in some examples below.

- If a recipient tests positive for only antibodies to infection, it is possible that passive transfer of antibodies has occurred due to receipt of intravenous immunoglobulin. If passive transfer is suspected, repeat testing should be carried out 4-6 weeks after the transfusion date. If it is the passive transfer of antibodies, then reactivity should have resolved within this time, and the recipient will not have any evidence of infection
- In recipients where only IgM antibodies are detected, reactivity for RNA/DNA and seroconversion (e.g., IgG) would also need to be confirmed before TTI investigations commenced. This is because IgM assays are often cross-reactive and non-specific, so isolated IgM reactivity is not usually diagnostic
- In recipients with evidence of a chronic infection, previous negative results are desired. This is to evidence transfusion as being the most likely source of infection
- For older cases of possible TTI, year of transfusion should be provided for the implicated transfusions in addition to the unit numbers to enable effective investigation by the Blood Services

Residual risk of HBV, HCV, or HIV

The chance, or residual risk, of a potentially infectious HBV, HCV or HIV ‘window period’ donation not

being detected on testing in the UK are estimated to be very low at less than 1 per million donations tested (Table 23.3) (JPAC, 2024a). The 'window period' is the time very early in the course of infection when tests in use do not detect the virus but there may be a sufficient amount for transmission. The calculations are made annually, but for HBV only consider the risk of non-detection of acute infections and not the risk of non-detection of an occult hepatitis B virus infection (OBI). The residual risk of HEV is not routinely calculated but has been previously estimated to be considerably higher than for HBV, HCV, or HIV. However, while HEV is a blood borne virus, the main route of transmission is zoonotic with humans generally exposed through diet (Harvala, et al., 2022).

Table 23.3: The estimated residual risk that a donation entering the UK blood supply is a potentially infectious HBV, HCV, or HIV window period donation: 2021-2023

	HBV	HCV	HIV
Number per million donations	0.70	<0.01	0.05
95% confidence interval	*(0.48-2.50)*		*(0.01-0.08)*
At 1.8 million donations per year, testing will miss a potentially infectious window period donation every:	1 year	50 years	10 years

Far fewer TTI are observed in practice than the estimated risks in Table 23.3 indicate, partly because the estimates have wide uncertainty, and the model used to calculate risk is based on the risk in all donations tested. The model does not incorporate pack non-use, recipient susceptibility to infection, or under-ascertainment/under-reporting, for example due to recipients dying from an underlying medical condition before a chronic asymptomatic viral condition is identified, or, in the case of HBV, an asymptomatic acute infection.

Blood donation testing and surveillance

Every blood donation in the UK is tested for markers of HBV, HCV, HEV, HIV, and syphilis, with some donations also tested for malaria, *Trypanosoma cruzi* and West Nile virus, depending on donor history. HTLV testing is undertaken for new donors and non-leucodepleted blood components at NHSBT and SNBTS; and in all donors for NIBTS and WBS. Information about donations tested and donors found positive is carefully monitored to help assure safety for recipients (NHSBT and the UKHSA Epidemiology Unit, 2024).

Anti-HBc screening for blood donations was rolled out as part of routine screening across the UK in 2022 in response to a review carried out by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) (Department of Health and Social Care, 2023). This increased detection of potentially transmissible HBV from donors with OBI, which have been removed from the blood supply.

HEV NAT screening of apheresis donations was changed from pooled to individual donations for WBS from November 2022, for SNBTS from April 2024 and NIBTS from November 2024. HEV testing at NHSBT is done on pooled donations.

Donations of plasma for medicine are tested for markers of hepatitis A virus (HAV) and parvovirus B19. In April 2024, screening began on frozen samples of donations collected in 2024 but will move to real-time screening in 2025. Screening started in Scotland from July 2024. The HEV screening process is currently under review by SaBTO, the report is expected to be published in 2025.

Emerging infections

Horizon scanning is performed by UK Blood Services to identify new and emerging pathogens which may threaten the safety of donated blood components, and to ensure that appropriate actions are taken to mitigate any risk identified (JPAC, 2024b).

The Emerging Infection Report produced by the NHSBT/UKHSA Epidemiology Unit is distributed monthly. This is reviewed by the Standing Advisory Committee on Transfusion-Transmitted Infection and may lead to further risk assessment and changes to the donor selection guidelines, or other blood safety measures, where necessary (JPAC, 2025).

Variant Creutzfeldt Jakob disease (vCJD) 2024

There were no vCJD investigations in 2024.

vCJD 1996-2024

Three vCJD incidents took place prior to the introduction of leucodepletion and other measures taken by the UK Blood Services to reduce the risk of vCJD transmission by blood, plasma, and tissue products. All these measures have been reviewed and endorsed by SaBTO (Department of Health and Social Care, 2013). Surveillance continues to look for any evidence that vCJD or CJD could still be transmitted via the blood supply with no case of vCJD being identified for investigation since 2016 and no evidence of sporadic CJD being transmitted by the blood supply (NCJDRSU, 2023). Several countries have removed their blood donor deferral for people who had spent time in the UK between 1980 and 1996, these include Australia, Canada, Republic of Ireland, and the US with the Food and Drug Administration (FDA) also removing the deferral for people who have received a transfusion in the UK since 1980 (FDA, 2022; Hoad, et al., 2023; AABB, 2023; IBTS, 2019).

Table 23.4: Number of confirmed TTI incidents, by infection, reported to NHSBT/UKHSA Epidemiology Unit for England, Northern Ireland, Scotland, and Wales, with transfusions between October 1996 and December 2024 (Scotland included from October 1998)

Year of transfusion	Bacteria	HAV	HBV	HCV	HEV	HIV	Malaria	Parvovirus (B19)	vCJD or prion	Total
1996	1	1	1	1	0	1(3)	0	0	1	6 (8)
1997	3	0	1	1	0	0	1	0	2	8
1998	3	0	1	0	0	0	0	0	0	4
1999	4	0	2 (3)	0	0	0	0	0	0 (1)	6 (8)
2000	6	1	1	0	0	0	0	0	0	8
2001	5	0	0	0	0	0	0	0	0	5
2002	1	0	1	0	0	1	0	0	0	3
2003	2	0	1	0	0	0	1	0	0	4
2004	0	0	0	0	1	0	0	0	0	1
2005	1	1	1	0	0	0	0	0	0	3
2006	2	0	0	0	0	0	0	0	0	2
2007	2	0	0	0	0	0	0	0	0	2
2008	4 (6)	0	0	0	0	0	0	0	0	4 (6)
2009	2 (3)	0	0	0	0	0	0	0	0	2 (3)
2010	0	0	0	0	0	0	0	0	0	0
2011	0	0	1 (2)	0	1 (2)	0	0	0	0	2 (4)
2012	0	0	0	0	2	0	0	1	0	3
2013	0	0	0	0	0	0	0	0	0	0
2014	0	0	0	0	1 (2)	0	0	0	0	1 (2)
2015	1	0	0	0	5 (6)	0	0	0	0	6 (7)
2016	0	0	0	0	0	0	0	0	0	0
2017	0	1	0	0	0	0	0	0	0	1
2018	0	0	0	0	1	0	0	0	0	1
2019	0	0	0	0	1	0	0	0	0	1
2020	0	0	0	0	0	0	0	0	0	0
2021	0	0	1 (2)	0	0	0	0	0	0	1 (2)
2022	0	0	0	0	0	0	0	0	0	0
2023	0	1	0	0	0	0	1	0	0	2
2024	0	0	0	0	0	0	0	0	0	0
Total number of incidents (recipients)	**37 (40)**	**5**	**11 (14)**	**2**	**12 (15)**	**2 (4)**	**3**	**1**	**3 (4)**	**76 (88)**

Table 23.5: Number and type of implicated components from confirmed TTI recipients, reported to NHSBT/UKHSA Epidemiology Unit for England, Northern Ireland, Scotland, and Wales, with transfusions between October 1996 and December 2024 (Scotland included from October 1998)

Year of transfusion	Cryoprecipitate	FFP	Platelet - apheresis	Platelets - pooled	Red blood cells	Total
1996	0	0	0	4	4	**8**
1997	0	0	1	1	6	**8**
1998	0	1	2	0	2	**5**
1999	0	0	1	2	5	**8**
2000	0	0	3	4	1	**8**
2001	0	0	1	4	0	**5**
2002	0	0	0	1	2	**3**
2003	0	0	1	2	1	**4**
2004	0	0	0	0	1	**1**
2005	0	0	0	2	1	**3**
2006	0	0	1	1	0	**2**
2007	0	0	0	0	2	**2**
2008	0	0	4	2	0	**6**
2009	0	0	2	0	1	**3**
2010	0	0	0	0	0	**0**
2011	0	4	0	0	0	**4**
2012	0	1	0	1	1	**3**
2013	0	0	0	0	0	**0**
2014	0	2	0	0	0	**2**
2015	1	3	0	2	1	**7**
2016	0	0	0	0	0	**0**
2017	0	0	1	0	0	**1**
2018	0	0	1	0	0	**1**
2019	0	0	1	0	0	**1**
2020	0	0	0	0	0	**0**
2021	0	2	0	0	0	**2**
2022	0	0	0	0	0	**0**
2023	0	0	0	0	2	**2**
2024	0	0	0	0	0	**0**
Total number of implicated components	**1**	**13**	**19**	**26**	**30**	**89**

Table 23.6: Outcome of confirmed TTI incidents and implicated components by infection, reported to NHSBT/UKHSA Epidemiology Unit for England, Northern Ireland, Scotland, and Wales, with transfusions between October 1996 and December 2024 (Scotland included from October 1998)

	Bacteria	HAV	HBV	HCV	HEV	HIV	Malaria	Parvovirus (B19)	vCJD or prion	Total number of incidents (total number of recipients)
Outcomes										
Death due to, or contributed to, by TTI	7 (8)	0	0	0	2	0	1	0	3 (4)	**13 (15)**
Major morbidity	5 (6)	2	5 (6)	0	8 (11)	2 (4)	2	1	0	**25 (32)**
Minor morbidity or not reported, or unkown	25 (26)	3	6 (8)	2	2	0	0	0	0	**38 (41)**
Implicated component types										
Cryoprecipitate	0	0	0	0	1	0	0	0	0	**1 (1)**
Fresh frozen plasma	0 (1)	0	2 (4)	0	5 (8)	0	0	0	0	**7 (13)**
Platelets	30 (33)	3	1 (2)	0	4	1 (3)	0	0	0	**39 (45)**
Red blood cells	7	2	8	2	2	1	3	1	3 (4)	**29 (30)**

Accompanying notes for Tables 23.4, 23.5 and 23.6

- *TTI of HCV, HEV, HIV or HTLV identified either before routine screening or through national lookbacks following the implementation of screening are recorded separately and do not form part of the main SHOT numbers*
- *Where applicable, number of recipients are included in brackets*
- *One recipient in 1998 received both red cells and FFP*
- *To the end of 2024, no routine blood donation screening has ever been in place for vCJD*
- *During 2024 HAV and parvovirus (B19) screening was implemented by UK Blood Services to facilitate collection of plasma for fractionation*
- *HTLV screening began in 2002*
- *HEV RNA screening began in April 2017 in the UK and was not in place at the time of the documented transmissions*
- *In the early malaria transmissions (1997, 2003), malaria antibody testing was not applicable at the time according to information supplied at donation*
- *HCV investigations where the transfusion was prior to screening are not included in the above table*
- *The year of transfusion may be prior to year of report to SHOT due to delay in recognition of chronic infection*
- *The two early HIV incidents (pre-1996 and in 1996) were associated with window period donations (anti-HIV negative/HIV RNA positive) before HIV NAT screening was in place. A third window period donation in 2002 was transfused to an elderly patient, who died soon after surgery. The recipient's HIV status was therefore not determined and not included*
- *In 2004 there was an incident involving contamination of a pooled platelet pack with Staphylococcus epidermidis, which did not meet the TTI definition because transmission to the recipient was not confirmed, but it would seem likely. This case was classified as 'not transfusion-transmitted'*
- *The vCJD case in 1999 was found to have the same blood donor as one of the 1997 transmissions*

and has therefore been counted as the same incident. Please note this was counted as two separate incidents in previous reports

- *A further prion case died but transfusion was not implicated as the cause of death. The outcome was assigned to major morbidity instead because although there was post-mortem evidence of abnormal prion proteins in the spleen the patient had died of a condition unrelated to vCJD and had shown no symptoms of vCJD prior to death*

For further information or alternative breakdown of data please contact the National Coordinator for Transfusion Transmitted Infections via the NHSBT/UKHSA Epidemiology Unit at epidemiology@nhsbt.nhs.uk.

Conclusion

Investigations of 136 reports of possible TTI in 2024 resulted in no confirmed transmissions (bacterial, viral or parasite).

This provides assurance of the safety of the UK blood supply as a result of the effective measures and haemovigilance systems in place to reduce TTI. Policies and procedures are constantly reviewed to see if any other mitigations are required, most recently SaBTO have reviewed current testing for occult hepatitis B resulting in additional tests being introduced to further reduce the risk of transmission of hepatitis B (Department of Health and Social Care, 2023). During 2024, HAV and parvovirus (B19) screening was implemented by UK Blood Services to facilitate collection of plasma for medicines.

Continued vigilance is needed, as highlighted by the two near miss cases investigated in 2024, which contributes to the haemovigilance of the blood supply.

Transfusion safety relies on rigorous microbiological vigilance at every step, from donor selection to post-transfusion monitoring. Bacterial contamination, viral transmission and other infection risks, though rare, can have serious consequences. As highlighted in the Infected Blood Inquiry: *'To ensure the greatest possible safety, we need to avoid complacency. There is no basis for assuming that threats are all in the past: but watchfulness and learning the lessons of what happened in the infected blood disaster are critical to this'* (IBI, 2024). Ensuring microbiological safety is not a single step; it is a chain of shared responsibility.

Recommended resource

Number of recipients with confirmed/probable Transfusion-Transmitted Infections (TTI)
Number of recipients with confirmed/probable Transfusion-Transmitted Infections (TTI) - Serious Hazards of Transfusion

SPECIAL CLINICAL GROUPS

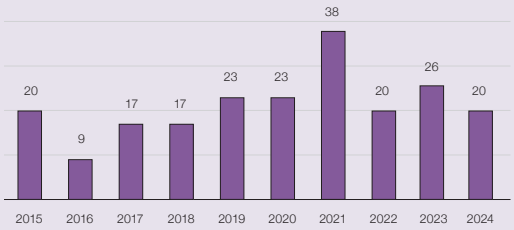
24 Cell Salvage (CS) n=20

Authors: Sarah Haynes and Rebecca Elder

Headline data 2024

Number of reports n=20
Deaths n=0
Major morbidity n=0

CS reports by year



Demographic data

Male n=11
Female n=9
Adults n=18
Paediatric n=2

Blood component data

Red cells n=20
Platelets n=0
Plasma n=0
Multiple components n=0
Other n=0

Key findings:

- There are fewer reports in 2024, suggesting under-reporting
- Avoidable procedural errors were the most reported incidents. Many of these represent themes that recur annually. Of the 20 incidents submitted, only 1 led to a change in practice
- Hypotension represents the most frequently reported adverse reaction, and not always associated with the use of a leucocyte depletion filter (LDF)

Gaps identified:

- Issues with labelling of the cell salvage reinfusion bag with incorrect patient identifiers
- Inadequate training of staff involved in cell salvage
- Lack of foresight and planning for elective cell salvage use in high-risk patients

Good practice:

- One procedural error was managed proactively through a change in practice with a safety briefing and introduction of a second check designed to prevent recurrence
- All machine/disposable malfunctions were recognised early, and the appropriate corrective actions undertaken to minimise impact on the patient
- Hypotensive reactions to salvaged red cells were recognised promptly and dealt with effectively, minimising complications

Next steps:

- Review current training needs and ensure that trained operators are available. Staff members should recognise the limits of their own sphere of competency and ask for help or retraining where there is unfamiliarity with processes and procedures
- Adequate, proactive planning of the use of cell salvage for elective surgeries in high-risk patients should be included early on in the surgical pathway

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

Any adverse events or reactions associated with cell salvage (autologous) transfusion methods, including intraoperative and postoperative cell salvage (washed or unwashed).

Introduction

In 2024, 20 cases were included, which is a reduction from previous years, suggesting the possibility of under-reporting. Reports were submitted by 14 different organisations, with one centre submitting 5 reports, 2 reports each from two others; and the rest were single reports from 11 other reporting sites.

Most reports involved patients undergoing elective surgery, 16/20 (80.0%). The greatest number of events were reported from orthopaedics (including one spinal surgery) and vascular surgery, with remaining reports occurring in six different specialities. All incidents were related to the intraoperative use of centrifugal washing devices.

Table 24.1: Cell salvage cases by speciality in 2024 (n=20)

Specialty	Elective	Emergency	Total
Cardiac	1	0	**1**
General	1	0	**1**
Hepatobiliary	1	0	**1**
Neurosurgery	1	0	**1**
Obstetrics	3	1	**4**
Orthopaedic	4	2	**6**
Plastics	1	0	**1**
Vascular	4	1	**5**
Total	**16**	**4**	**20**

There were 17 adverse events, 9 of which were attributable to avoidable errors, and 8 machine/disposable failures. There were 3 adverse reactions, which were reported as hypotension, unrelated to hypovolaemia. Only 1 of these reactions occurred when using a LDF.

Of all incidents, avoidable procedural error was the most reported incident.

Deaths and major morbidity related to transfusion n=0

There were no deaths or major morbidity related to cell salvage.

Cell salvage adverse events n=17

Eight incidents related to machine/disposable failure, with an additional 9 avoidable procedural errors.

Equipment failure n=8

There were 8 reports of equipment failure, 4 of which were reported to the Medicines and Healthcare products Regulatory Agency (MHRA) under the Yellow Card scheme.

There were 4 device malfunctions, with 1 sensor fault and 3 software failures. In all cases, the correct measures were taken to avoid or minimise consequences to the patient by finding an alternative device and continuing the cell salvage process. In 2 cases, the advanced age of the device was thought to be a contributory factor to the machine failure, despite all devices being on preventive maintenance contracts.

There were 4 issues related to cell salvage disposables. In all cases, the correct action was taken to replace the faulty disposable item and minimise any potential impact to the patient.

Procedural errors n=9

There were 9 reports of avoidable errors. Only 1 case identified the error as occurring due to inadequate training.

In 3 incidents, errors in setting up or using the cell salvage device occurred. In 2 cases, incorrect assembly of the disposables or inadequate priming of anticoagulant resulted in clot formation in the collected blood, and replacement of the disposables with a new set. In a 3rd report, interference with the device by an untrained staff member resulted in device failure.

Two incidents involved reinfusion bags incorrectly labelled with previous patient details. One incident included the collection of blood into a kit prelabelled with a previous patient's details who had since died, without requiring cell salvage. The error was noticed after having left theatre, and cell salvaged blood was discarded. The other incident also included an incorrectly labelled reinfusion bag which was noted, and more concerningly, subsequently altered and transfused regardless.

Case 24.1: Incorrectly labelled blood

A different patient's details from a previous day were on the transfusion label attached to the transfusion record. This was identified in theatre recovery, where the details were amended by the anaesthetist and the transfusion subsequently continued.

Labelling of the cell salvage reinfusion bag with correct patient identifiers should be done at point of contact with the patient. The United Kingdom Cell Salvage Action Group (UKCSAG) has a standardised label that is available from all intraoperative cell salvage (ICS) manufacturers. Unintentional transfusion of ABO-incompatible blood remains a 'Never Event', with significant patient safety ramifications, and safety standards such as checking patient details are accurate are in place to help prevent this. Deviations from correct processes leave patients vulnerable to catastrophic harm.

Two incidents related to the elective care of Jehovah's Witnesses. In 1 case, staff failed to anticipate the need for a LDF until postoperatively, despite the patient having elective surgery for a rectal cancer. This was attributed to the surgery proceeding from laparoscopic to open surgery, which may have necessitated the urgent set up of cell salvage.

In the 2nd incident, cell salvage was requested for a craniotomy. The operating department practitioner and anaesthetists reported they were not proficient or trained in operating cell salvage. They were however encouraged to read some printed instructions and continue setting it up. It was consequently done incorrectly. This was rectified by a trained member of staff but represents unacceptable practice with individuals acting beyond their scope of competency and without adequate training. Of note is the potential morbidity and mortality risks from a lack of planning and preparation in a potentially high-risk elective setting, in a patient who had declined an allogenic blood transfusion.

One case involved the incorrect preparation of swab wash, where saline for irrigation was used instead of intravenous saline and subsequently transfused back to the patient. This represents the only procedural error where a change in practice has been identified. This involved a safety briefing and introduction of a second check of solutions added to the surgical field with the cell salvage operator. This case highlights the importance of set up and preparation, and communication between the scrub staff and cell salvage operators at the World Health Organisation (WHO) team brief (WHO, 2009) as part of the pre-surgery check.

