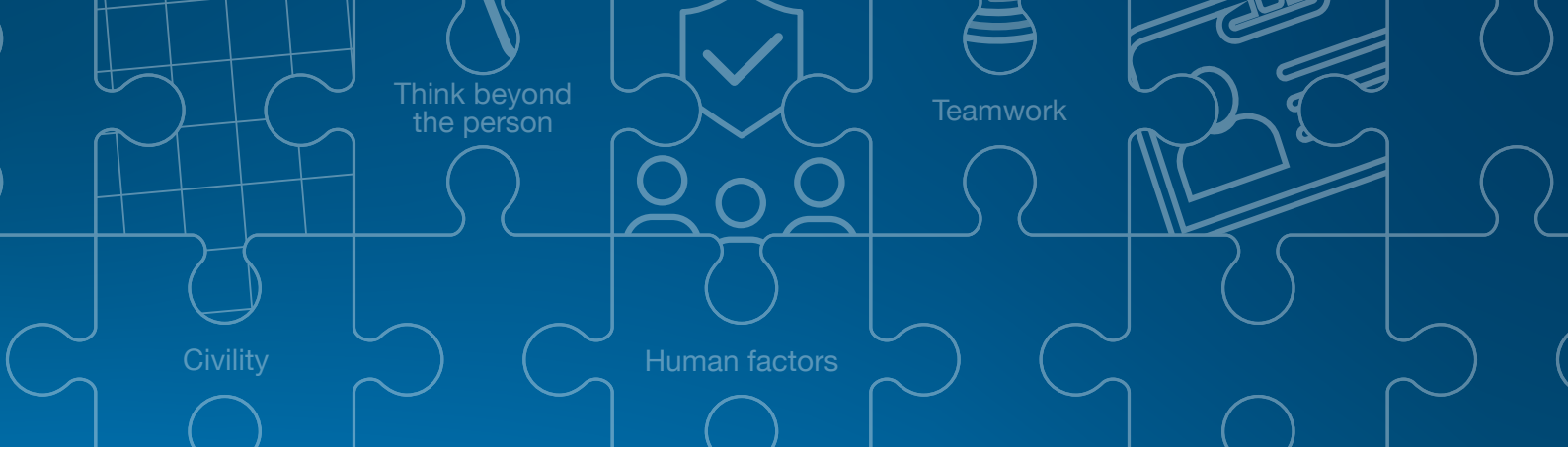

ANNUAL SHOT REPORT 2022

SHOT is affiliated to the Royal College of Pathologists
This report is produced by SHOT working with MHRA

MHRA

SHOT
Serious Hazards of Transfusion

Serious Hazards of Transfusion (SHOT)

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Dr Elizabeth Love	Former National Medical Coordinator of SHOT

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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Please cite this work as:

S Narayan (Ed) D Poles et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2022 Annual SHOT Report (2023). https://doi.org/10.57911/wz85-3885

This work was undertaken by SHOT. The work was funded by NHS Blood and Transplant, Northern Ireland Blood Transfusion Service, Scottish National Blood Transfusion Service and the Welsh Blood Service through the UK Forum.

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Published July 2023

ISBN 978-1-9995968-5-9

Illustrations by Jenny Leonard https://jennyleonardart.com/
Design, vector illustration & production of the report by ARC www.e-arc.co.uk

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Contents

Please see the beginning of each chapter for a glossary of abbreviations used

Foreword

1

Many in the transfusion world in the UK have been involved, over the last few years, giving evidence to the Infected Blood Inquiry. This Inquiry is now concluded, and its chair, Sir Brian Langstaff, is preparing his final report. The Inquiry has been hugely important, first, because it gives an opportunity for those tragically infected or affected, at last to receive explanations, compensation and closure. But it is also particularly important because it lifts the lid on historic, but widespread cultural problems in the way that health services are delivered and gives us an opportunity to learn from those mistakes. Although concentrating on transmissible infection, the lessons learned are much more widely generalisable to other transfusion harms and to healthcare-associated injury more widely.

While giving evidence to the Inquiry, I felt reassured that many of the lessons had already been learned, and that, already, we were moving on. Within weeks, my complacency has been seriously undermined. Many of the reassurances I gave the Inquiry, based on historical data, have now been questioned by the data presented and analysed in this year's Annual SHOT Report.