Case 24.2: A distracted operator

A patient underwent elective orthopaedic surgery with cell salvage. The cell salvage operator experienced some difficulty in using the machine, ascribed to unfamiliarity with the software. This resulted in blood not being washed. Upon reflection, the reporter identified several factors that may have also contributed to the error. 'The operation was coming to an end, and they were trying to keep an eye on the patient too. The cell salvage machine had been positioned at the back of the anaesthetic machine, so (that) they could not see the patient and it was difficult to get round…the lines were entangled with other cables. Hence, they were very distracted'.

Despite being in an elective setting, the reporter implies that the cell salvage operator was also a member of the anaesthetic team and was distracted due to additional responsibilities. The 2022 UKCSAG survey highlighted that only 20% of cell salvage procedures are carried out by a supernumerary operator (Kumar, et al., 2024). Whilst utilising an existing member of the theatre team has been deemed to be safe, it should be noted (as for any clinical task) that cell salvage operators must be allowed to prioritise and focus on the job in hand. This incident also highlights the importance of environment design and layout in maintaining vigilance and situational awareness, to uphold patient safety.

Learning points

- Local incident reporting processes should represent an opportunity for shared learning, debriefs, and to strengthen or address current safety policies
- The WHO team brief represents an opportunity for the entire theatre team to communicate, discuss and highlight any concerns regarding cell salvage (WHO, 2009)
- Deviations from recommended processes and suboptimal safety checks pose a risk to patient care. Staff education and training is vital

Cell salvage adverse reactions n=3

There were 3 reports of adverse reactions, all of which comprised marked hypotension, with no other obvious surgical cause. Two out of 3 patients were admitted to the high dependency unit/intensive care unit postoperatively, although these admissions were planned and not attributed to the adverse reactions. A LDF was used in only 1 of the cases, involving the resection of malignant tissue.

Case 24.3: Hypotensive reaction in a patient receiving cell salvaged blood

A patient was undergoing a major vascular procedure. Shortly before finishing, the transfusion of cell salvaged blood was commenced. The patient became profoundly hypotensive, which was compounded by a further bolus of cell salvaged blood. The patient was managed with fluid boluses and an infusion of vasopressors. The patient recovered shortly after and did not require further blood pressure support.

Without further details, it is unclear whether the case represents a reaction to transfusion of cell salvaged blood, hypovolaemia or a cardiac event. A transfusion reaction was initially not suspected by the anaesthetic team either, but it is important to highlight that hypotensive reactions can potentially still occur without the use of a LDF.

Learning points

- Hypotension represents the most frequently reported adverse reaction. It is not always associated with the use of a LDF
- Hypotension should be managed by stopping the infusion, fluid resuscitation and vasopressors as required, whilst all possible other causes are excluded or managed before restarting the transfusion

Conclusion

SHOT has frequently recognised that there have been issues with training in the use of cell salvage and inaccurate labelling of cell salvaged blood. Despite having been flagged in previous Annual SHOT Reports, similar errors continue to occur.

Inadequate training continues to contribute to errors which highlights the need to standardise training across cell salvage practitioners. Refresher training should also be available to staff as appropriate. Practitioners involved in cell salvage should be encouraged to regularly review their training needs and identify areas where retraining or further training is required to ensure competency is achieved/maintained.

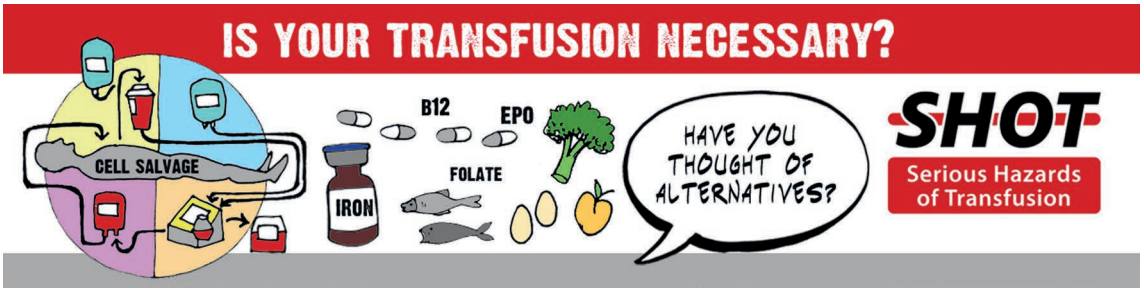
The incidents reported also reveal a lack of preparedness, planning and multidisciplinary communication in both emergency high-risk patients and the elective setting, with significant implications for patient safety.

The paucity of incidents reported needs to be addressed to achieve a more accurate picture of incidents occurring during the use of cell salvage. In conjunction with UKCSAG, more needs to be done to address under-reporting and reframe incident reports as learning opportunities.

Recommended resources

SHOT Bite No. 21: Cell Salvage – Insights from SHOT reports
https://www.shotuk.org/resources/shot-bite-no-21/

UK Cell Salvage Action Group - Intraoperative Cell Salvage Education
https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group/intraoperative-cell-salvage-education



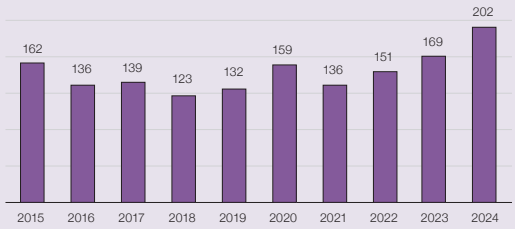
Paediatric Cases n=202

Author: Anne Kelly

Headline data 2024

Number of reports n=202
Deaths n=2
Major morbidity n=25

Paediatric cases by year



Key findings:

- A large proportion of paediatric reports to SHOT were in infants <1 year
- Febrile, allergic, and hypotensive reactions (FAHR) continue to be a significant cause of morbidity in children

Gaps identified:

- Prescribing errors due to knowledge gaps around blood component prescribing. Protocols do not always consider the nuances for different patient groups such as those with sickle cell anaemia and neonates
- Transfusion-associated circulatory overload (TACO) may be under-reported in paediatrics due to difficulties in recognition

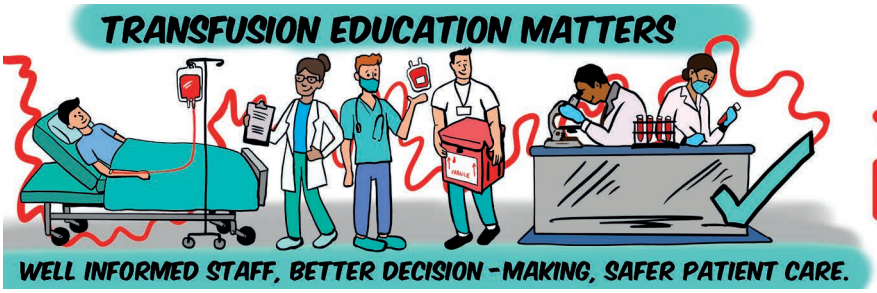
Good practice:

- Multi-disciplinary team meetings between clinical and scientific staff from Blood Services and hospitals facilitate timely management of complex cases
- The identification of a donor with pseudohyperkalaemia following a high potassium result in a blood component. This is an excellent example of the impact of transfusion research on direct patient care

Next steps:

- Ongoing education in the correct prescribing of blood components for infants and children is vital

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).



SHOT
Serious Hazards of Transfusion

Definition:

Paediatric cases comprise all reports for patients under 18 years of age, including all paediatric cases from the other chapters in this report. Paediatric reports have been subdivided by recipient age group: neonates ≤28 days; infants >28 days and <1 year; children ≥1 year to <16 years and young people aged 16 to <18 years.

Introduction

The total number of paediatric cases reported to SHOT in 2024 has increased compared to 2023 (202 vs 169). Paediatric cases account for 202/2312 (8.7%) of total reports if near miss (NM) and right blood right patient (RBRP) are excluded and 340/3998 (8.5%) if NM and RBRP are included.

Figure 25.1: Trends in paediatric reports 2015-2024

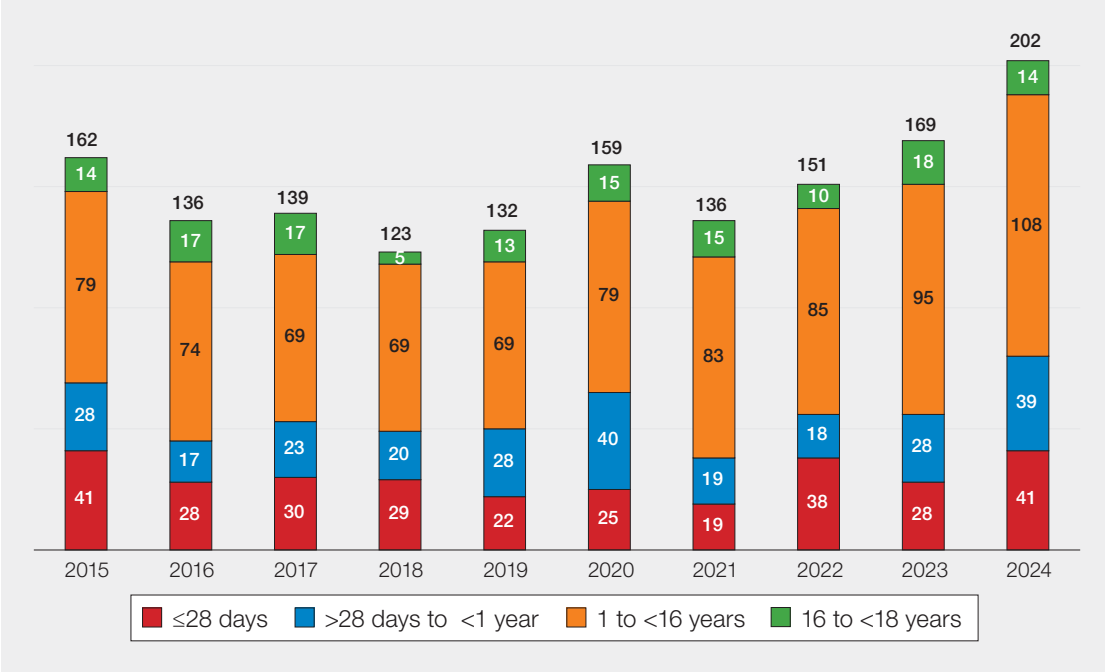
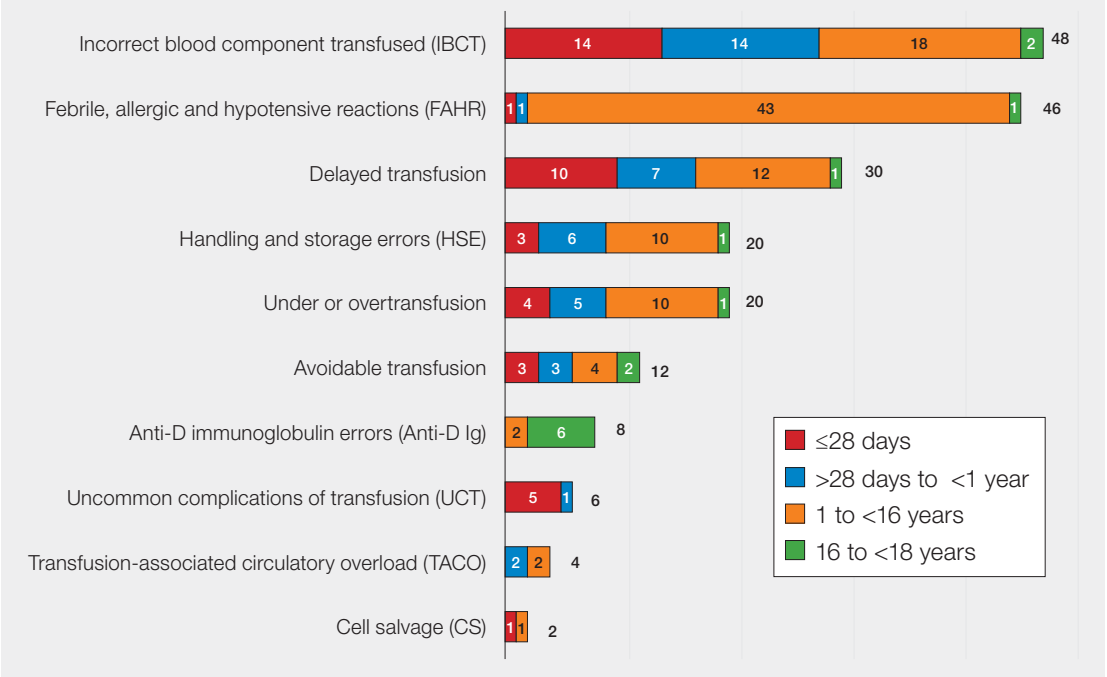


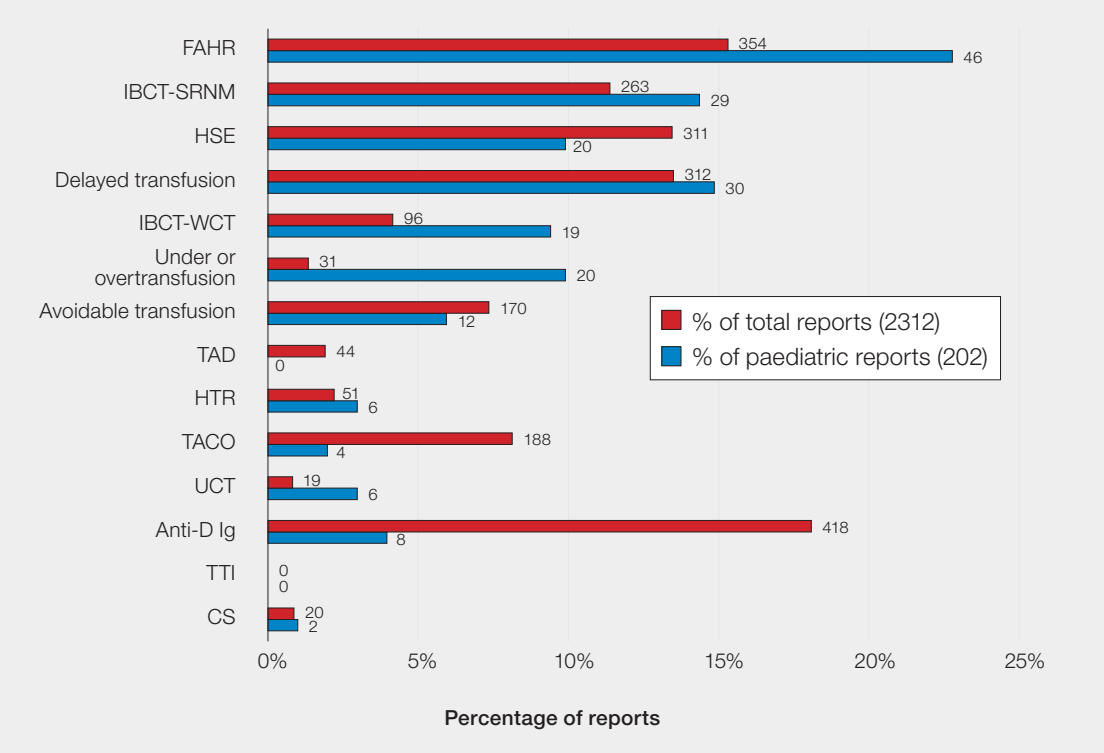
Figure 25.2: Summary of paediatric cases by category and age in 2024 (n=202)



Paediatric reports were over-represented in FAHR, incorrect blood component transfused (IBCT) (in both specific requirements not met (SRNM) and wrong component transfused (WCT)), delayed and under or overtransfusion, uncommon complications of transfusion (UCT) and also this year in haemolytic transfusion reactions (HTR) due to 3 reactions in 1 patient.

Clinical errors remain slightly more common than laboratory errors: 76/140 (54.3%) clinical versus laboratory errors 64/140 (45.7%). The most common categories for clinical errors remain avoidable, under and overtransfusion, delayed transfusion and handling and storage errors (HSE).

Figure 25.3: Percentages of paediatric and total reports in each category in 2024 (n=202)



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

Deaths related to transfusion n=2

There were 2 paediatric deaths related to transfusion reported to SHOT in 2024. One in the delayed transfusion category and 1 in TACO.

Case 25.1: Lack of platelet concessionary release policy for a neonate with thrombocytopenia (imputability 2 – probable)

A very sick preterm neonate required a platelet transfusion prior to tertiary centre transfer. The baby had disseminated intravascular coagulation and required a central line. Platelets were requested but no neonatal/infant specification units were available on site. Due to a lack of concessionary release policy for emergency and failure of the clinical team to communicate the urgency of transfusion, 6 hours elapsed before an adult specification component was authorised. This delayed transfer and contributed to the death.

This case highlights both the importance of communication between clinical and laboratory teams around the urgency of transfusion and the need for pre-agreed hierarchies for the release of components in emergencies. The importance of concessionary release, particularly with relation to neonatal/infant specification components, was highlighted in the 2023 Annual SHOT Report (Narayan, et al., 2024).

Case 25.2: TACO following red cell transfusion in an infant with severe iron deficiency anaemia (imputability 2 - probable)

A 10kg infant was admitted to the emergency department with severe iron deficiency anaemia (haemoglobin (Hb)18g/L). The child received a total of 140mL (14mL/kg) of red cells in 3 aliquots over a 2.5-hour period. The post-transfusion Hb was 51g/L. The child had not received any other fluids and had no previous cardiac disease. Following transfusion, the child deteriorated with evidence of fluid overload and heart failure and was admitted to the paediatric intensive care unit (PICU). There was some response to furosemide, however, the child died.

Of note the volume and rate of red cells were appropriate for age and weight. It is not clear how symptomatic the child was pre transfusion but clearly transfusion was indicated for this patient.

Learning points

- For concessionary release of standard adult components to neonates and infants, laboratories are recommended to have pre-agreed hierarchies in place (New, et al., 2016; New, et al., 2020)
- TACO is likely under recognised in children. Although a formal TACO pre-transfusion risk assessment for children does not exist it is known from previous SHOT data that many of the same adult risk factors apply
- TACO can occur with small or appropriate volumes of component

Major morbidity n=25

There were 25 cases of major morbidity. In line with previous Annual SHOT Reports, the most reported category was FAHR (17) followed by HTR (4) under and overtransfusion (2) and TACO (2). One of the TACO cases is discussed in Case 25.3, and the undertransfusion case is described in Case 25.7.

Case 25.3: TACO causing major morbidity in an infant following overtransfusion of red cells

A 2.5kg infant received 121mL of red cells (48mL/kg) due to a prescribing and administration error. The infant became bradycardic and suffered a cardiac arrest. The pre-transfusion Hb was 77g/L, post-transfusion Hb 190g/L. Chest X-ray showed pulmonary oedema. The infant also developed hyperkalaemia with a potassium of 8.5mmol/L. Venesection and treatment for hyperkalaemia was required. The following pre-transfusion risk factors for TACO were also present: additional crystalloid, cardiac disease, and renal impairment.

Error-related reports n=140

Paediatric error reports continue to increase year-on-year. Reports were 140 in 2024, versus 120 in 2023 and 101 in 2022.

Incorrect blood component transfused (IBCT) n=48

More errors were laboratory, 35/48 (72.9%) than clinical, 13/48 (27.1%) in overall IBCT reports.

IBCT-wrong component transfused (WCT) n=19

IBCT-WCT clinical errors n=7

Three cases involved transfusion of adult specification components to infants or neonates. In all cases, the appropriate neonatal/infant specification blood components were available for emergency use in the same satellite refrigerator. In 2 cases, O D-positive red cells were given in error: one D-negative teenager post haemopoietic stem cell transplant (HSCT) due to an error on a transplant protocol and another D-negative teenager with major haemorrhage in the emergency department (ED) due to a collection error. In the final 2 cases, cryoprecipitate was given instead of fresh frozen plasma (FFP) due to prescribing errors.

IBCT-WCT laboratory errors n=12

There were 5 cases where D-positive red cells were transfused to D-negative recipients. These included a chronically transfused patient with an anomalous test result and an older child for whom the major haemorrhage protocol had been activated. In 2 cases adult specification components were transfused to infants or neonates; one of these was due to the maternity refrigerator being out of order and the other to miscommunication. Testing was incomplete in 2 cases, with components issued on only one valid sample. On 2 occasions, children post liver transplant (group B liver) received group O Octaplas® in error. The final case was a child who had received a HSCT overseas, with mixed field reaction on initial testing who received a unit of A D-positive platelets instead of A D-negative.

IBCT-specific requirements not met (SRNM) n=29

The majority, 23/29 (79.3%), of these errors were laboratory, and 6/29 (20.7%) were clinical.

IBCT-SRNM clinical errors n=6

Clinical errors included 4 failures to request irradiated components; 2 with Di George syndrome, 1 with severe combined immunodeficiency and 1 post HSCT. The remaining 2 cases involved failure to use a blood warmer in a major haemorrhage situation, and a failure to request phenotype-matched components for a sickle cell patient.

IBCT-SRNM laboratory errors n=23

There were 16 cases related to testing errors. In 10 cases testing was incomplete, which included failure to perform testing on a maternal sample in 6 cases, failure to investigate a mixed field (due to unreported previous transfusion) in a neonate and incomplete testing of a child with autoimmune haemolytic anaemia (AIHA) (Case 25.4). Other testing errors were 4 cases of inappropriate electronic issue; cases included a neonate with maternal antibodies, a neonate with a positive direct antiglobulin test (DAT), an infant post liver transplant. There were 2 further cases where components were issued without a valid sample.

Case 25.4: Incomplete testing for a child with AIHA

A young child presented to the ED with a Hb of 24g/L and a presumptive diagnosis of AIHA. The major haemorrhage protocol was activated, and the patient was appropriately transfused with group O D-negative red cells. A subsequent group and screen sample showed a dual population of group O and group A red cells. Antibody screen was weakly positive and DAT strongly positive for IgG and C3d. Antibody testing was reported as negative in-house on an alternative method and two units of red cells were manually crossmatched by the hospital transfusion laboratory and transfused to the patient. Samples should have been sent to the reference laboratory for further testing and antibody identification but instead the component was issued in the hospital.

Learning points

- The investigation of a positive DAT and antibody screen in a child can be complex. Unless appropriate skills exist in-house, liaison with specialist reference laboratory teams is vital
- Clinical teams therefore need to be aware of the potential delay in provision of best red cell component for the child
- Clear communication between clinicians and laboratory staff is required in urgent situations to ensure timely issue of blood components
- Transfusion laboratories require access to adequate senior support at all times

In 4 cases irradiated components were not provided for 2 infants post intrauterine transfusion, 1 infant post HSCT, and the last case involved a patient on purine analogues.

Phenotype-matched components were not selected for 2 patients (1 with HbSS and 1 with HbSC) and in the final case there was a failure to provide cytomegalovirus-negative components for a neonate.

Delayed transfusions n=30

Transfusion delays in children continue to be significant and occur at all stages of the transfusion process. The largest subcategory in delays was due to lack of availability of appropriate blood components (7 cases), with 1 case discussed in the transfusion-related deaths section (failure of concessionary release) and 3 following knowledge gaps about the component specification or patient requirement. One of these 7 cases involved a major haemorrhage situation.

Six delays were due to errors in request/prescribing. These included a case where appropriate follow-up for a neonate with a positive DAT was not arranged and they later presented with significant anaemia. Three cases involved testing errors, 1 of which is discussed below. A summary of all the cases of delays can be found in the supplementary material on the SHOT website.

Four cases involved exchange transfusion including: insufficient red cells for neonatal exchange; delay in a neonate with HDFN due to short expiry and delay for twin infants exchange transfusion for severe pertussis due to failure of communication of urgency and volume required.

Case 25.5: Confusion around the requirement for a maternal sample in a neonate

A neonate had symptomatic anaemia (pallor, tachypnoea, and desaturation, Hb 79g/L) and a paedipack was requested. The baby had been transfused 2 days previously. The maternal transfusion history had been checked (negative for antibodies) on an antenatal sample but a current maternal sample had not been obtained or tested. The laboratory picked up the earlier error when a new request for transfusion was made. At this point a maternal sample was requested. The mother was bought back into the hospital, a sample taken, and the red cells eventually transfused after a 7-hour delay.

In general, it is advisable to request a maternal sample. However, if the transfusion is urgent and the maternal sample not readily available then it is important not to delay transfusion and the testing can proceed on the neonatal sample.

Learning points

- In neonates (and infants <4 months of age) ideally an antibody screen should be performed on a maternal sample
- If a maternal sample is unavailable then the maternal transfusion history should be obtained, and an antibody screen performed on the baby's sample
- If the antibody screen is negative (and DAT if indicated) with no anomalous group, then no further pre-transfusion testing is required until the infant is 4 months old (New, et al. 2016; New, et al., 2020)

Avoidable transfusions n=12

Most of the avoidable transfusions in children were due to a decision based on inaccurate results.

There were 2 confirmed diluted samples; 1 due to an arterial line sampling device in a preterm baby and another due to an incorrect sampling technique in an infant on PICU. In another case, it was not clear whether the avoidable transfusion was following a diluted sample or inappropriate volume. This is discussed in Case 25.6. In 2 cases, the wrong patient's results were used (wrong blood in tube); a triplet was transfused based on a sibling's result and another child transfused based on a result from a different patient (the sample had been labelled away from the patient). Incorrect documentation was used in 2 cases: an inaccurate post-transfusion Hb, and a transcription error of a result from a telephone call. Platelet clumping resulted in 2 erroneous platelet counts, 1 with documented platelet clumps. One transfusion was based on an erroneous result as a repeat full blood count (FBC) prior to transfusion was normal but not checked until afterwards.

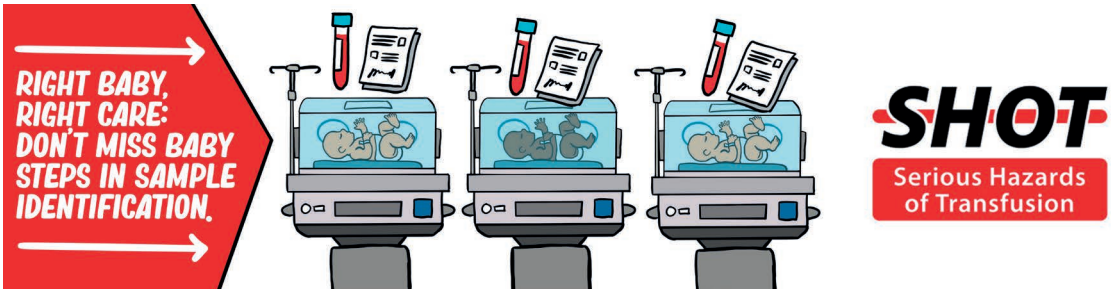
Finally, there were 2 cases with avoidable use of O D-negative components; 1 delay due to multiple issues in an infant with specific transfusion requirements and 1 delay in switching to fully crossmatched red cell units in a teenager with major haemorrhage.

Case 25.6: Avoidable red cell transfusion due to issues with a blood sample and not looking at trend

A teenager with sarcoma was undergoing proton beam therapy and was reviewed in the shared care centre. The Hb was noted to be 79g/L and a two-unit red cell transfusion was requested (a Hb of 100g/L was the transfusion threshold for proton beam). A FBC taken prior to the second unit was 131g/L but the result was not seen until after the unit was given. In retrospect, the initial Hb of 79g/L was considered unexpected based on the trend for the patient. In addition, there was miscommunication between the oncology centre and shared care as it was not realised that chemotherapy had been discontinued 4 months previously.

Learning points

- It is vital to consider whether a blood test result could be erroneous, for example by looking at the trend of blood results, other results obtained at the same time for a patient and the clinical context
- All relevant information that may impact on transfusion decisions must be communicated between tertiary and shared care centres
- In children as for adults (unless bleeding or chronically anaemic), the maximum transfusion volume should be single unit red cell transfusion and then Hb and patient reassessed (NICE, 2015)



Under and overtransfusion n=20

Undertransfusion n=9

One case of undertransfusion was associated with major morbidity. This case highlights again the risks of neonatal exchange transfusions, which are performed infrequently.

Case 25.7: Undertransfusion during exchange transfusion for a neonate

Insufficient red cells were administered to a neonate (pre-exchange Hb 136g/L) undergoing an exchange transfusion, resulting in a post-transfusion Hb of 108g/L. This was due to the use of a fluid giving set (with a smaller diameter) rather than a blood giving set which resulted in fewer red cells being transfused than anticipated. The neonate became hypovolaemic and had a cardiac arrest but survived.

The other cases were: a neonate was undertransfused due to insufficient volume supplied to allow for line priming; 4 cases due to incorrect calculation or use of the paediatric prescribing formula; 2 administration related, 1 of which was due to pump programming. There was also a failure of concessionary release in an exchange transfusion for a child with sickle cell anaemia (only six out of the eight red cell units were given).

Learning points

- Exchange transfusion in neonates remains a complex process which is now infrequently performed. Resources are available to support this (see 'Recommended resources')
- Exchange transfusion in neonates, infants and in older children requires close liaison between clinical and laboratory staff

Overtransfusion n=11

There were 5 administration errors, all of which were due to pump programming errors, with a combination of both volume and rate errors.

Prescribing errors occurred in 6 cases. In one case, a 7.5kg infant was admitted with bloody diarrhoea and Hb of 64g/L who received 40mL/kg of red cells (300mL) and required venesection. The post-transfusion Hb was 184g/L. An infant with thrombocytopenia suffered major morbidity due to bleeding following an overtransfusion of red cells. Two children were overtransfused due to not using the correct formula and prescribing in units rather than millilitres. A child with a congenital anaemia was overtransfused due to the inappropriate use of a thalassaemia protocol. The remaining case is described in Case 25.8.

Case 25.8: Overtransfusion in a child with sickle cell anaemia due to a prescribing error

An overtransfusion error was discovered in retrospect following an audit of practice. A teenager with sickle cell anaemia was admitted with diarrhoea and vomiting. Pre-transfusion Hb was 83g/L. The transfusion calculation was performed incorrectly and 1080mL (26mL/kg) of red cells were given. Post-transfusion Hb was not recorded. There was insufficient documentation to be able to judge whether the transfusion was indicated at all.

Learning points

- Children with sickle cell anaemia are particularly vulnerable to the risks of overtransfusion
- Factors to consider when prescribing red cells in this patient group are diagnosis, steady state Hb, HbS% and individualised transfusion targets and additional risks, such as hyperviscosity (Davis, et al., 2017a; Trompeter, et al., 2020b)

Cell salvage n=2

One case involved a neonate having cardiac surgery who only had a fraction of the salvaged blood reinfused while still on bypass and could not receive the rest due to mislabelling of the bag. The other case involved a teenager and was due to centrifuge failure.

Handling and storage errors (HSE) n=20

The majority of HSE errors were clinical errors 17/20 (85.0%).

There were 9 pump programming errors and 1 incorrect giving set used. Cold chain errors occurred in 4 cases; 3 refrigerator failures and 1 red cell unit was placed in a non-blood refrigerator. In 4 cases blood

components were transfused over a prolonged period (>5hours), in 1 case the reservation period due to sample validity was exceeded, and in the final case a time-expired unit of cryoprecipitate was transfused.

Anti-D immunoglobulin (Ig) errors n=8

There were 8 paediatric cases related to anti-D Ig errors. The age range of these cases was between 14 to 17 years old, all of them related to errors in pregnancy. Three cases resulted in omission or late administration of routine antenatal anti-D Ig prophylaxis. In 1 of these cases the review of the incident resulted in improvements in multiple areas; staffing, training, information technology and documentation. There were 3 cases where the cell free fetal deoxyribonucleic acid testing result was available (predicted D-negative fetus), but the result was not checked by clinical or laboratory staff prior to issuing and administration. All these unnecessary administrations of anti-D Ig were following potentially sensitising events. In 2 cases immunisation to the D antigen had already occurred, however the antibody status was not checked by the biomedical scientist prior to issuing anti-D Ig resulting in inappropriate anti-D Ig administration.

Transfusion-related reactions n=62

Febrile, allergic, and hypotensive reactions (FAHR) n=46

The majority of FAHR were in children between the ages of 1 year and 16 years, with only 1 being in a newborn and 1 in an older infant. Platelets were implicated in 25/46 (54.3%) cases, compared to 52.8% in 2023 and 68.6% in 2022.

Figure 25.4: Summary of paediatric FAHR reports by component from 2015-2024

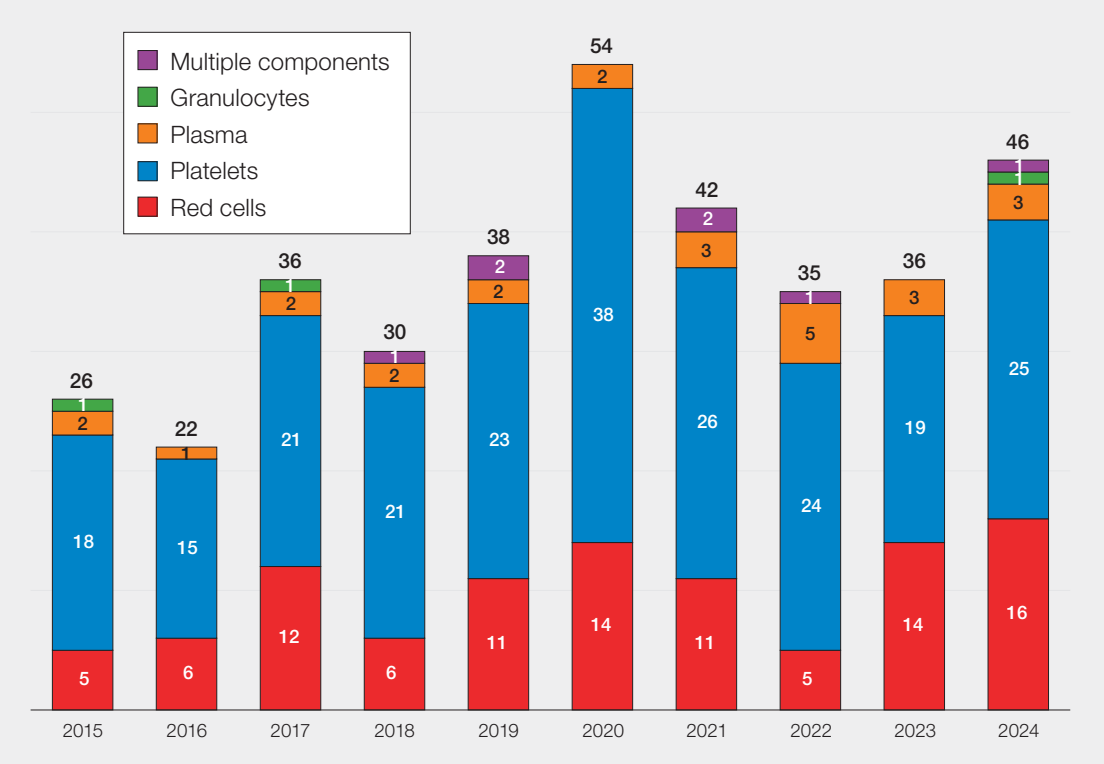
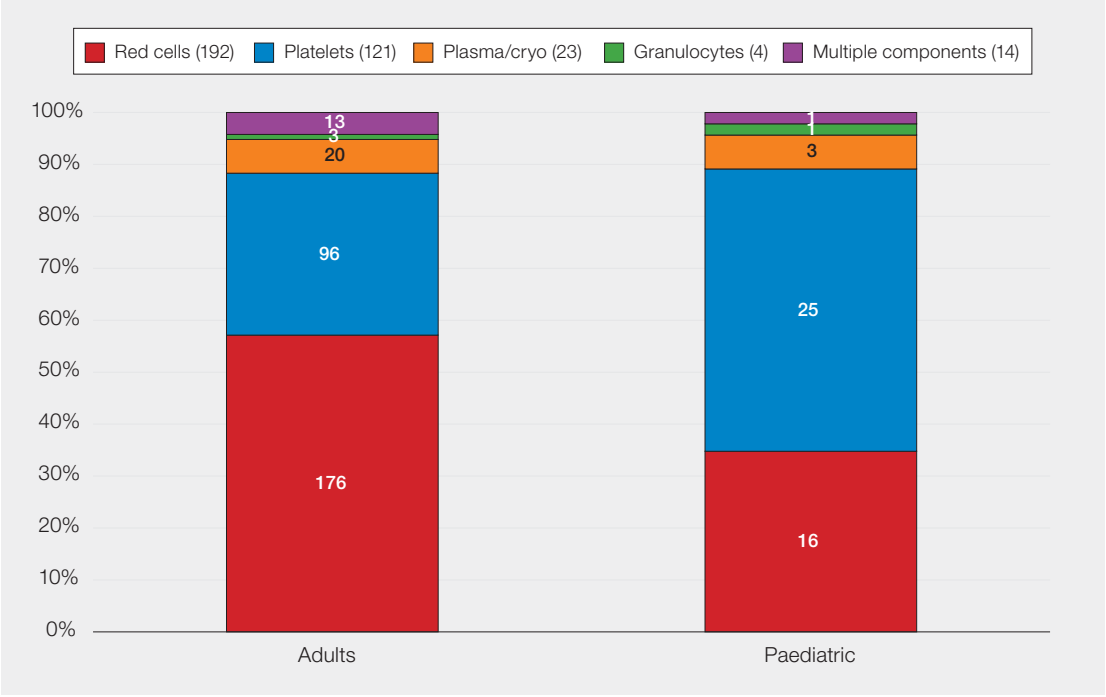
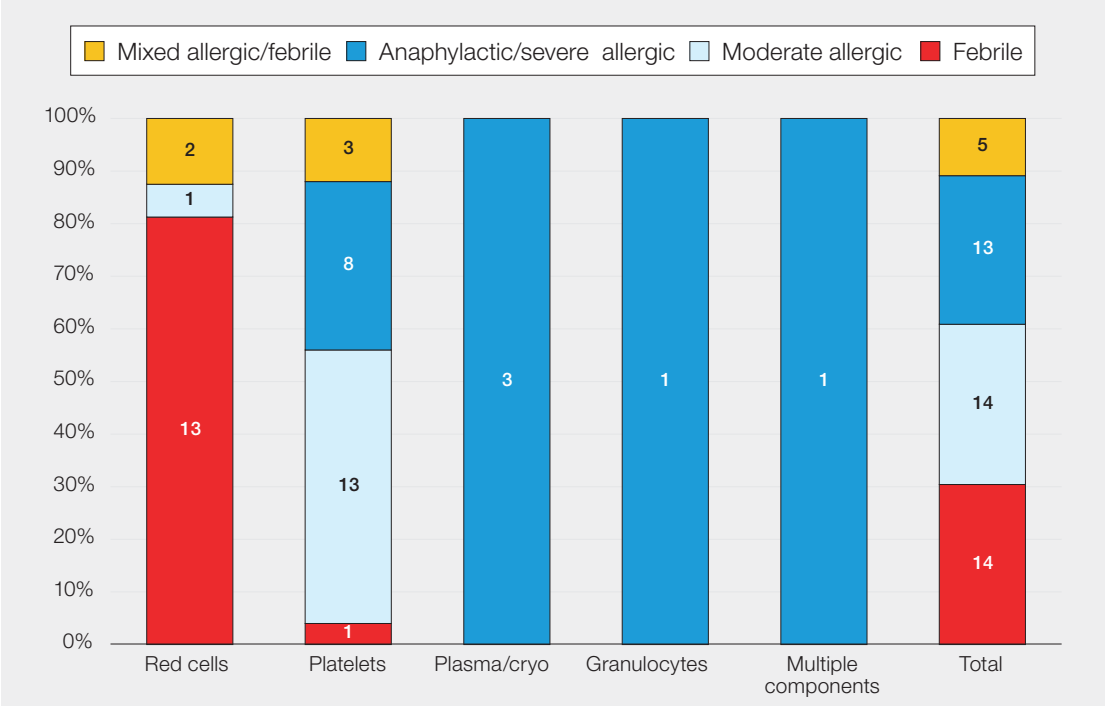


Figure 25.5: Paediatric FAHR reports in 2024 (n=46)
a: Comparison of proportions of adult and paediatric reports by component types



b: Percentages of reaction types in paediatric FAHR related to different component types



Haemolytic transfusion reactions (HTR) n=6

Three reactions were in older children with sickle cell anaemia. One was an acute haemolytic reaction with possible anti-Lu[a] and 1 delayed haemolytic transfusion reaction (no antibodies were identified). Both children were managed with intravenous immunoglobulin (IVIg) and steroids. The final case was a child with sickle cell disease who had hyperhaemolysis. The other 3 HTR all occurred in one patient (Case 25.9).

Case 25.9: Recurrent acute haemolytic transfusion reactions in a complex post HSCT child

A young child post HSCT for immunodeficiency had a gradually dropping Hb. The pre-transfusion DAT was positive (C3d) with investigations and crossmatch being performed by the Blood Service. Following

transfusion of only 60mL of red cells the child developed fever, abdominal pain and dark urine. The post-transfusion eluate was difficult to resolve with both an autoantibody and possible anti-E and anti-Jk^{b}. The child received two further red cell transfusions with sequential changes to management including: lowered transfusion threshold, phenotype-matched red cells, folate supplementation, treatment for mycoplasma, blood warmer, immunosuppression for presumed autoimmune haemolytic anaemia (steroids and IVIg). Post-transfusion investigations showed a pan-reactive red cell antibody with the only negative reaction being in the cord blood cell. Further serology from the International Blood Group Reference Laboratory (IBGRL) showed ongoing incompatibility with all cell types (including cord, In(Lu), adult ii and A1). Fortunately, the patient responded to immunosuppression and has not required further transfusion. A follow-up sample was planned to be sent to IBGRL 3 months from the last transfusion for further investigation.

This child with complex serology and clinical picture was managed via a series of multidisciplinary team meetings, facilitated by the Blood Service reference laboratory team. This allowed clinical and scientific staff from the Blood Service, hospital transfusion laboratory and the treating team to discuss and devise optimal care. This included an individualised transfusion threshold, consideration of erythropoietin and ongoing immunosuppression. In addition, a plan was developed for any future transfusion support including potential use of complement blockade, optimally matched components, and further testing.

Learning point

- Complex cases require multidisciplinary working across Blood Services and hospitals to provide optimal care for patients

Pulmonary complications of transfusion in neonates and children n=4

All pulmonary complications in 2024 were classified as TACO.