While some of the alarming upward trend in errors and harms may reflect better reporting, there is undoubtedly a very strong underlying signal that all is not well. In particular, after several years of improvement and sustained safety in key areas, such as ABO-incompatibility, this year we saw 2 deaths and 1 case of major morbidity.

The key issues across these cases related to portering and collection errors, stressed situations, leading to shortcuts, over-ridden procedures, and an absence of final pre-administration checks. In each case, a series of errors lined up to contribute to the harm. Key, however, in this seems to be a willingness to disregard formalised procedures and safety checks in pressured situations. One might surmise that this is related to staff training, staff numbers and availability.

A similar story is told in many other chapters of this year's Annual SHOT Report. Laboratory errors this year numbered 431, an increase of 11% on 2021. The chapter authors commented in the key messages that 'a mismatch in workload and staffing levels had some impact upon over half of all laboratory incidents. When staffing levels are unsafe, this must be escalated'. In their recommendations they observe that 'many errors occur due to establish procedures not being followed. It is important that laboratory staff understand the 'why' of an action before they move onto the 'how'.

Transfusion-associated circulatory overload (TACO) continues to be the major cause of harm. As with other categories of harm, the number of cases reported in the 2022 Annual SHOT Report is the highest to date, at 160, a 22% increase on the previous year.

Included in these were 8 deaths and 25 cases of major morbidity. SHOT has maintained for several years that 'a formal pre-transfusion risk assessment for TACO should be undertaken'. By and large, this is still not happening, and therefore, the final safety-net, again, is missing.

Across the board, there are common themes. Many of these relate to departure from established procedure particularly under stressed situations, communication, and staff training. We in the transfusion world are not alone in this. A recent Air Accident Investigation Branch report described the fatal crash of a light aircraft, in some part, due to weather, piloting experience, and training, but in large part to the way that air traffic control handled the situation. Distraction was a major element. Communication at all levels was poor; and the established procedures for dealing with the emergency were completely disregarded. The similarities between the human factors elements and root causes leading to the final poor outcome are strikingly similar to those we have seen in this year's Annual SHOT Report. The major

difference is the very small number of incidents in the aviation industry resulting in a fatal outcome or significant harm, compared with the very large numbers in healthcare.

After years of sustained improvement, there is a real risk that this is faltering, and could be lost. To prevent this, it is crucial that we adhere to good human factors, training, good communication, high levels of staff training, and no matter how stressed or busy the situation, that we do not set aside correct procedure in the heat of the moment. Workarounds are simply not acceptable. Escalation of these situations, and of resource and staffing levels to senior management is also important, even if painful, and even if the chances of this leading to a resolution seem slim. If we have learned only one thing from the Infected Blood Inquiry, it is that our patients have a right to expect this.

Professor Mark Bellamy, Past President, Intensive Care Society; Professor of Critical Care, The Leeds Teaching Hospitals NHS Trust, and Chair of the SHOT Steering Group

References

Air Accidents Investigation Branch. AAIB Report: Mudry Cap 10B (G-BXBU), Fatal Accident, 12 August 2021 (2023). https://www.gov.uk/government/news/aaib-report-mudry-cap-10b-g-bxbu-fatal-accident-12-august-2021 [accessed 03 May 2023].

Infected Blood Inquiry (2023). https://www.infectedbloodinquiry.org.uk [accessed 03 May 2023].

Participation in United Kingdom (UK) Haemovigilance

2

Author: Debbi Poles

Key SHOT messages

- Reporting levels have increased again after the slight reduction during the COVID-19 pandemic
- Analysis shows potential under-reporting from some NHS organisations. It is important that healthcare organisations submit reports across all types of reporting categories i.e., errors, reactions and near misses
- Reports where the error occurred in the ED have almost doubled since 2020

Recommendation

- Participation data from each NHS Trust/Health Board should be reviewed and analysed to identify any areas of concern and/or under-reporting to focus improvement efforts

Action: Hospital transfusion teams and hospital transfusion committees

Abbreviations used in this chapter

ED	Emergency department	**NHS**	National Health Service
MHRA	Medicines and Healthcare products Regulatory Agency	**SABRE**	Serious adverse blood reactions and events
		UK	United Kingdom

Introduction

Participation in haemovigilance reporting is on the increase again after a slight dip during 2020 and 2021, likely due to COVID-19 pressures. There were 4371 reports submitted via SABRE in 2022, which is an increase of 283 (6.9%) compared to 4088 in 2021.