One case was associated with mortality (Case 25.2) and one with major morbidity (Case 25.3). A 3rd case involved a child with severe iron deficiency anaemia (Hb 30g/L) who developed signs of moderate fluid overload after an appropriate volume of red cells (13mL/kg).

The final case involved a 22kg child with leukaemia (pre-transfusion Hb 89g/L) who was also receiving hyperhydration. They were transfused with platelets and 25mL/kg of red cells prior to portacath insertion. One hour after the transfusions, a drop in saturations was noted together with an increase in temperature. A chest X-ray showed evidence of atelectasis and basal consolidation. The fluid balance was significantly positive (>1 litre). The child improved with supportive measures.

Transfusion-transmitted infections (TTI) n=0

There were no cases of TTI in children or neonates in 2024.

Uncommon complications of transfusion (UCT) n=6

Four cases involved neonates on the same neonatal unit. Three of these occurred during the same week and received a separate paedipack from the same blood donor. The red cell units were all transfused at between 24 and 30 days of shelf life. The neonates developed red urine post transfusion, but no other markers of haemolysis were found. The Blood Service investigated the donor thoroughly and no cause was found. The 4th case occurred 7 months later, on the same neonatal unit as the 3 previous cases. A cause has not been found and the blood on this occasion was from a different donor. All neonates recovered from this episode uneventfully.

There was also 1 case of transfusion-associated necrotising enterocolitis in a pre-term baby and a case of high potassium in a bypass circuit (Case 25.10).

Case 25.10: High potassium in a bypass circuit for a neonate undergoing cardiac surgery

High potassium levels (19 mmol/L) were found in an irradiated large volume transfusion unit when

performing equipment prime prior to bypass. The unit was day 3 post donation, and it was 15 hours post irradiation. The unit was filtered and washed and due to clinical urgency, was transfused once potassium levels were within normal/usual range. Subsequent testing of the donor by the Blood Service confirmed that the donor was heterozygous for a genetic variant, associated with familial pseudohyperkalaemia.

Familial pseudohyperkalaemia causes an increased leak of potassium from red cells during cold storage (Bawazir, et al., 2014).

Learning point

- This case illustrates the importance of checking the potassium in bypass fluids prior to connection to the child and is recommended in the British Society for Haematology guidance (New, at al., 2016)

Paediatric error reports with no harm n=138

The numbers of cases of no harm/near miss are summarised below.

Table 25.1: Paediatric error reports with no harm in 2024 (n=138)

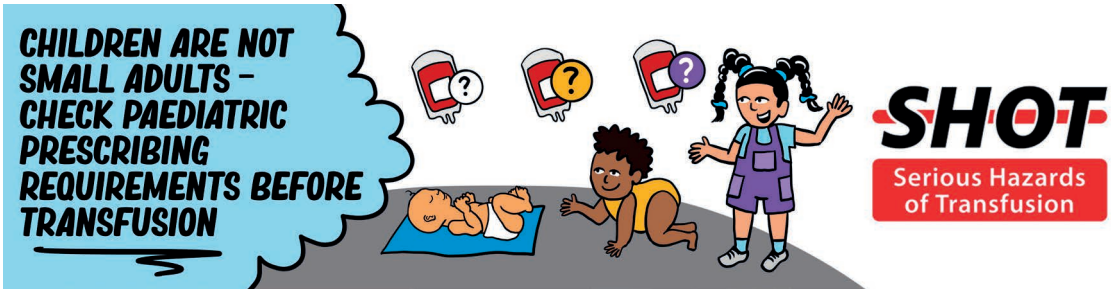
	≤28 days	>28 days-<1 year	1-<16 years	16-<18 years	Total
RBRP	3	4	7	2	**16**
NM	14	7	30	4	**55**
NM-WBIT	44	5	15	3	**67**
Total	**61**	**16**	**52**	**9**	**138**

Of note for the WBIT cases 44/67 (65.7%) were neonates which reflects some of the complexities of patient identification in this age group.

Conclusions

Paediatric transfusion safety requires meticulous attention to detail; small errors can have significant consequences. Weight-based prescribing, effective identity checks, and vigilant monitoring are essential at every stage. Children may present with subtle signs of transfusion reactions, so early recognition and clear communication between teams are vital. Paediatricians and neonatologists should be able to recognise transfusion reactions that can occur in various clinical settings and initiate appropriate management. Laboratory investigation in neonates and infants <4 months and children with antibodies can be complex.

Paediatric teams should have access to local paediatric transfusion guidelines, and these must be aligned with national guidelines. Induction training of paediatric staff should include specific requirements and weight-based prescribing to address errors in calculation of blood transfusion volumes and prescribing specific requirements (e.g., irradiation). Appropriate use of blood components with special requirements, and a culture that encourages reporting of both excellence and near misses all contribute to safer care. By learning from such events, safety of transfusions for our youngest and vulnerable patients can be improved.



Recommended resources

SHOT video: Paediatric SHOT
https://www.shotuk.org/resources/paediatric-shot/

SHOT webinar: Accurate and complete patient identification in paediatric transfusion
https://www.shotuk.org/resources/webinar-on-accurate-and-complete-patient-identification-for-safe-transfusion-in-paediatrics/

Exchange transfusion educational videos (HEE/NHSBT)
Videos describing manual red cell exchange for sickle cell for patient <40kg
https://www.youtube.com/watch?v=e2itKcfXQAE
and for patients >40kg
https://www.youtube.com/watch?v=5QFiLziDxbc

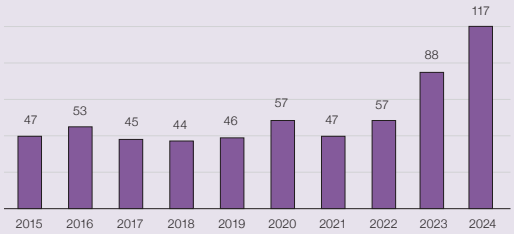
26 Haemoglobin Disorders n=117

Author: Joseph Sharif

Headline data 2024

Number of reports n=117
Deaths n=3
Major morbidity n=14

Haemoglobinopathy cases by year



Key findings:

- The number of reports related to haemoglobin disorders have increased year-on-year
- Haemolytic transfusion reactions (HTR) are a particular problem in patients with sickle cell disease (SCD) and make up a significant proportion of all HTR reported to SHOT
- There were 3 deaths following HTR, all were in patients with SCD
- Reports of febrile, allergic, and hypotensive reactions (FAHR) more than doubled in 2024
- Cases of specific requirements not met (SRNM) continue to be reported

Gaps identified:

- Lack of awareness among healthcare professionals regarding the significant risks associated with transfusion, particularly in SCD
- Advice from haematologists specialising in SCD is not always sought prior to transfusion decisions
- National guidance is not always adhered to as demonstrated by examples of unnecessary and unclear indications for transfusion

Good practice:

- It is encouraging to see an increasing trend in reports received in this category as under-reporting continues to be an issue

Next steps:

- Haematology teams must be involved in the management of haemoglobinopathy patients presenting to secondary care and be consulted regarding transfusion decisions
- All haemoglobinopathy patients should have a baseline extended red cell phenotype or genotype prior to transfusion
- It is important to gain a full transfusion history from the patient and inform the transfusion laboratory when patients present to an unfamiliar hospital. The national database (Specialist Services Integrated Clinical Environment (Sp-ICE) or equivalent) should be checked, and the patient's base hospital transfusion laboratory asked for previous transfusion records

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

This chapter includes all incidents reported in patients with a significant haemoglobinopathy including sickle cell disease and thalassemia.

Introduction

The total number of haemoglobinopathy cases reported for 2024 was 117, which included 76 cases in SCD patients and 41 cases in thalassaemia patients.

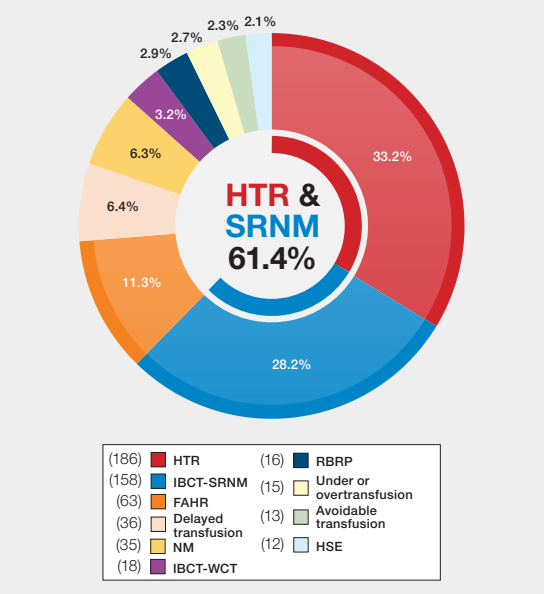
Table 26.1: Cases involving haemoglobin disorders reported in 2024 (n=117)

SHOT category	Sickle cell disease	Thalassaemia	Total
Haemolytic transfusion reactions (HTR)	20	1	**21**
Incorrect blood component transfused-specific requirements not met (IBCT-SRNM)	16	4	**20**
Febrile, allergic, and hypotensive reactions (FAHR)	11	17	**28**
Delayed transfusion	5	3	**8**
Avoidable transfusion	2	1	**3**
Under or overtransfusion	5	3	**8**
Handling and storage errors (HSE)	1	4	**5**
IBCT-wrong component transfused (IBCT-WCT)	2	0	**2**
Right blood right patient (RBRP)	4	1	**5**
Near miss (NM)	8	4	**12**
NM-wrong blood in tube (NM-WBIT)	2	3	**5**
Total	**76**	**41**	**117**

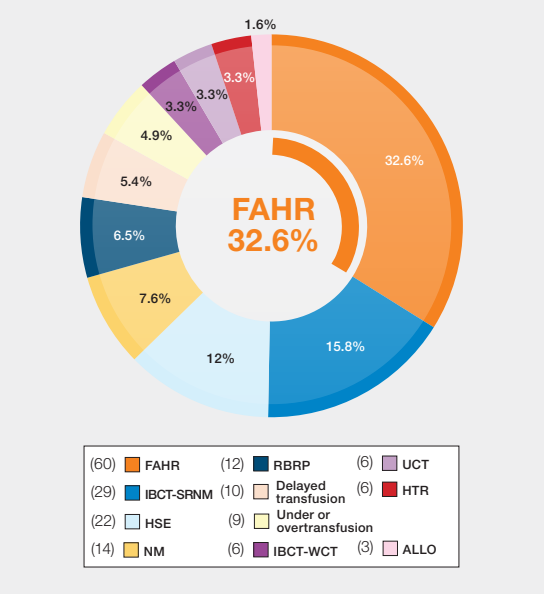
The most frequent reports in SCD were HTR and IBCT-SRNM. The most frequent reports in thalassaemia patients were FAHR.

Figure 26.1: Cumulative data for adverse transfusion events in patients with haemoglobin disorders 2010 to 2024

a. Sickle cell disease (n=560)



b. Thalassaemia (n=184)



ALLO=alloimmunisation; FAHR=febrile, allergic or hypotensive reactions; HSE=handling and storage errors; HTR=haemolytic transfusion reactions; IBCT=incorrect blood component transfused; NM=near miss; RBRP=right blood right patient; SRNM=specific requirements not met; TACO=transfusion-associated circulatory overload; TTI=transfusion-transmitted infection; UCT=uncommon complications of transfusion; WCT=wrong component transfused

Categories with 2 or fewer reports are not included in the figures

Deaths related to transfusion n=3

There were 3 deaths in cases of SCD in the context of a HTR.

Case 26.1: Acute presentation following recent transfusion resulted in patient death (imputability 2 – probable)

A patient with SCD and a history of red cell alloimmunisation received one unit of red cells for concerns over evolving chest syndrome with severe chest pain and hypoxia. The patient was discharged 5 days later but re-presented within 24 hours with severe pain and rapidly progressive multi-organ failure. They were admitted to critical care but died within 48 hours. The working diagnosis was delayed HTR/hyperhaemolysis.

Case 26.2: Death secondary to hyperhaemolysis (imputability 2 – probable)

A patient with SCD and a history of red cell alloimmunisation presented with a sickle cell crisis and was given two units of red cells. The patient was discharged the following day but then re-presented 6 days later with recurrent pain, weakness, dark urine, and a falling haemoglobin (Hb). They were admitted to critical care and died within 48 hours of admission. The working diagnosis was hyperhaemolysis.

The third death has been described in Chapter 21, Haemolytic Transfusion Reactions (HTR), Case 21.1.

Major morbidity n=14

There were 14 cases associated with major morbidity in 2024. These included 10 HTR, all with SCD, and 4 FAHR, 2 with SCD and 2 with thalassaemia.

Febrile, allergic, and hypotensive reactions (FAHR) n=28

There were 28 reports of FAHR, 11 of which were in patients with SCD, and 17 occurred in patients with thalassaemia. All patients made a full recovery. Case 26.3 illustrates a case of FAHR in a patient with thalassemia.

Case 26.3: Febrile reaction in a young child with thalassaemia leading to major morbidity

A young child with thalassaemia was attending an outpatient department for routine red cell transfusion. The first red cell unit was given uneventfully, but during observations to administer a second unit, they became unresponsive. They had chills, rigors, developed a fever of 40.6°C and tachycardia (heart rate 142 beats per minute). The child was treated with paracetamol, antihistamine, and admitted to the paediatric ward for observation overnight. A repeat group and screen sample was tested but did not indicate incompatibility. The red cell unit was sent to the Blood Service for bacterial and fungal culture testing, the results of which were negative. They were discharged the following morning with no further concerns. Local investigation showed that staff dealt with the reaction promptly and appropriately.

Learning points

- All areas administering blood components need to be appropriately equipped, and staff trained, to manage a severe acute reaction. This includes settings where transfusion is given in outpatient settings. Prompt recognition and timely management of reactions is vital to ensure patient safety
- The possibility of a febrile or allergic reaction should be explained to patients/guardians when taking consent for transfusion and relevant patient information leaflets should also be provided

Haemolytic transfusion reactions n=21

The 21 cases reported included 10 cases of hyperhaemolysis, 10 cases of delayed haemolytic transfusion reaction, and 1 acute reaction. Twenty of the cases were in SCD patients which included 3 transfusion-related deaths.

Intravenous immunoglobulin (IVIg) use was reported in 13 cases and intravenous corticosteroids in 11 cases. Eculizumab was reportedly used in 2 cases.

Case 26.4: SCD patient transfused without haematologist advice

A patient with SCD and a history of a previous HTR with multiple red cell antibodies was admitted under the renal team with a Hb of 41g/L. There were clear instructions from the haematology consultant not to transfuse the patient without discussion. A decision to transfuse was made without discussion with haematology which resulted in a further drop in Hb to 37g/L. A new alloantibody (anti-Fy^a) was identified on antibody screen. The patient was treated with IVIg, corticosteroid and further red cell transfusion. The patient died subsequently but the cause of death was not recorded as being related to transfusion.

Case 26.5: Hyperhaemolysis despite IVIg and corticosteroid prophylaxis in thalassaemia

A patient with non-transfusion dependent thalassaemia was admitted with significant anaemia. The patient was transfused one unit of red cells and due to a history of hyperhaemolysis, they also received IVIg and corticosteroid. The patient presented 8 days later with recurrent haemolysis which was managed appropriately, and they recovered fully.

Learning points

- Hyperhaemolysis can recur when a patient with a history is transfused despite the use of prophylactic IVIg and corticosteroid
- Transfusion in patients with red cell antibodies, especially with a history of haemolysis, carries significant risk. This requires early specialist input and risk-benefit assessment prior to transfusion support

IBCT-Specific requirements not met n=20

The specific requirements of blood transfusion for SCD and thalassaemia patients include ABO, extended Rh- and K-matched red cell units. Blood should also be antigen-negative for any clinically significant red cell antibodies and HbS negative for SCD patients. Where possible, blood should be <10 days old for simple transfusion and <7 days old for exchange transfusion but older blood may be given if the presence of red cell antibodies makes the provision of blood difficult (Davis, et al., 2017b).

There were 20 reports of IBCT-SRNM for patients with SCD (n=16) and thalassaemia (n=4).

Case 26.6: Difficulties ascertaining specific requirements of a new patient during a cyber-attack on the hospital electronic patient record system

A patient with SCD presented to a hospital that was not their usual base hospital with a sub-arachnoid haemorrhage and transfusion was requested. Although the laboratory information management system (LIMS) was shared between the new hospital and base hospital, there were different procedures for each system recording specific requirements. The request was made during downtime on the LIMS following a hospital cyber-attack. The patient had a Sp-ICE record; however, this was not accessed due to a discrepancy in the demographic data. The patient was known to be D-variant and should receive D-negative units. The crossmatch sample reacted strongly with anti-D reagent and therefore, the laboratory issued two units of D-positive red cells.

Case 26.7: Poor communication with laboratory

Blood components were requested for a SCD patient, but the only clinical detail provided on the request was 'HbSC'. The laboratory staff did not recognise from the limited information provided that this was a SCD patient and therefore the red cell units issued were not extended phenotype matched or HbS-negative. This was incidentally discovered when laboratory staff looked up the haemoglobinopathy screening results at a later date.

A similar case was reported from another hospital where poor communication from clinical teams to transfusion laboratories about specific transfusion requirements meant that appropriately matched red cells were not transfused.

Case 26.8: No extended phenotype-matched red cells provided for a thalassaemia patient

A patient with thalassaemia was admitted to the stroke unit. Group and antibody screen on admission was sent without indicating the patient had a haemoglobinopathy. Two units of red cells were requested that were not extended phenotype-matched and the patient inappropriately received one E-positive unit.

These cases highlight the importance of clear communication between clinical and laboratory staff when requesting blood for patients with haemoglobinopathies. Some electronic patient record systems specifically ask if a patient has a haemoglobinopathy when requesting blood components, to ensure specific requirements are provided. Confirming that the laboratory staff have received all the key information to ensure patient's specific transfusion requirements are met is vital.

Near miss n=17

There were 5 cases of wrong blood in tube (WBIT) events and 12 reports in other NM categories. Ten of these cases were in patients with SCD and 7 were in thalassaemia patients

Case 26.9: Missed specific requirements for a haemoglobinopathy patient undergoing exchange transfusion

A patient with SCD and multiple red cell antibodies, required a six-unit red cell exchange transfusion. Biomedical scientist (BMS) 1 pre-ordered the red cell units from the Blood Service. Three of the six red cell units ordered did not have the correct antigen-negative requirements. BMS 2 began crossmatching the red cell units during the night shift but realised they did not meet the patient's antigen requirements. BMS 2 found replacement red cells from routine stock which met antigen requirements, but one red cell unit was not HbS-negative. The laboratory information management system (LIMS) did not alert BMS 2 to the missing requirement at issuing.

The nurse conducting the pre-administration check identified that the red cell unit was not HbS-negative and contacted the laboratory. The exchange transfusion was completed with appropriate units.

An effective investigation was carried out locally for this near miss event. Findings included gaps in staff knowledge, incomplete training, and suboptimal LIMS functionality. BMS 1 had recently been signed off as competent for ordering blood components and was yet to complete the competency regarding antigen-negative requirements. Staffing issues meant that appropriately trained and competent staff were not available to carry out this task. The lack of LIMS alert was later investigated by the information technology (IT) supplier and found to be due to a limitation within the software version, preventing the alert appearing with some components.

Robust pre-administration checks and knowledge of patient requirements helped identify the error in this case. Staffing issues must be identified and addressed to ensure appropriately skilled and competent staff are available to perform key tasks. Staff should have sufficient knowledge of specific transfusion requirements including the impact of receiving blood that does not meet these requirements. Both laboratory and clinical areas should maximise the potential of IT systems to support safe issue and administration of blood components.

Conclusion

Blood transfusion in haemoglobinopathy patients remains a vital aspect of care. Transfusion is however not without risk. Decision-making requires specialist input to ensure there is a clear indication for transfusion and clear communication with the laboratory to ensure the appropriate blood components are selected. Patients with complex transfusion requirements should also involve transfusion specialists to discuss the most suitable and available red cells.

The roll out of the National Health Service (NHS) blood group genotyping programme is anticipated to significantly improve care for patients with SCD, thalassaemia, and rare anaemia by providing more accurate phenotypic information and leading to the potential to provide more precisely matched red cells (NHSBT, n.d.). The NHS became the first healthcare system in the world to provide a new blood group genotyping test when this was introduced in January 2022 (NHSE, 2024a).

A position paper on International Collaboration for Transfusion Medicine (ICTM) Guideline 'Red blood cell specifications for patients with hemoglobinopathies: a systematic review and guideline' provides a UK perspective on this guidance (Trompeter, et al., 2020b). The authors of this paper reviewed each of the recommendation from the ICTM guideline and evaluated applicability for transfusion practice in the UK and their relevance to British Society for Haematology and other national guidelines. A recent updated systematic review and clinical practice guideline from the ICTM guidelines recommends that ABO, RhDCcEe, and K-compatible red cells are selected for individuals with SCD and thalassaemia, even in the absence of alloantibodies, and that red cells which are antigen-negative to already existing clinically significant antibodies are chosen (Wolf, et al., 2025). The paper also highlights the need for comparative research to define the benefit, impact, cost-effectiveness, and feasibility of extended red cell matching strategies to prevent alloimmunisation.

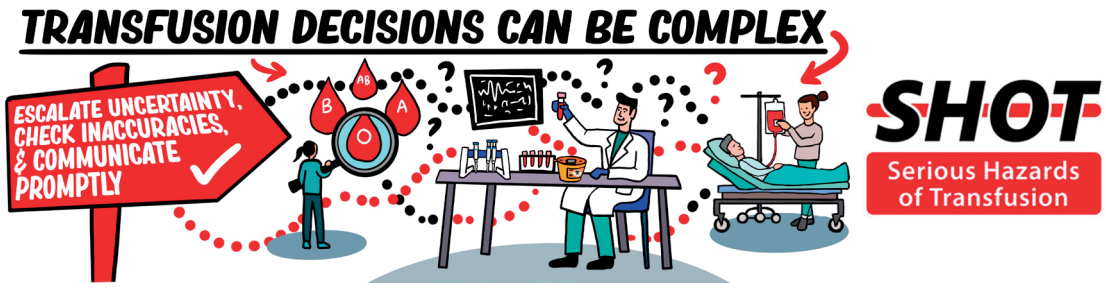
Recommended resources

SHOT Bite No. 14: Transfusion Errors and Reactions in Patients with Haemoglobinopathies
https://www.shotuk.org/resources/shot-bite-no-14/

SHOT Bite No. 31: The role of Sp-ICE in preventing Haemolytic Transfusion Reactions (HTR)
https://www.shotuk.org/resources/shot-bite-no-31/

SHOT Video: Haemolytic Transfusion Reactions in patients with Haemoglobinopathies
https://www.shotuk.org/resources/haemolytic-transfusion-reactions-in-patients-with-haemoglobinopathies/

SHOT Safety Notice 02: SRNM 2022
https://www.shotuk.org/resources/safety-alerts-and-safety-notices/safety-notices/



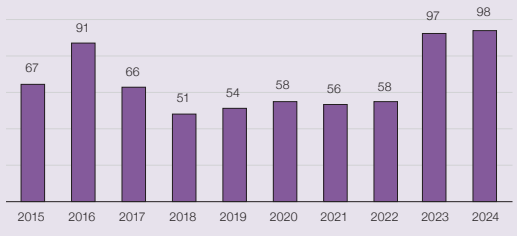
27 Transfusion Errors in Transplant Cases n=98

Authors: Jennifer Davies, Vera Rosa and Shruthi Narayan

Headline data 2024

Number of reports n=98
Deaths n=0
Major morbidity n=0

Transplant cases by year



Key findings:

- Transfusion errors in transplant recipients continue to be reported
- While the total reports received were comparable to 2023, there was a change in the distribution of cases between near misses and errors resulting in an incorrect transfusion
- Incorrect blood component transfused-specific requirements not met (IBCT-SRNM) account for most of the reports

Gaps identified:

- Suboptimal information technology (IT) functionality
- Knowledge gaps and staff unfamiliarity with IT systems
- Complex systems leading to workarounds
- Transplant protocols not clearly detailing transfusion requirements and not communicated to all staff involved in patient care

Good practice:

- Formal investigations incorporating human factors analysis are being used for errors enabling identification of all contributory factors
- Sharing specific requirements with patients enables understanding and can prevent errors
- The number of near miss events reported relating to transplant recipients has increased suggesting errors are being picked up by controls in place

Next steps:

- Haemopoietic stem cell transplant (HSCT) protocols should include guidance on ABO/D compatibility for post-transplant transfusion practice and should be easily accessible
- Electronic patient record systems should include decision support for safe transfusions
- Laboratory information management systems (LIMS) should include rules for ABO/D compatibility for HSCT patients that cannot be overridden and is not reliant on notes or flags

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Introduction

HSCT are an important treatment option for patients with haematological malignancies. The number of HSCT have increased over the last two decades in the UK (BSBMTCT, n.d.). The patient and donor may have different ABO/D groups, and so subsequent transfusion with blood components may not follow the normal compatibility rules well known by laboratory and clinical staff and controlled by LIMS. Patients are often referred to a specialist centre for the transplant and then return to their local hospital for post-transplant care. As highlighted in previous Annual SHOT Reports, transplant centres should provide a protocol for patients that includes the ABO/D group of the donor, ABO/D group of blood components for transfusion and any other specific requirements, such as irradiated blood components.

SHOT data continue to highlight challenges with provision of appropriate blood components post-HSCT. Shared care introduces communication challenges, transplant protocols may not be sent to the local hospital, or there may be delays in transferring the information into the clinical notes and LIMS. Selection of ABO/D appropriate components in the laboratory often relies on staff reading notes or flags in the LIMS. LIMS rules for controlling ABO/D compatibility for HSCT was noted in the top ten of items that users would like to have in the SHOT UK Collaborative Reviewing and reforming IT Processes in Transfusion (SCRIPT) user survey in 2021 (Davies, et al., 2023). Conversely, in the SCRIPT supplier survey in 2021, 7 of the 10 suppliers stated that their LIMS did include this functionality. This gap is likely related to failures to configure rules or upgrade systems, as described in the chapters covering errors with information technology in previous Annual SHOT Reports. Where there has been an ABO/D mismatch between HSCT recipient and donor, this can cause anomalous blood groups in the post-transplant phase, and often the recipient will never show the full ABO forward and reverse group of the donor. This causes challenges within the laboratory, LIMS may not support release of components without a confirmed ABO/D group, consequently laboratory staff may be forced to report a 'safe' ABO group appropriate for red cells but not necessarily for plasma components (SHOT, UKTLC and NEQAS, 2024). Patients undergoing solid organ transplants (SOT) also have specific requirements for transfusion, these are subject to similar challenges to the HSCT, with communication and IT support being key to success.

Deaths and major morbidity related to transfusion n=0

There were no deaths or major morbidity following transplant-related errors in 2024.

A detailed review of all cases of deaths and major morbidity reported to SHOT related to HSCT recipients is being planned to be carried out in the future.

Summary of cases

A total of 98 cases are included in this chapter, 26 related to a wrong component transfused (IBCT-WCT) event and 32 where specific requirements were not met (IBCT-SRNM). There were 40 near miss cases, 16/40 (40.0%) related to provision of irradiated components and 8/40 (20.0%) related to the selection of an incorrect blood group. The majority of these were identified using a formal pre-transfusion check and 1 was noted by the patient. In addition, there were 13/40 (32.5%) wrong blood in tube reports which were mostly detected by laboratory staff during testing or authorisation of results.

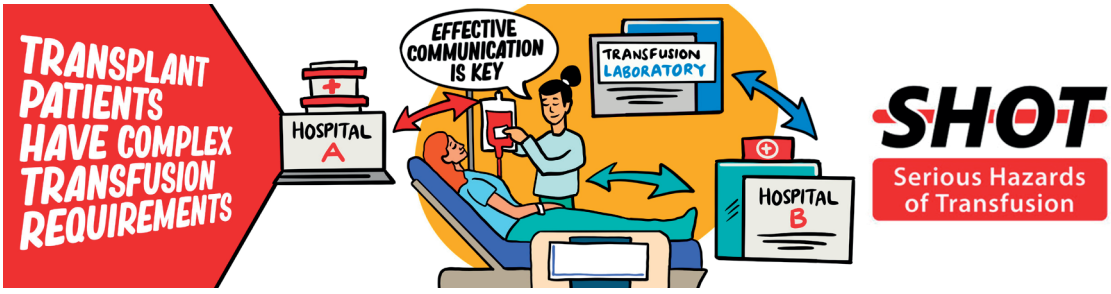
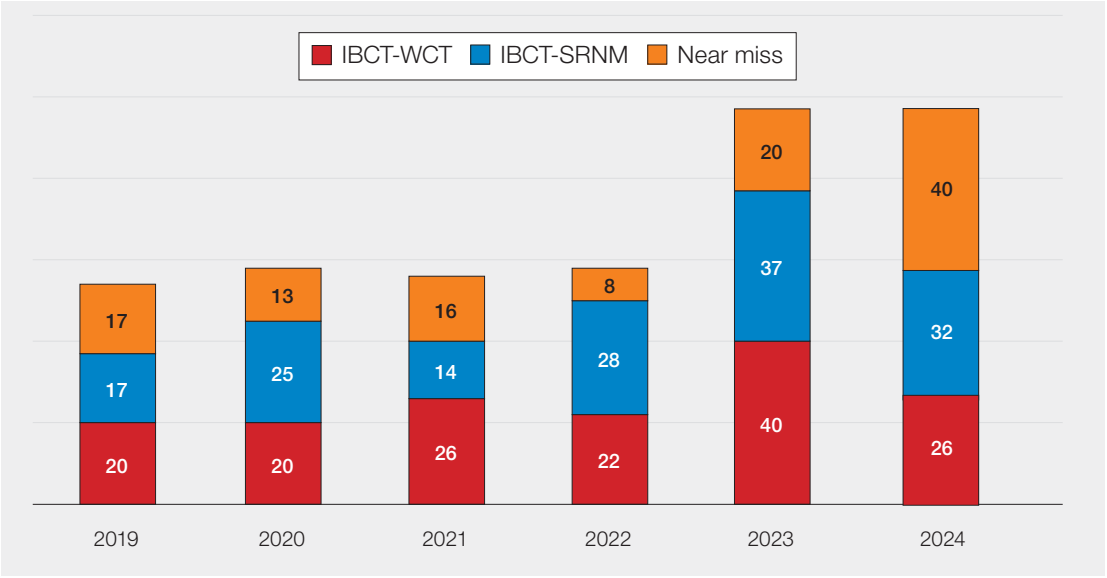


Figure 27.1: Number of transplant-related reports (HSCT and SOT) from 2019 to 2024



IBCT-SRNM=incorrect blood component transfused-specific requirements not met; IBCT-WCT=IBCT-wrong component transfused

Errors where the blood component was transfused mainly involved red cell components, 26/58 (44.8%). Platelet components accounted for 16/58 (27.6%) reports and in 3/58 (5.2%) reports, multiple components were involved. IBCT-WCT errors mainly occurred in the laboratory, 19/26 (73.1%), whereas IBCT-SRNM errors were more equally spread between laboratory, 15/32 (46.9%) and clinical, 17/32 (53.1%) settings. The majority of errors occurred in HSCT patients, for both IBCT-WCT and IBCT-SRNM, 50/58 (86.2%), with only 8/58 (13.8%) occurring in SOT.

IBCT-WCT summary n=26

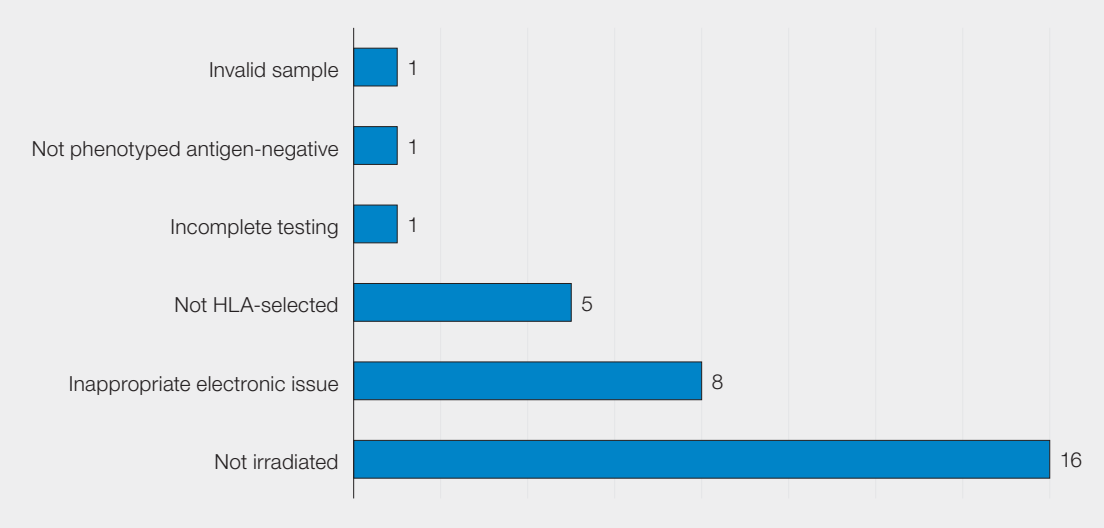
Of the 26 IBCT-WCT errors reported, 19 were laboratory errors with 17/19 cases related to the component selection step. In 7 cases where clinical errors were reported, 5 were at the transfusion request step. For SHOT reporting, all cases where a component has been transfused that is not consistent with ABO group specified for the relevant phase of transplant are discussed in this chapter and classified as wrong ABO/D group in transplant recipients (n=22). In addition, there was 1 case involving an ABO-incompatible transfusion of group O fresh frozen plasma (FFP) to a group A transplant recipient during a major haemorrhage. There were 2 transplant patients who received transfusions intended for other patients but were fortuitously ABO-compatible. These were a case where human leucocyte antigen (HLA)-selected platelets were transfused to the wrong patient, and a transfusion of red cells was connected to the wrong patient. In the final case, the wrong component type was transfused; platelets were prescribed for the patient, but red cells were transfused in error.

In 19/26 (73.1%) cases, IT was a contributory factor. Issues identified included a lack of functionality within the LIMS, failure to heed or failure to update the flag in the LIMS. In a few cases, IT was seen to have been able to prevent an error but was ineffective, lack of communication meant that IT could not be updated, and incorrect information was recorded in the LIMS.

IBCT-SRNM summary n=32

Failure to provide irradiated blood components accounted for 16/32 (50.0%) errors, and 8/32 (25.0%) cases were related to inappropriate use of electronic issue of red cells. Lack of communication of the specific transfusion requirements accounted for 15/32 (46.9%) of the errors and involvement of IT was cited in 25/32 (78.1%). Similar to IBCT-WCT, IT involvement related to failures to heed or update flags or was seen as an improvement. In 1 case, an incomplete LIMS replacement led to failure to provide irradiated components, this is described in Case 27.1. This case demonstrates the reliance on the LIMS and the importance of ensuring all relevant information is available in the current system.

Figure 27.2: Errors related to specific requirements not met in transplant recipients in 2024 (n=32)



HLA=human leucocyte antigen

Case 27.1: Missed requirement for irradiated blood components following LIMS replacement

Prior to the implementation of the new LIMS, data migration from the old LIMS took place but the most recent data had not been yet migrated. To address this gap in data migration, an interim process was implemented to check patient's notes on the legacy LIMS. A check label on the request form to confirm this process was implemented. Prior to the implementation of the new LIMS, all staff were trained, and instructions provided. In this case, the transplant information was in the legacy LIMS, but the biomedical scientist (BMS) did not check when processing the request in the new LIMS. Another BMS performed the crossmatch but also did not check the legacy LIMS. There was reliance on the first check and the instructions for use of the check label were not clear.

Shared care

Addressing communication issues with patients in shared care settings is crucial for ensuring safe, coordinated and patient-centred care. Communication failure between hospitals which share the care of transplant patients is a recurring theme in recent years. For example, when a patient has the transplant at a transplant centre, the information about the transplant, changes in ABO/D group and specific transfusion requirements may not be communicated to the local hospital or its transfusion laboratory. The transplant may have taken place several months or years before and specific transfusion requirements in the post-transplant period may vary. It is also important to keep the primary care team informed.

Case 27.2: Patient transfused non-irradiated red cells pre transplant with shared care barriers

A patient with relapsed high-grade lymphoma received a unit of non-irradiated red cells at their local hospital, 6 days prior to stem cell harvest. The request form did not indicate the patient's diagnosis, or the need for irradiated red cells. The requirement for irradiated blood components was also not recorded on the prescription. Furthermore, there was incomplete communication from the transplant centre to the local hospital regarding the specific transfusion requirement. The error was discovered when a second request for irradiated red cells was received. Laboratory staff acted promptly to contact the ward and asked for the transfusion to be stopped and added flags to the LIMS. Contributory factors included the haematology ward at the local hospital not using the organisations' electronic patient record and relying on handwritten documentation. Following this event, a system had been set up for the transplant centre to notify the local transfusion laboratory, the transfusion practitioner and clinical staff about specific requirements using secure email. The patient was given an irradiated components card, relevant information leaflet and had the rationale for specific requirement explained to them.

In shared care settings, clear role definition, consistent information sharing, and patient involvement are critical. Leveraging technology, ensuring effective structured handovers between clinical and laboratory teams across all sites is vital. Continuously seeking patient and staff feedback can significantly improve quality and patient experience enhancing transfusion safety.

Learning point

- Information relating to safe and appropriate transfusion for HSCT and SOT patients must be easily accessible, clear, and concise in clinical and laboratory settings

Incident investigation and human factors summary

It was encouraging to note that a formal investigation had been completed for 69/98 (70.4%) of cases including all near miss cases and wrong blood in tube events. Where the contribution of human factors had been noted, these mainly related to communication, gaps in knowledge and the fact that this is a unique cohort of patients with very particular transfusion needs. Staff may not be familiar with transfusion requirements for this patient cohort and so instructions must be easily accessible, clear, and concise. This is particularly important where patients are being treated in non-specialist settings.

Conclusion

Transfusion in HSCT and SOT patients is complex. Shared care requires that communication pathways are effective for every case and include both clinical and laboratory teams. There is clearly a reliance on LIMS to support safe practice in the laboratory. Flags and notes in the LIMS are not effective in preventing errors. LIMS suppliers should ensure that where current versions do not support safe practice for HSCT and SOT patients, this functionality is in development, with a clear roadmap for delivery, and that this is shared with customers. Where electronic patient record systems are being implemented, functionality for safe practice and decision support should be considered. Training and competency assessment for laboratory staff should include transfusion in transplant patients. Organisations should use the resources currently available to identify and address gaps in processes.

Recommended resources

Safe Transfusion in Haemopoietic Stem Cell Transplant Recipients
https://www.shotuk.org/resources/safe-transfusions-in-haemopoietic-stem-cell-transplant-recipients/

Good practice guidance document for managing indeterminate ABO blood groups to support safe decision-making
https://www.shotuk.org/resources/good-practice-guidance-document-for-managing-indeterminate-abo-blood-groups-to-support-safe-decision-making/

SCRIPT surveys and resources
https://www.shotuk.org/resources/current-resources/script/

SHOT
Serious Hazards of Transfusion

Immune Anti-D in Pregnancy n=68

Authors: Vera Rosa and Susan Robinson

Key findings:

- 68 cases were analysed by SHOT, 13 women or birthing people with no previous pregnancy (NPP) and 55 women or birthing people with previous pregnancies (PP)
- There were 94.1% live births and 43.8% of babies that required treatment for haemolytic disease of the fetus and newborn (HDFN)
- Data regarding multiple (>2) pregnancies and high body mass index (BMI) (>30) continue to be collected to assess their impact as contributory factors for D immunisation

Gaps identified:

- Omission or late administration of anti-D immunoglobulin (Ig) following potentially sensitising events (PSE) continues to be an identifiable risk factor for D immunisation
- Anti-D Ig may be less effective in preventing D immunisation in gestations beyond 40 weeks
- Lack of awareness or knowledge gaps resulting in missed reporting when two SHOT submissions are required: one report for D immunisation and one report for anti-D Ig administration error

Good practice:

- Correct management of pregnancy was identified in 55.9% cases reported to SHOT
- There was an increase of D immunisation cases reported to SHOT in 2024 compared to 2023, potentially suggesting a better awareness of the reporting requirements

Next steps:

- Cases of alloimmune anti-D found for the first time in pregnancy should be reported to SHOT, aiming to provide a complete data set after delivery
- Hospital transfusion teams and women's services to check the advice in guidelines, policies and reflex pathways regarding women or birthing people typed D variant is to assign a D-negative treatment pathway
- Systems should be in place to support women or birthing people with complex social situations who are less likely to report PSE resulting in inequitable care
- The British Society for Haematology (BSH) and the National Institute for Health and Care Excellence (NICE) should update their respective guidelines to address discrepancies to facilitate consistent practice and optimise safety

For all abbreviations and references used, please see the **Glossary** and **Reference list** at the end of the full Annual SHOT Report. Please see the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/annual-shot-report-2024/).