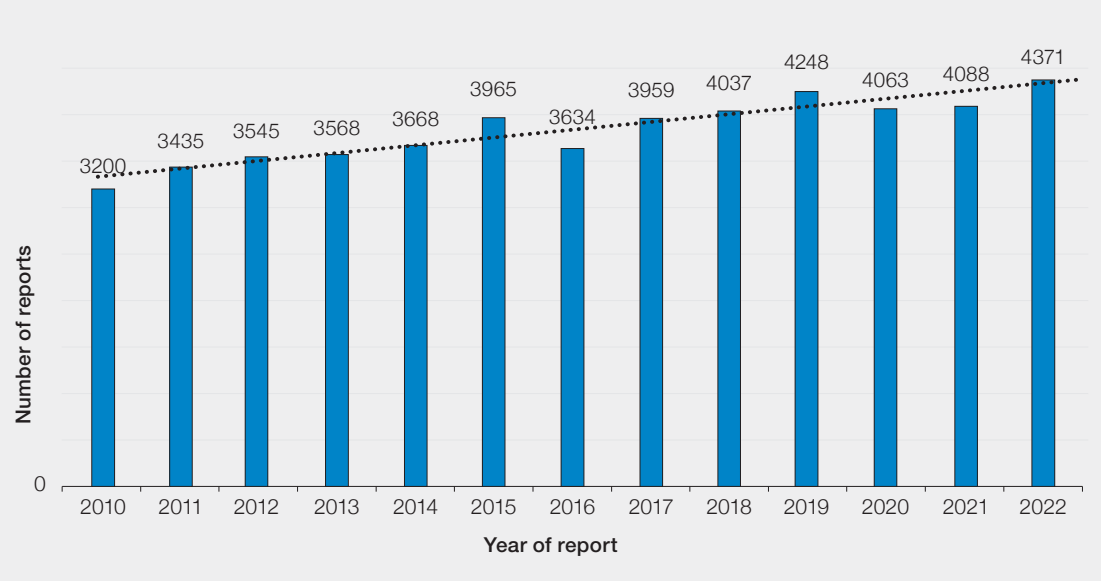


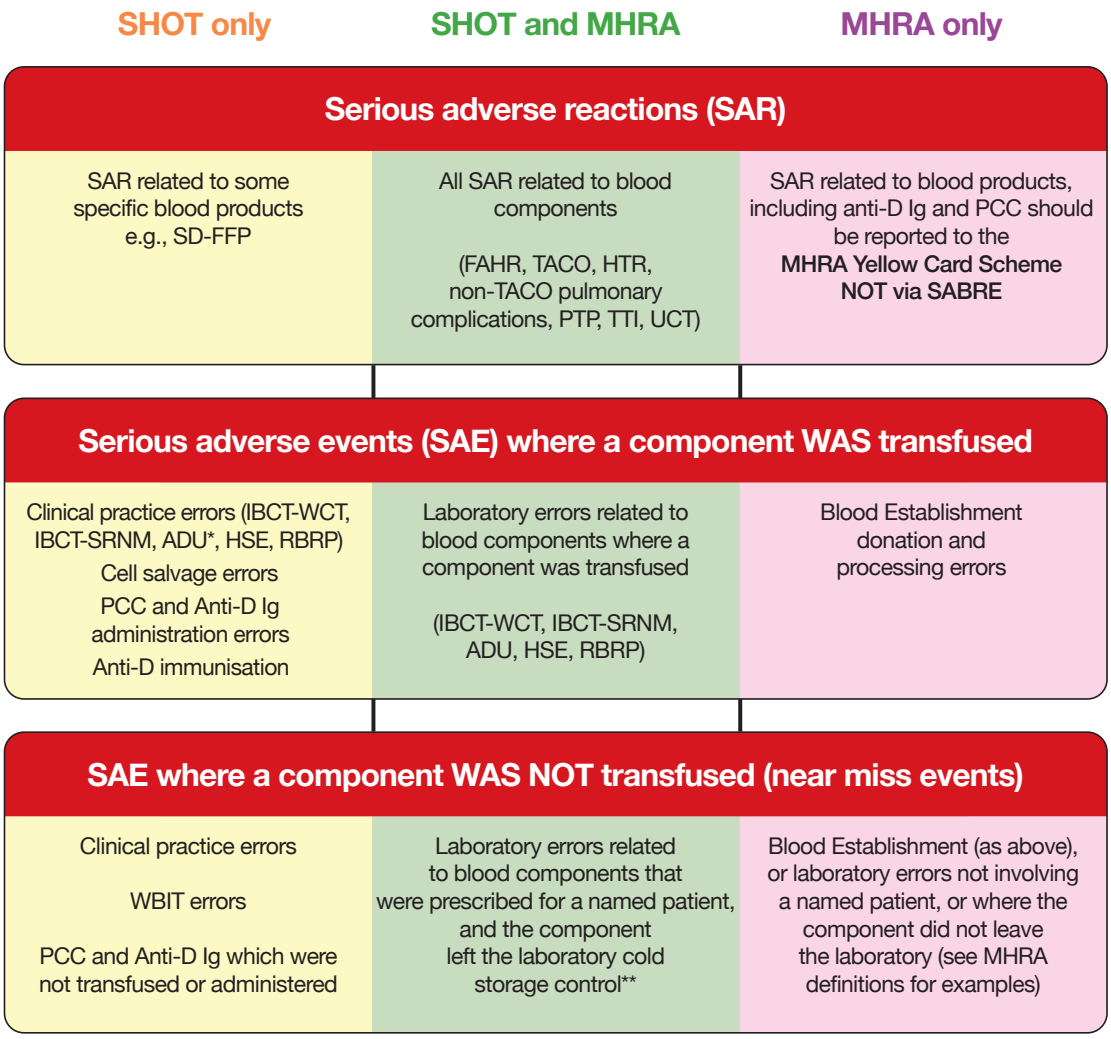
Figure 2.1: Haemovigilance reports submitted by year 2010-2022