Definition:

Cases of D-negative pregnant women and birthing people who become sensitised and are found to have developed immune anti-D, which is detected during pregnancy, either at booking or later in the index pregnancy

Introduction

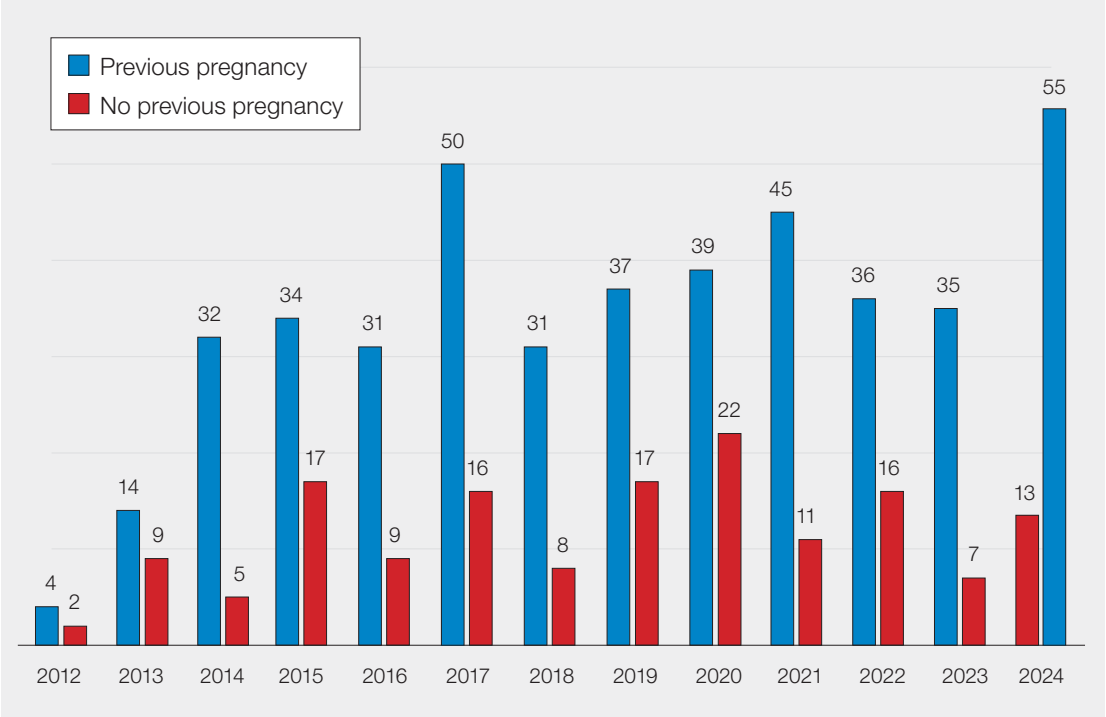
Since 2012, SHOT has been collecting and analysing cases of D immunisation where the antibody is first detected during pregnancy. This category includes cases where the management of pregnancy was suboptimal e.g., errors in anti-D Ig administration, but also cases where immunisation occurred despite ideal management of pregnancy. The information collected in this category aims to improve understanding of the causes of continuing D immunisation. For example, BMI/weight and birth beyond 40 weeks are two factors that have been analysed to understand their impact in D immunisation as mentioned in other studies (Davies, et al., 2011; Sørensen, et al., 2022; Ngan, et al., 2024). NICE has estimated that there are 65,000 D-positive births in the United Kingdom (UK) per year where the mother is D-negative (NICE, 2008). As 68 cases of D immunisation were reported in 2024, this represents an estimated ratio of 0.1% cases of D-negative women or birthing people who have been immunised. Of these 68 cases, immune anti-D was identified in 25 cases at booking. In 39 cases immune anti-D was identified during pregnancy, and in 2 after birth. In 64/68 (94.1%) cases, the index pregnancy resulted in live births. However, in 28/64 (43.8%) cases, the baby required treatment for HDFN. Treatments included phototherapy, intravenous immunoglobulin (IVIg), intrauterine transfusion (IUT), top-up transfusions and exchange transfusions.

Results

In 2024, a total of 68 D immunisation cases were reported to SHOT, 13 with women or birthing people with NPP, and 55 in women or birthing people with PP. Since reporting in this category began in 2012, SHOT has collected data on 152 NPP cases and 443 PP cases. Reporting has been fairly consistent as per Figure 28.1; however, data suggests that cases of D immunisations remain under-reported (Narayan, et al., 2019).

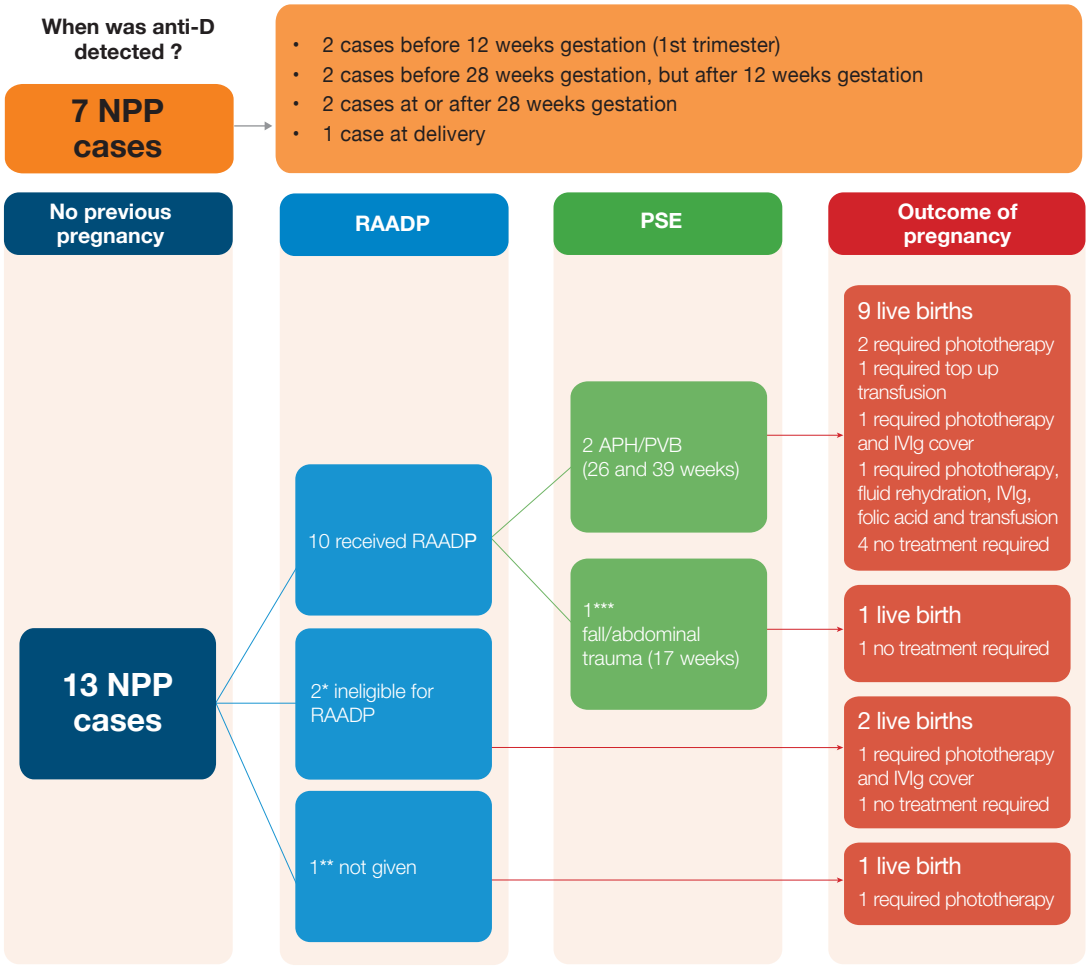
Information regarding multiple (>2) pregnancies and high body mass index (BMI) (>30) continues to be collected to assess their impact as contributory factors for D immunisation. In 2024, there were 21/68 (30.9%) cases of multiple pregnancies and 15/68 (22.1%) cases with a high BMI.

Figure 28.1: Number of SHOT reports of D immunisation by year, 2012-2024



No previous pregnancy n=13

Figure 28.2: Summary of the 2024 NPP data (n=13)



APH=antepartum haemorrhage; IVIg=intravenous immunoglobulin; NPP=no previous pregnancy; PSE=potentially sensitising event; PVB=per vaginal bleeding; RAADP=routine antenatal anti-D Ig prophylaxis

**Immune anti-D detected before 28 weeks gestation (at 12^{+4}- and 27-weeks' gestation)*

***Woman concealed pregnancy until 37 weeks gestation*

****PSE at 17^{+5} weeks, anti-D Ig given beyond 72 hours post PSE. Anti-D and anti-C detected at birth.*

Case 28.1: Anti-D Ig administered in error for a case with known immune anti-D

Immune anti-D was identified while testing the first group and screen sample at 37 weeks due to a concealed pregnancy. The sample was insufficient to complete investigations. Further samples were received 4 days later and sent to the referral laboratory for quantification. A verbal report was provided by the reference laboratory which confirmed the presence of immune anti-D (result level: 1.5IU/mL). The birth was at 38 weeks gestation, but the presence of immune anti-D was not checked resulting in anti-D Ig being issued and administered unnecessarily. The baby's group was O D-positive, and no treatment was required for HDFN.

In this case, the suboptimal management of pregnancy could not be avoided as the pregnancy was concealed. As such, RAADP was not given in a timely manner and if any PSE occurred, they were not reported or managed. Despite the immune anti-D identified and confirmed by the reference laboratory, the healthcare record was not updated. This led to unnecessary administration of anti-D Ig post birth. This highlights the importance of interoperability between the different laboratory and clinical information technology (IT) systems.

Case 28.2: Confirmation of D immunisation potentially masked by large fetomaternal haemorrhage (FMH)

A woman gave birth to a D-positive baby at 40 weeks gestation. No evidence of the presence of immune anti-D in the antenatal testing. The FMH volume post birth was calculated to be 101.5mL and 17,000IU anti-D Ig was administered. In the follow-up sample, a bleed of 17mL was identified and a further 3,000IU anti-D Ig was administered. The second follow-up sample showed a volume of <1mL bleed and a further 500IU anti-D Ig was administered. The baby needed a top-up transfusion to treat HDFN post birth. Two weeks after birth, a maternal sample was taken where anti-D, anti-C and an autoantibody were identified. The sample was not referred for quantification or further investigation. One year later, the antibodies remained detectable.

This case highlights the complexity of immune anti-D in pregnancy. The nature of the anti-D, if immune or passive, cannot be differentiated by standard laboratory testing. The quantification of the antibody is proved to be the most useful technique available to understand if anti-D is immune or prophylactic even though this technique does not always provide a definite conclusion. As mentioned in the 2023 Annual SHOT Report, it is important to consider a long-term follow-up e.g., 3 to 6 months for women or birthing people who have had a large FMH bleed at birth (Narayan et al., 2024). This follow-up will help to identify cases where D immunisation have occurred even despite recommended practice.

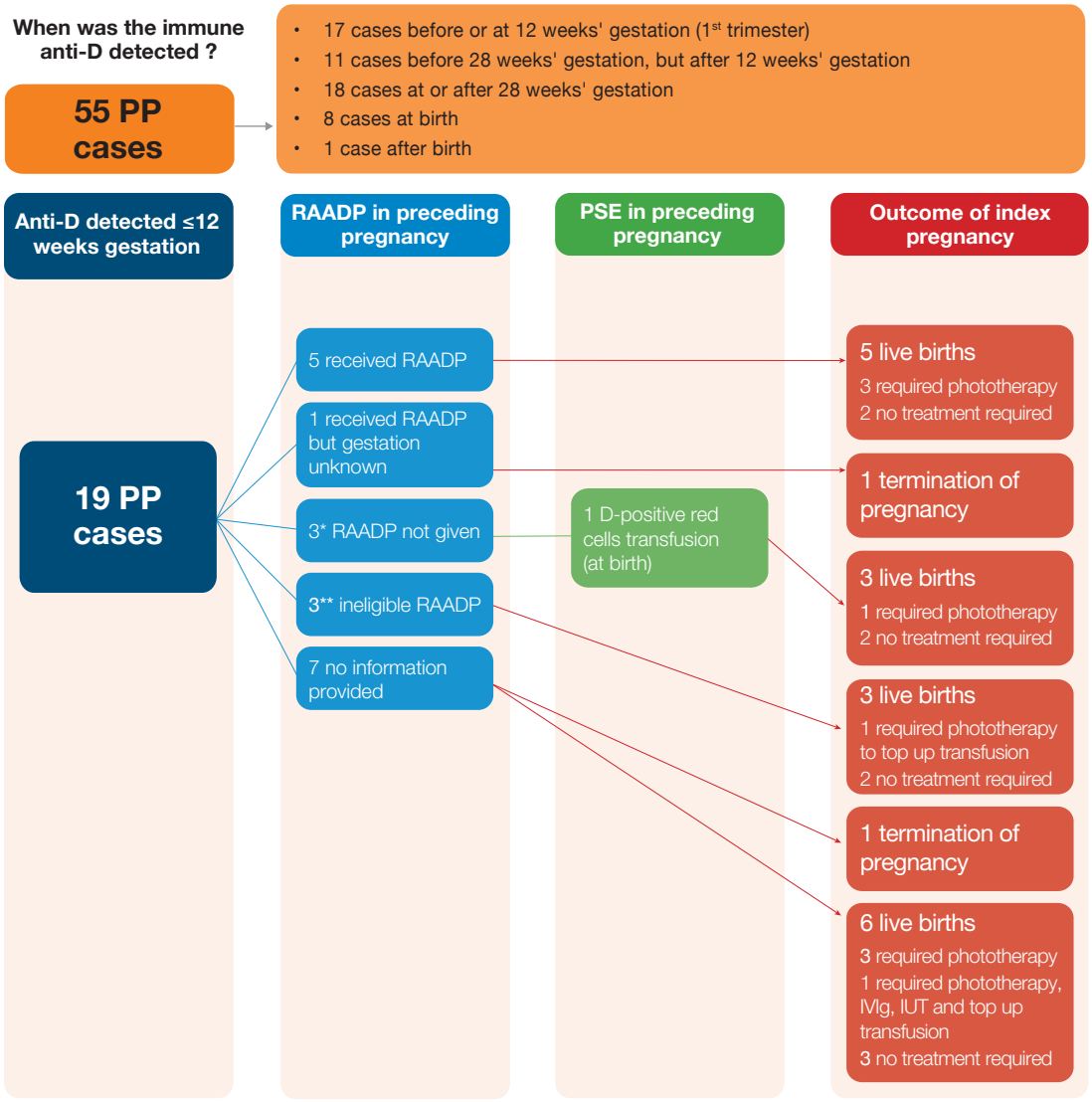
Learning points

- Confirmation of immune anti-D can be masked by the presence of prophylactic anti-D Ig administered as part of antenatal management. Referring samples for quantification should be part of the laboratory process to help confirm the nature of the antibodies
- The benefit of a long-term D immunisation follow-up should be considered on a case-by-case basis

No previous pregnancy n=55

The index pregnancy in these cases refers to the current pregnancy; the pregnancy in which alloimmune anti-D was first detected.

Figure 28.3a: Summary of the 2024 PP data (n=55) where anti-D was detected ≤12 weeks gestation (n=19)



IUT=intrauterine transfusion; IVIg=intravenous immunoglobulin; PP=previous pregnancy; PSE=potentially sensitising event; RAADP=routine antenatal anti-D Ig prophylaxis
**1 case RAADP was not part of the policy, 1 case D-variant woman treated as D-positive*
***2 cases of miscarriage <12 weeks gestation and 1 case immune anti-D already present*

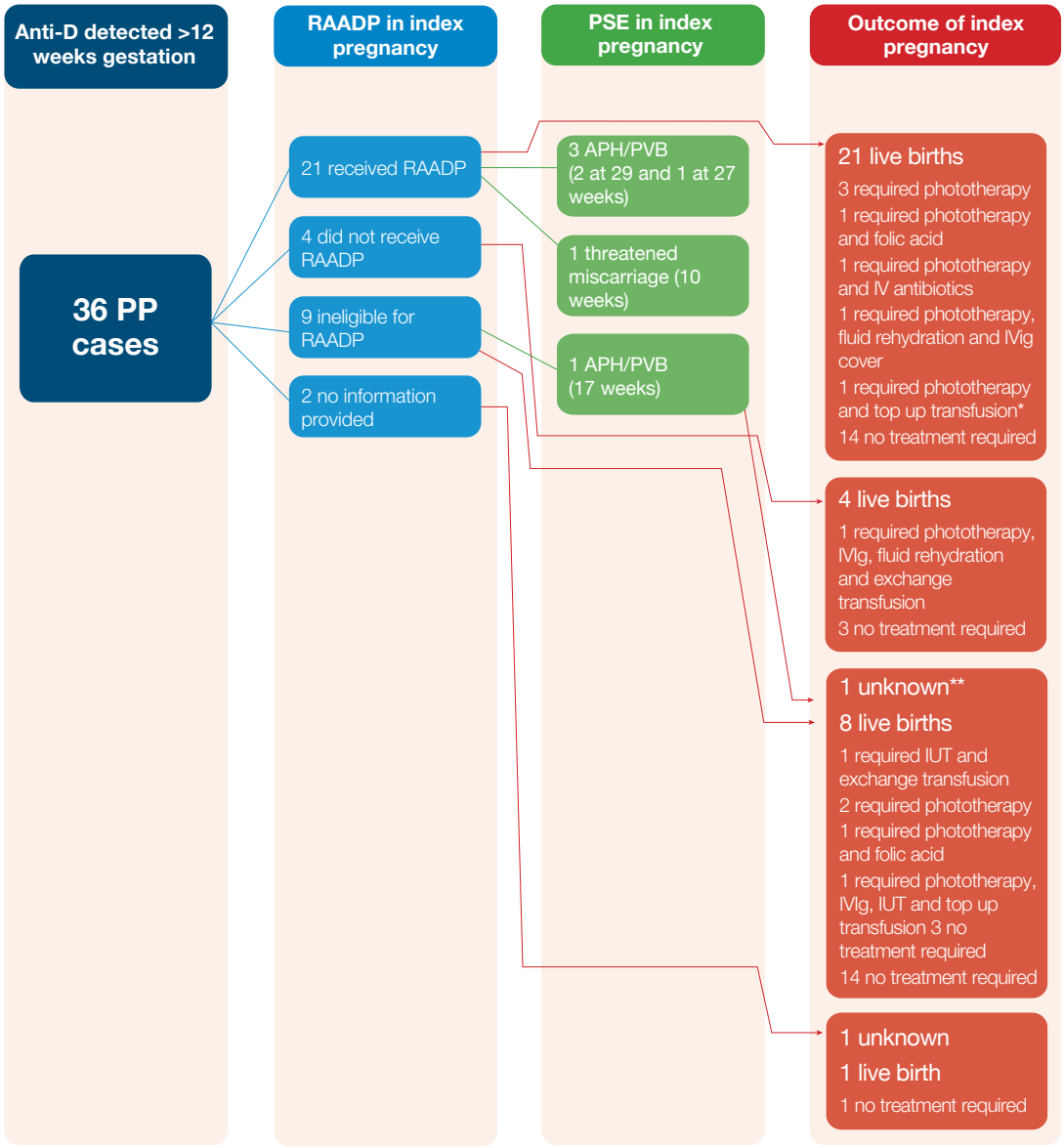
Case 28.3: D-variant identified by the presence of immune anti-D

Immune anti-D was identified with a level of 0.8IU/mL at booking (11 weeks gestation) in the index pregnancy. This was the woman's third pregnancy, and all prior samples were grouped as D-positive. In the previous pregnancy, a sample had been referred to the reference laboratory for serological D-status investigation. This was reported as weak D and recommended the woman to be treated as D-positive. In the previous pregnancy, during birth, the woman received a unit of D-positive red cells in accordance with the reported D-status. In the index pregnancy, when anti-D was identified, samples were referred to the International Blood Group Reference Laboratory (IBGRL) for genotyping who confirmed that the woman was D-variant and had been immunised. The birth in the index pregnancy took place at 37 weeks gestation and the baby received phototherapy for treatment of HDFN.

This case highlights the complexities of the D antigen and the limitations of the standard serological techniques. In some D-variant types, as the case above, an accurate D-status is only likely to be identified after the woman or birthing person has been immunised. Due to the complexity of the D antigen and

its many polymorphisms, when anti-D is detected in individuals that have been previously grouped as D-positive (or weak D), samples should be referred for genotyping to confirm the true D-status and the recommended practice to follow.

Figure 28.3b: Summary of the 2024 PP data where anti-D was detected >12 weeks gestation (n=36)



APH=antepartum haemorrhage; IUT=intrauterine transfusion; IV=intravenous; IVIg=IV immunoglobulin; PP=previous pregnancy; PSE=potentially sensitising event; PVB=per vaginal bleeding; RAADP=routine antenatal anti-D Ig prophylaxis
**Twin pregnancy, one of the twins required transfusion as well as phototherapy*
*** 1 case pregnant woman moved abroad no information available including birth*

Case 28.4: Discrepancy between guidelines in early pregnancy results in D immunisation

A woman attended the early pregnancy unit at 10^{+4} weeks gestation reporting a PVB (no pain but bleed equivalent to a period and still ongoing). A group and screen sample was not taken, and anti-D Ig was not given. This was the recommended practice as per the NICE guidelines. The woman returned at 14^{+5} weeks gestation with another PVB episode where immune anti-D was identified during laboratory testing. The result of anti-D quantification was 0.3IU/mL, and although there were no records of the woman receiving anti-D Ig in this pregnancy, it was advised to continue prophylaxis. Immune anti-D was confirmed later during pregnancy. This case was reported to

highlight discrepancies between the BSH and NICE guidelines as according to BSH, anti-D Ig should have been given when the woman reported the first PSE at 10^{+4} weeks gestation. The antibody status of the booking sample tested before 10^{+4} weeks was negative.

It is recognised that discrepancies between guidelines increases the risk of errors impacting safety. SHOT has highlighted these issues through multiple routes so that appropriate actions can be taken.

Conclusion

The 2024 data demonstrates that issues continue to occur in the management of D-negative pregnant women and birthing people, which is reflected in this chapter and in Chapter 8, Adverse Events Related to Anti-D Ig. Errors resulting in D immunisation can have an impact on the outcome of pregnancy. These can be prevented if there is a plan for action to understand and minimise the contributory factors present in the system. Throughout this chapter, complexities inherent to biology and methodologies have also been discussed to increase awareness and share the learning.

Complex social situations can significantly impact reporting and care provided. Factors affecting these must be explored and addressed to ensure safe care is provided for all.

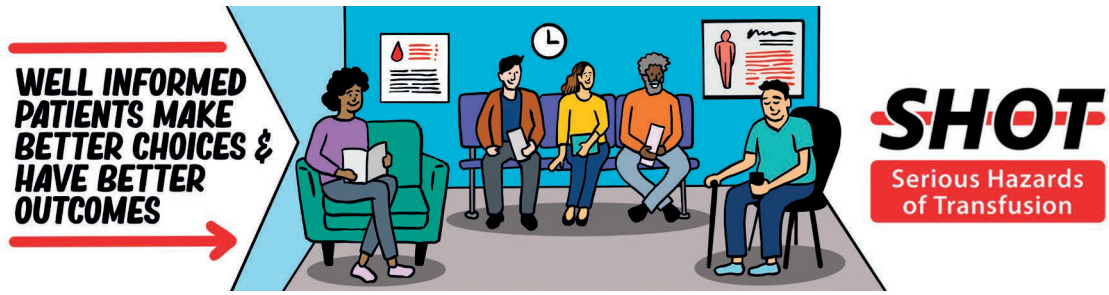
Detailed information about the cases and associated potential contributory factors for D immunisation will be available on the supplementary data on the SHOT website.

Recommended resources

SHOT Bite No 29 – Differences of reporting errors related to anti-D Ig and immune anti-D
https://www.shotuk.org/resources/shot-bite-no-29/

Anti-D immunoglobulin errors and immunisation in pregnancy: Insights from SHOT https://www.shotuk.org/resources/anti-d-immunoglobulin-errors-and-immunisation-in-pregnancy-insights-from-shot/

SHOT videos: Anti-D Immunoglobulin errors and immunisation in pregnancy: Insights from SHOT
https://www.shotuk.org/resources/anti-d-immunoglobulin-errors-and-immunisation-in-pregnancy-insights-from-shot/



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- Hospital transfusion teams for submitting case reports to the scheme

All collaborators who have contributed to this Annual SHOT Report.

Medicines and Healthcare products Regulatory Agency (MHRA) Report

29

Authors: Chris Robbie, Mike Dawe and Shirley Stagg

Key MHRA messages

There has been an increase in the number of serious adverse event (SAE) reports made during 2024. The types of reports and the human factors involved remain largely similar to previous years and therefore the key messages remain unchanged. Special attention must be given to improving the quality and depth of investigations to uncover the human factors involved. These must be addressed with suitable corrective measures that seek to improve quality systems rather than addressing only the members of staff involved.

Summary

The recent change in Serious Adverse Blood Reactions and Events (SABRE)/SHOT reporting platform has presented the MHRA's two person Haemovigilance Team with an enormous challenge. The significant increase in workload as a result of implementing these changes means it has been difficult to produce our normal annual report. The report presented here will be the usual raw data, but with limited commentary.

SABRE report data

Table 29.1 and Figure 29.1 show the total numbers of reports and the numbers of reports submitted as SAE and serious adverse reaction (SAR) for the previous 10 years.

Table 29.1: Submitted confirmation reports 2015–2024

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
SAE	764	1027	1076	1198	1197	1093	1143	1118	1325	1371
SAR	262	464	508	408	497	590	526	710	731	677
Total	**1026**	**1491**	**1584**	**1606**	**1694**	**1683**	**1669**	**1828**	**2056**	**2048**

Figure 29.1: Submitted confirmation reports 2015-2024

SAE=serious adverse event; SAR=serious adverse reaction

Serious adverse events n=1371 (+46)

Definition: (Department of Health, 2005) Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

Table 29.2: Total number of SAE reports by event category

Event category	Number of reports
Materials	0
Apheresis collection	2
Whole blood collection	4
Testing of donations	7
Processing	8
Distribution	15
Donor selection	87
Storage	292
Other	956
Grand total	**1371**

Table 29.2 shows the total number of SAE reports received by event category. Proportions of reports received remain similar to previous years.

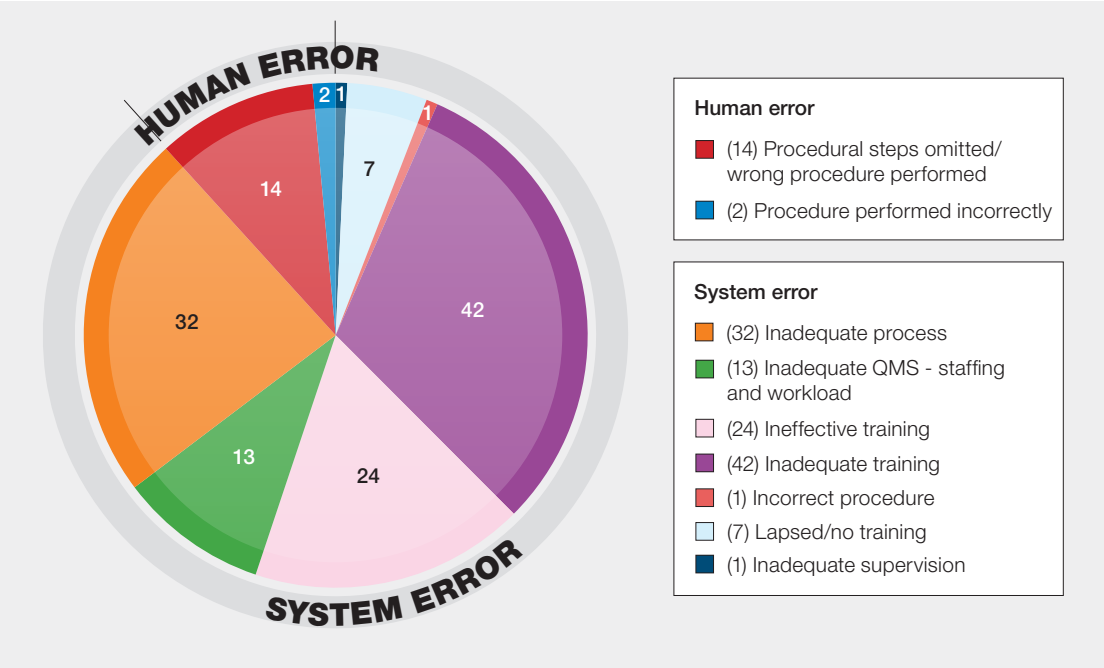
Storage data n=292 (-34)

Storage remains the second largest individual error category (after 'other') and comprises of all Blood Safety and Quality Regulations (BSQR) reportable storage SAE in both the laboratory and clinical areas. The MHRA Haemovigilance Team lead has broken this category down further to try and identify specific storage error sub-types, Table 29.3. For a description of the sub-categories used, see Appendix 1.

Table 29.3: SAE storage error sub-classifications

Storage sub-classification	2024 (+/- 2023)	2023 position
Incorrect storage of component	136 (-20)	1
Component expiry	42 (-16)	2
Sample expiry	39 (+3)	4
Return to stock error	22 (-15)	3
Failure to action alarm	21 (+12)	6=
Security	15 (+2)	5
Storage temperature deviation	9 (NC)	6=
Miscellaneous	7 (NC)	8
30- or 60-minute rule	1 (NC)	9
Total	**292 (-34)**	**X**

Figure 29.2: Root causes of incorrect storage of components sub-category (n=136)



QMS=quality management system

As the single largest sub-category of storage, Figure 29.2, shows the breakdown of incorrect storage by root cause.

89% of all incorrect storage of component errors are related to one or more deficiencies in the quality system, with only 11% related to human error where staff have knowingly followed the wrong procedure or skipped steps in a process.

24% demonstrate either inadequate design of processes to maintain the quality and safety of blood and blood components or involved multiple system failures.

54% are in some way related to training:

- 18% show the training to be ineffective
- 31% show the training to be inadequate
- 5% show staff have either not received training or their previous training has lapsed

Common themes from the narratives of incorrect storage of component reports show:

- Processes and procedures are not clear on how blood should be stored safely and correctly
- Errors are made when staff do not handle blood regularly and have forgotten their training
- Training of staff in blood and blood component storage is not given a high enough priority during staff induction training
- Training material does not always cover all aspects of storage e.g., how to distinguish between components and their different storage requirements
- Errors often occur because shifts are not staffed with adequate numbers of trained staff
- Agency/bank staff training is not adequate
- Agency/bank staff are expected to handle components without having been trained in the local procedures

All storage errors are covered by the requirements of the BSQR. Most of these storage errors occur in clinical areas. It is still a widely held belief that storage errors in clinical areas are clinical errors and that

investigation and reporting of these errors is not covered by the BSQR. This is, and has always been, incorrect. All storage errors that affect the quality and safety of blood and blood components must be fully investigated as per the requirements of the BSQR and the Good Practice Guide (GPG) (Department of Health, 2005; EDQM, 2023).

Recommendation

- Hospital Trusts/Health Boards must improve all areas relating to the quality and safety of blood and blood component storage and the investigation of such storage errors

Action: Hospital transfusion teams

Other n=956 (+82)

Table 29.4: 'Other'

Other sub-category	2024 (+/- 2023)	2023 position
Incorrect blood component issued (IBCI)	196 (+2)	1
Pre-transfusion testing error (PTTE)	170 (+22)	2
Sample processing error (SPE)	167 (+21)	3
Component collection error (CCE)	151 (+24)	4
Data entry error (DEE)	115 (+26)	6
Component labelling error (CLE)	95 (-20)	5
Incorrect blood component ordered (IBCO)	16 (+9)	9
Component available for transfusion past de-reservation (CATPD)	14 (+4)	8
Failed recall (FR)	13 (-11)	7
Unspecified (UNSPEC)	7 (+6)	13
Expired component available for transfusion (ECAT)	5 (-1)	10
Handling damage (HD)	4 (+1)	12
Incorrect blood component accepted (IBCA)	3 (-1)	11
Total	**956 (+82)**	**X**

Table 29.4 shows the number of reports in the 'other' category of SAE. There has been an increase in events that fall into this category. This increase is likely to have been partly due to the increase in errors reported as a result of the South London cyber-attack. The increase in workload resulting from having to resort to manual processes increased the numbers of reports from the sites affected.

Please see Appendix 2 for a description of the subcategories.

Human and system error categories and human factors

The BSQR requires that 'preventable causes' of SAE are investigated and reported (Department of Health, 2005). The GPG also states 'Where human error is suspected or identified as the cause of the deviation, this should be formally justified and care should be exercised so as to ensure that process, procedural or system-based errors or problems are not overlooked, if present.' (EDQM, 2023).

What this means is that for all SAE reported on SABRE, the root cause investigation must first identify any system-based causes, or 'human factors'. Human factors are all the factors which influence an individual's behaviour. These can be factors associated with an organisation itself, the task or the process being undertaken, including the environment and equipment used as well as factors associated with an individual's personality and actions. Therefore, human factors, or ergonomics, are exactly the system-based factors reporters are required to investigate according to the requirements of the BSQR and the GPG.

The MHRA assign a category on review of an SAE report to reflect the most prominent causative factor.

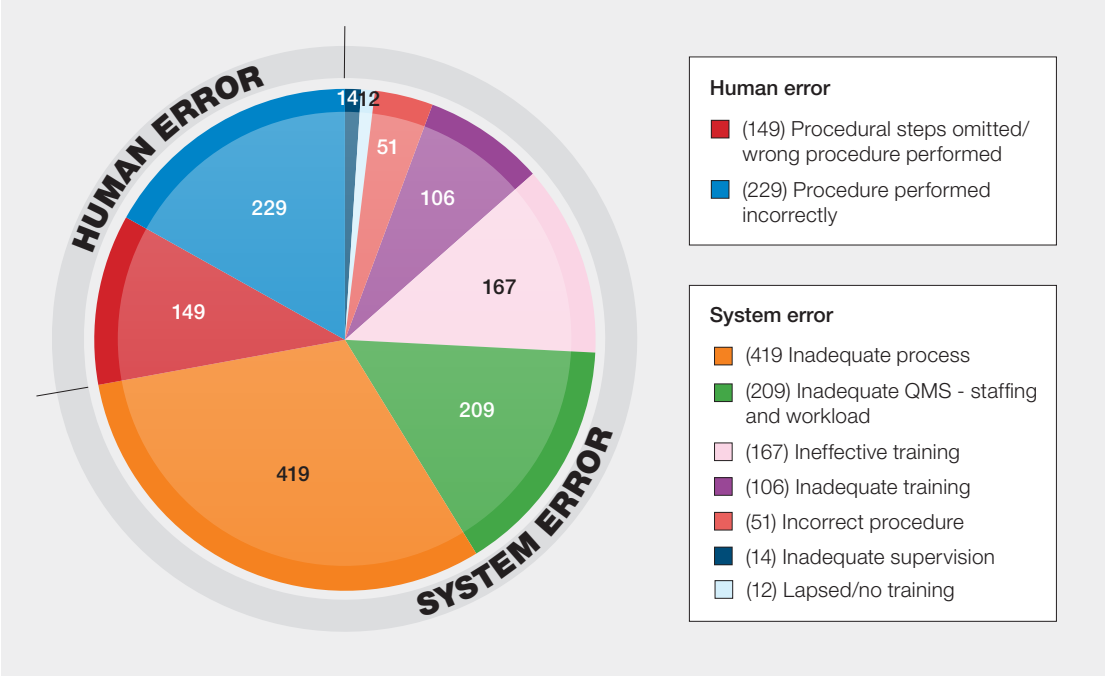
Assessment of these reports can distinguish between events caused by system errors and human errors (slips/lapses/omissions). For a description of the categories used, see Appendix 3.

Table 29.5 shows the breakdown of reports in the human/system error sub-categories.

Table 29.5: Human/system error sub-categories, 2024

Human error sub-category	Total 2024 (+/- 2023)	2023 position
System error/inadequate process	419 (+23)	1
Human error/procedure performed incorrectly	229 (-23)	2
System error/inadequate quality management system (QMS) – staffing and workload	209 (+64)	4
System error/ineffective training	167 (-28)	3
Human error/procedural steps omitted/wrong procedure performed	149 (+5)	5
System error/inadequate training	106 (+10)	6
System error/incorrect procedure	51 (-1)	7
System error/inadequate supervision	14 (+3)	9
System error/lapsed/no training	12 (-3)	8
Total	**1356 (+50)**	**X**

Figure 29.3: Human/system error sub-categories (n=1356)



QMS=quality management system

NOTE: These numbers should be used as guidance only. The quality of this data is limited by a number of factors.

- The root cause (RC) of incidents are usually the result of many contributory factors. The sub-category chosen reflects the most likely reason for the main SAE category. If multiple factors are involved relating to the QMS, then 'inadequate process' has been chosen as the sub-category rather than choosing a category that best fits the main SAE reported
- The sub-category chosen is based on the information in the report. A limited investigation or a report which does not provide MHRA with enough information may not be sub-categorised appropriately

Table 29.5 shows an increase in reports attributable to human factors. The largest increase is in the 'staffing and workload' sub-category. While the South London cyber-attack would have accounted for

some of this increase, it did not account for all of it.

Common themes from the narrative of these investigation reports show:

- 31% of these reports either demonstrate a weak process or system design or involve multiple system deficiencies
- Inadequate process errors may involve the poor identification and mitigation of distractions
- 15% of these reports are directly related to staffing, workload, or skill-mix issues and is now the second largest 'system error' sub-category. However, it must be noted that some of the 31% inadequate process reports, may also include some aspects of staffing and workload issues
- Many reports note errors are made when staff are 'busy'. It may not always be possible to directly link these to staffing and workload since improved prioritisation of workloads may have prevented the error from occurring
- Many reports do not reflect the seriousness of the event as they only reflect actual harm and not potential harm
- Many confirmation reports initially assign a RC as human error without fully identifying process or system deficiencies
- Many corrective and preventive actions (CAPA) are initially proposed to be reminding staff to 'be more vigilant' and to 'follow procedures'. This is not acceptable as it demonstrates a failure to identify genuine causes and adequate CAPA
- RC are often identified as a failure to perform an adequate second check. Failure to perform second checks are not RC as the error has already occurred by the time the second check would be performed
- Many reports continue not to be reported 'as soon as known'. This especially applies to the confirmation report
- Many confirmation reports are delayed due lack of engagement from clinical areas or by reviews of investigation reports

Recommendations

- All reporters must continue to thoroughly investigate all SAE, even those with no actual harm to patients. It is through thorough investigations that improvements can be identified to reduce risks to the quality and safety of blood and blood components and reduce the risk of harm to patients
- When investigating an incident, reporters must have taken care to ensure that process, procedural or system-based errors or problems have not been overlooked. For example, if distractions have been identified then these distractions must be addressed in the CAPA to avoid reoccurrence
- CAPA must correct the error made and not just rely of making error checking more robust
- Engagement from staff in clinical areas must be improved. It is the responsibility of the Trust to ensure all SAE are investigated and reported in a timely manner as per the requirements of the BSQR
- Reporters are reminded to report 'as soon as known'. You are required only to submit a confirmation report with RC and 'proposed' CAPA. Changes to CAPA following review can be added to SABRE reports as footnotes

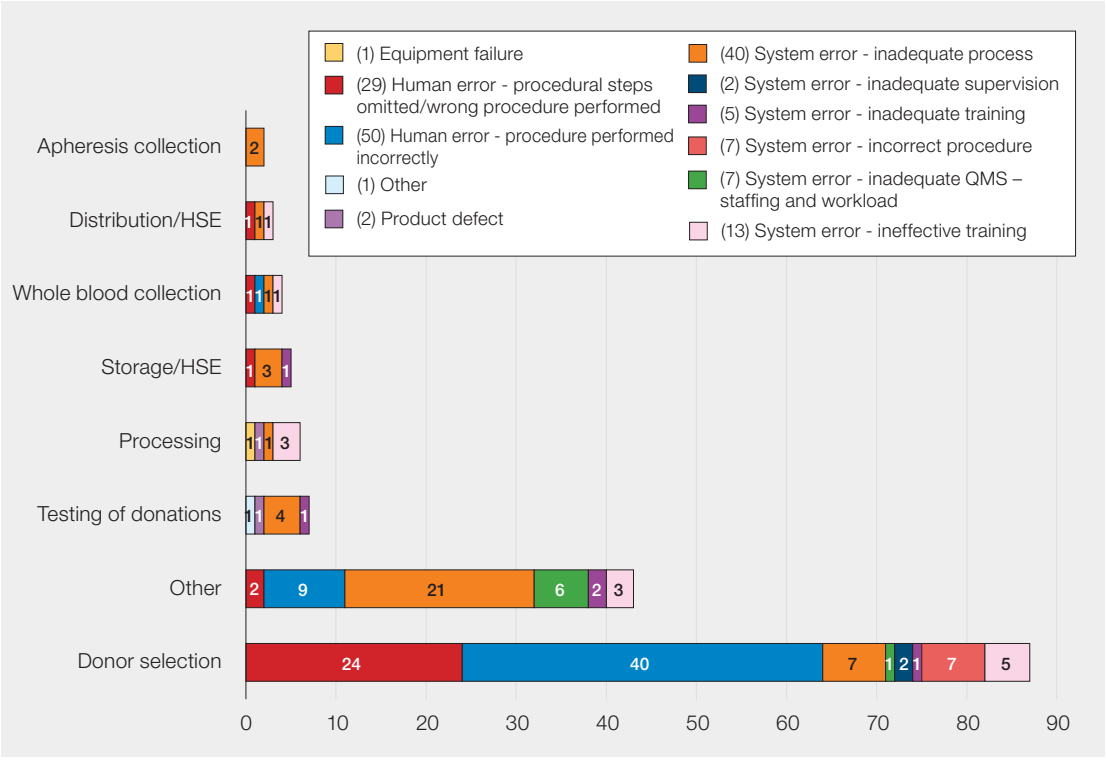
Action: Hospital transfusion teams

Blood establishment reporting n=157 (+12)

Although reports from blood establishments (BE) are included in the main analysis, the specific nature of the SAE reports from BE are lost in the greater numbers of reported hospital transfusion laboratory

SAE. Figure 29.4 displays the reported BE SAE in 2024.

Figure 29.4: Blood establishment SAE event category by specification (n=157)

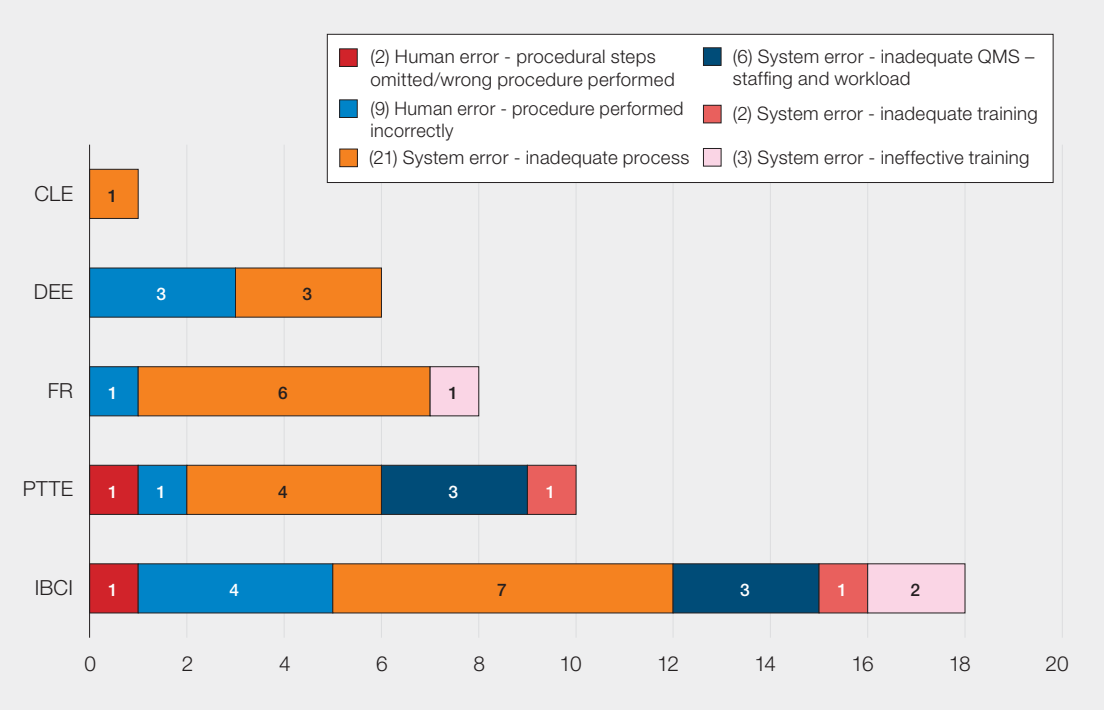


QMS=quality management system

The majority of the reports fall into the donor selection category and typically involve errors where a donor is accepted despite requiring deferral for travel, medical or life-style reasons. Although the diagram indicates that most of these reports are due to 'human' error, i.e., slips, lapses and omissions, this is usually because the error is not spotted until after the donor's next donation. This makes it difficult to assess if the error is a 'system' error. However, all BE when reporting donor selection errors perform recalls and assess the current donation for the deferral reason. Also, processes, procedures and training are regularly reviewed so the risk to the patient is classed as low.

Figure 29.5 shows a breakdown of the 43 reports which fall into the 'other' category.

Figure 29.5: BE reports in 'other' category (n=43)



See Appendix 2 for key to category abbreviations

QMS=quality management system

Much work has been done by SHOT in collaboration with MHRA and Blood Establishments to improve reporting of SAE relating to work in diagnostic and blood issue laboratories. This accounts for an increase in the total number of reports and is likely to increase in coming years.

Serious adverse reactions (SAR)

Definition: (Department of Health, 2005) an unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity…blood establishments and the person responsible for the management of a hospital blood bank shall notify the Secretary of State (Competent Authority) of any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components:

(i) Collected, tested, processed, stored or distributed by the blood establishment, or
(ii) Issued for transfusion by the hospital blood bank

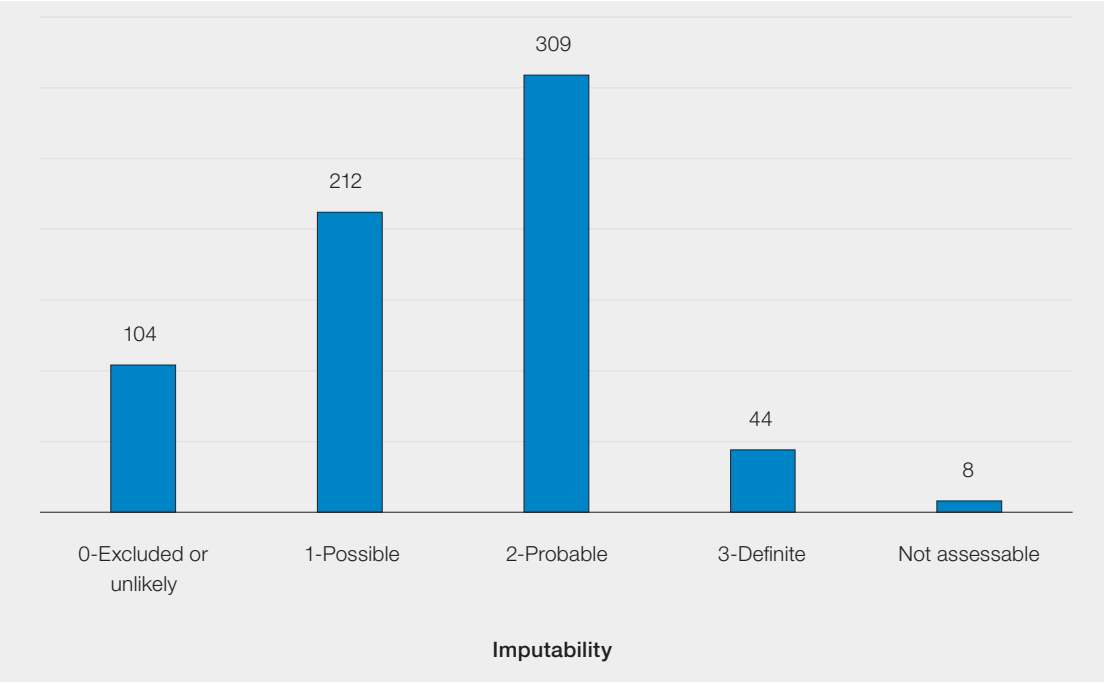
Blood products

Adverse reactions involving blood products (i.e. licensed medicines such as anti-D Ig, Octaplas® (solvent detergent-treated fresh frozen plasma), or coagulation factor concentrates should be reported to the MHRA via the Yellow Card scheme (https://yellowcard.mhra.gov.uk).

Summary of SAR report data

To avoid any confusion the MHRA will only supply, in this Annual SHOT Report, total SAR figures that qualify for reporting to MHRA under the BSQR, see Figure 29.6.

Figure 29.6: SAR reports, by imputability, reported to SABRE in 2024 (n=677)



MHRA inspection report

An overview of the compliance management escalation processes used by the good manufacturing practice inspectorate, including information on the Inspection Action Group and Compliance Management Team referral processes, is available from the MHRA inspectorate blog:

https://mhrainspectorate.blog.gov.uk/2017/02/06/overview-of-compliance-management-escalation-processes-used-by-the-gmp-inspectorate/

Summary of significant issues identified at inspected sites has remained fairly consistent from the previous year and included:

Management of change

The control of change continues to be a deficiency that is commonly raised at blood inspections. The deficiencies raised include:

- The absence of a user requirement specification
- The lack of a validation master plan to guide management through the validation and qualification of the change
- Inadequate or absence of a risk assessment and actions to mitigate risks
- The lack of evidence of sign off of stages of the change control prior to implementation
- The lack of validation evidence to show that the system was fit for task before implementation
- Failure to carry out a post implementation effectiveness check

Management of non-conformances

The management of non-conformances is regularly raised as a deficiency due to the following:

- Inadequate investigation for an appropriate root cause therefore the inadequate implementation of an effective CAPA to avoid reoccurrence

- Failure to consider the potential for harm as well as actual harm especially Trusts using the Datix system
- The lack of an adequate justification for human error being identified as a root cause
- The lack of justification for the late closure of deviations and performing impact risk assessments
- Tracking and trending systems employed not identifying recurring problems due to an emphasis on consequence rather than root cause

The availability of trained and competent staff

Issues with adequate capacity within the laboratory is an ongoing problem and is often raised as highlighted by:

- The absence of an effective capacity management plan or similar document to ensure adequate management of blood transfusion operations and the quality management system
- The inadequate management of risk register entries such as reducing the risk score without an appropriate justification
- Risk scores being reduced before the suggested mitigation was in place and deemed effective
- Staff working significantly above their contracted hours to ensure staff rotas are adequately staffed
- Trusts failing to meet several quality metric targets

Blood collection and training

Blood collection and training was not being adequately managed in that:

- Blood collection training and competency audits showing that Trusts were not meeting their key performance indicators for staff blood collection training
- Inadequate systems in place to control infrequent users of the system and blocking staff who had left the Trust

Steps to control access to blood component storage areas

Steps to control unauthorised access was not being adequately managed in that:

- Main access doors being unsecured and propped open
- Issue refrigerators being located in areas that was used by hospital staff and patients as a thoroughfare
- The doors to the blood component refrigerators and freezers not being closed and locked
- Where keypad access was being used to access blood component storage areas had no record of ever being changed

Computerised patient databases and data integrity measures

There have been several examples where patient and result data bases have never been checked for the integrity of the stored data evidenced by:

- There was no record that sites had reviewed the retention of backed-up data on the laboratory information management system (LIMS)
- The laboratory had no evidence that they had performed any audit checks to detect the potential presence of duplicate patient records on their LIMS database
- The laboratory had no evidence that the backed-up testing records on the automated blood transfusion analysers had ever been checked

Recall

- The timelines set for recall procedures had not been formalised

For further information on MHRA and the Regulation of Blood please refer to the MHRA website:

Blood regulation and safety - GOV.UK

The MHRA Blood forum was launched in June 2016 as a tool to help those involved in blood component collection, processing, testing and distribution to comply with the EU Blood Directives, UK Statutory Instruments, and good practice requirements. It provides the ideal opportunity for extended communication between peers and allows users to put forward their comments and get 'real-life' examples of ways in which they can manage robust quality procedures that ensure compliance and which dovetail with their own business needs and resources.

https://forums.mhra.gov.uk/forumdisplay.php?60-Blood-Forum

Appendices

Appendix 1: Storage subcategories

Component expiry	A component has time expired and not been removed from the storage location according to laboratory procedures
Incorrect storage of component	A component has not been stored in the correct location
Sample expiry	A sample has expired and the component has not been removed from the supply chain for the original patient
Return to stock error	A component has been returned to the supply chain in error instead of being quarantined or discarded
Failure to action alarm	A storage location alarm has been activated but not actioned according to the procedure
Storage temperature deviation	The storage temperature has gone out of specification without an alarm being activated
Security	A storage location is accessible to staff or public who are not authorised to do so
30- or 60-minute rule	Red cells are returned to a refrigerator after 30 or 60 minutes have elapsed contrary to local procedures for return of unused red cells
Miscellaneous	Any other storage event affecting the quality and safety of blood or blood components

Appendix 2: Other subcategories

Incorrect blood component issued (IBCI)	Blood issued which does not meet the patient's specific requirements
Sample processing error (SPE)	Sample incorrectly receipted into the laboratory that should have been rejected
Component labelling error (CLE)	Typically transposition of labels
Pre-transfusion testing error (PTTE)	Any error in the process of testing patient samples and the interpretation of results
Component collection error (CCE)	Any error in the collection of components from storage locations, or the handover of components on collection from the laboratory
Data entry error (DEE)	Transcription errors of data, including both electronic and hand-written data
Failed recall (FR)	Failure to recall components in a timely manner
Unspecified (UNSPEC)	Any error affecting the quality and safety of components not specified elsewhere
Component available for transfusion past de-reservation (CATPD)	Expired components which were incorrectly collected, prior to their scheduled re-stock by the laboratory
Expired component available for transfusion (ECAT)	Any component issued for a patient, where the component expires prior to the planned transfusion
Incorrect blood component ordered (IBCO)	Components ordered from a blood establishment that do not meet the patient's specific requirements
Handling damage (HD)	Damage to a component affecting its quality and safety
Incorrect blood component accepted (IBCA)	Blood accepted into a laboratory for a specific patient where the special requirements have not been matched

Appendix 3: Human error subcategories

Procedure performed incorrectly	Failure to carry out a step(s) correctly
Procedural steps omitted/wrong procedure performed	Missing a key step or not following the procedure
Inadequate process	Inadequate design of a process. Also includes multiple causative factors
Incorrect procedure	Process not properly described in the SOP
Ineffective training	Training not understood by operator
Inadequate training	Training process not fit for purpose
Lapsed or no training	Carrying out a procedure without any formal training
Inadequate QMS – staffing and workload	Staffing levels below the minimum level, or unacceptably high workload has resulted in staff making errors. It is also important to consider an appropriate skill-mix when deciding on minimum staffing levels
Inadequate supervision	Errors have been made by trainees or inexperienced members of staff and should have been noticed by adequate supervision

Glossary of terms

AABB	Association for the Advancement of Blood & Biotherapies
ABOi	ABO-incompatible
ACE	Acknowledging continuing excellence
ADL	Activities of daily living
AHTR	Acute haemolytic transfusion reaction
AI	Artificial intelligence
AIHA	Autoimmune haemolytic anaemia
anti-HBc	Hepatitis B core antibody
APH	Antepartum haemorrhage
ATD	Adult therapeutic dose
BCP	Business continuity plan
BE	Blood establishment
BMI	Body mass index
BMJ	British Medical Journal
BMS	Biomedical scientist
BSH	British Society for Haematology
BSQR	Blood Safety and Quality Regulations
CAPA	Corrective and preventive action
CAS	Central Alerting System
CATPD	Component available for transfusion past de-reservation
CCE	Component collection error
cffDNA	Cell-free fetal deoxyribonucleic acid
CI	Confidence interval
CLE	Component labelling error
CMV	Cytomegalovirus
CS	Cell salvage
CT	Computed tomography
DAE	Donor adverse event
DAT	Direct antiglobulin test
DEE	Data entry error
DHTR	Delayed haemolytic transfusion reaction
DIC	Disseminated intravascular coagulation
DNA	Deoxyribonucleic acid
DOB	Date of birth
EBA	European Blood Alliance
EBMS	Electronic blood management system
ECAT	Expired component available for transfusion
ED	Emergency department
EI	Electronic issue
EPO	Erythropoietin
EPR	Electronic patient record
EU	European Union
FAHR	Febrile, allergic, and hypotensive reactions
FBC	Full blood count
FDA	Food and Drug Administration
FFP	Fresh frozen plasma
FMH	Fetomaternal haemorrhage
FR	Failed recall
G&S	Group and screen
GI	Gastrointestinal
GP	General practitioner
GPG	Good Practice Guide
HAV	Hepatitis A virus
Hb	Haemoglobin
HD	Handling damage
HDFN	Haemolytic disease of the fetus and newborn
HEV	Hepatitis E virus
HFE	Human factors and ergonomics
HFIT	Human Factors Investigation Tool
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigen
HNA	Human neutrophil antigen
HSCT	Haemopoietic stem cell transplant
HSE	Handling and storage errors
HTLV	Human T-cell lymphotropic virus
HTR	Haemolytic transfusion reaction
IBCA	Incorrect blood component accepted
IBCI	Incorrect blood component issued
IBCO	Incorrect blood component ordered
IBCT	Incorrect blood component transfused
IBCT-SRNM	Incorrect blood component transfused-specific requirements not met
IBCT-WCT	Incorrect blood component transfused-wrong component transfused
IBGRL	International Blood Group Reference Laboratory
IBI	Infected Blood Inquiry

ICH	Intracranial haemorrhage
ICS	Intraoperative cell salvage
ICTM	International Collaboration for Transfusion Medicine
ICU	Intensive care unit
ID	Identification
Ig	Immunoglobulin
IHN	International Haemovigilance Network
IM	Intramuscular
IR	Interventional radiology
IRC	International Revised Consensus
ISBT	International Society of Blood Transfusion
IT	Information technology
IUT	Intrauterine transfusion
IV	Intravenous
IVIg	Intravenous immunoglobulin
JPAC	Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee
LDF	Leucocyte depletion filter
LDH	Lactate dehydrogenase
LIMS	Laboratory information management system
MAIGA	Monoclonal antibody immobilisation of granulocyte antigens assay
MALDI-ToF	Matrix-assisted laser desorption/ ionisation time-of-flight
MCV	Mean corpuscular volume
MH	Major haemorrhage
MHP	Major haemorrhage protocol
MHRA	Medicines and Healthcare products Regulatory Agency
MLST	Multi-locus sequence typing
NAT	Nucleic acid testing
NatPSA	National Patient Safety Alert
NBTC	National Blood Transfusion Committee
NHS	National Health Service
NHSBT	National Health Service Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
NICE	National Institute for Health and Care Excellence
NIPT	Non-invasive prenatal testing
NM	Near miss
NPP	No previous pregnancy
OBI	Occult hepatitis B virus infection
OMC	Outside medical care
PACE	Probe, alert, challenge and escalate
PAS	Patient administration system
PBM	Patient blood management
PCC	Prothrombin complex concentrates
PfM	Plasma for Medicine
PICU	Paediatric intensive care unit
PID	Patient identification
PP	Previous pregancy
PPID	Positive patient identification
PSE	Potentially sensitising event
PSIRF	Patient Safety Incident Response Framework
PTTE	Pre-transfusion testing error
PVB	Per vaginal bleeding
QMS	Quality management system
RAADP	Routine antenatal anti-D Ig prophylaxis
RBRP	Right blood right patient
RC	Root cause
RCA	Root cause analysis
RCM	Royal College of Midwives
RCN	Royal College of Nursing
RNA	Ribonucleic acid
SABRE	Serious Adverse Blood Reactions and Events
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SAE	Serious adverse event
SAR	Serious adverse reaction
SCD	Sickle cell disease
SCRIPT	SHOT United Kingdom Collaborative Reviewing and reforming IT Processes in Transfusion
SD	Solvent-detergent
SDC	Serious donor complication
SD-FFP	Solvent detergent-treated fresh frozen plasma
SDH	Subdural haemorrhage
SNBTS	Scottish National Blood Transfusion Service
SNP	Single nucleotide polymorphism
SOP	Standard operating procedure
SOT	Solid organ transplant

SPE	Sample processing error
Sp-ICE	Specialist Services Integrated Clinical Environment
SRNM	Specific requirements not met
T2024	Transfusion 2024
TACO	Transfusion-associated circulatory overload
TAD	Transfusion-associated dyspnoea
TEG	Thromboelastography
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
TTP	Thrombotic thrombocytopenia purpura
UCT	Uncommon complications of transfusion
UK	United Kingdom
UKCSAG	United Kingdom Cell Salvage Action Group
UKIBTN	United Kingdom and Ireland Blood Transfusion Network
UKNEQAS	United Kingdom National External Quality Assurance Scheme
UKTLC	United Kingdom Transfusion Laboratory Collaborative
UNSPEC	Unspecified
vCJD	Variant Creutzfeldt Jakob disease
WBIT	Wrong blood in tube
WBS	Welsh Blood Service
WCT	Wrong component transfused
WHO	World Health Organisation
YCFF	Yorkshire Contributory Factors Framework

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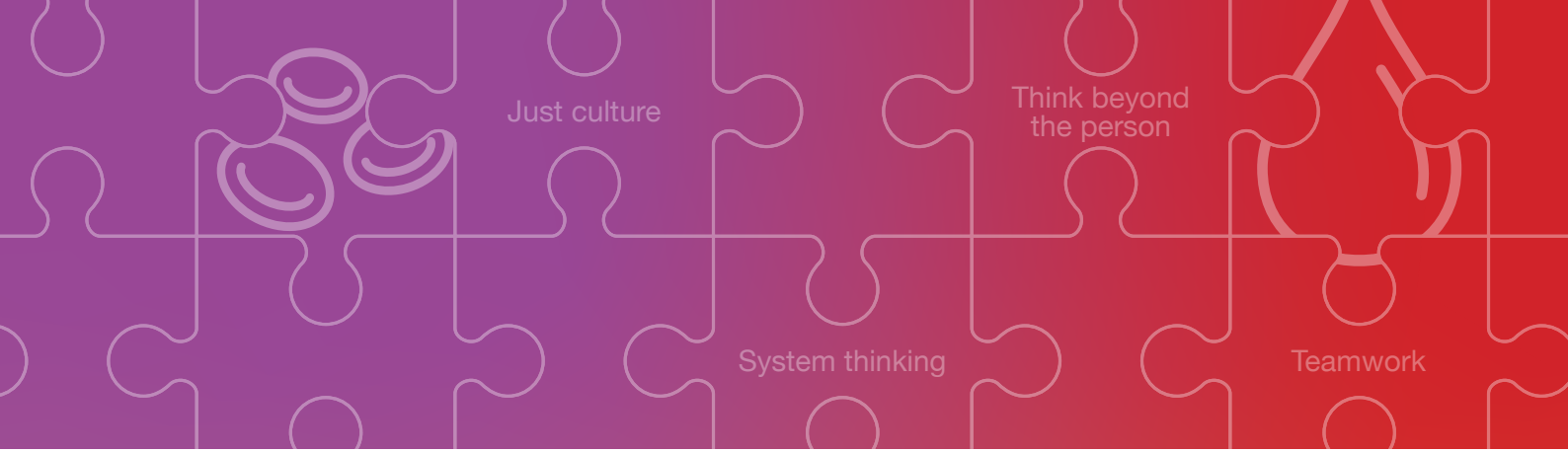

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