Reporting to SHOT and the MHRA

The 4371 reports submitted via the SABRE reporting portal are not always at the same stage of completion or included in the same way by both SHOT and the MHRA. There are differences in reporting criteria for both organisations. Figure 2.2 highlights the main differences and commonalities in reporting criteria between the two organisations.

These differences account for the large numbers of reports that were withdrawn or excluded by each organisation. There were only 314/4371 (7.2%) reports that were withdrawn by both SHOT and the MHRA as not fulfilling either organisation's reporting criteria. Of these 314 reports, 33 were mild reactions, which are not reportable to either SHOT or the MHRA, and 29 were duplicate reports submitted in error.

Figure 2.2: SHOT and the MHRA reporting criteria



This infographic is for guidance purposes only. It may not cover all reportable events and does not represent a change to existing reporting requirements.

Full reporting definitions for SHOT and MHRA (Joint UK Haemovigilance User Guide) are available at: https://www.shotuk.org/reporting/ and for BSQR definitions of blood components/products see https://www.legislation.gov.uk/uksi/2005/50/made. A 'blood component' means a therapeutic constituent of human blood (red cells, white cells, platelets, and plasma) that can be prepared by various methods; while a 'blood product' means any therapeutic product derived from human blood or plasma.

* Includes cases where a component should have been transfused but was not due to a significant delay.
** Clinical errors relating to collection, storage and distribution, or where the primary error was in the laboratory, but detected later in the clinical area are MHRA-reportable.

ADU=avoidable, delayed and under/overtransfusion; 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 transfused; Ig=immunoglobulian; MHRA=Medicines and Healthcare products Regulatory Agency; PCC=prothrombin complex concentrates; PTP=post-transfusion purpura; RBRP=right blood right patient; SABRE=Serious Adverse Blood Reactions and Events; SD-FFP=solvent-detergent fresh frozen plasma; TACO=transfusion-associated circulatory overload; TTI=transfusion transmitted infections; UCT=uncommon complications of transfusion; WBIT=wrong blood in tube

Figure 2.3 details how the 4371 reports were included by each organisation. Only 1171/4371 (26.8%) of reports were accepted for inclusion in the 2022 analysis by both SHOT and the MHRA, and this demonstrates the differences in reporting criteria between the two organisations.

There were 412 reports to SHOT that were submitted during 2022, but still incomplete at the end of December 2022. This equates to 9.4% of all submitted cases, which is marginally better than in 2021 where there were 465/4088 (11.4%) cases that were still incomplete at the end of the calendar year. Once completed, these reports will be included in subsequent Annual SHOT Reports.

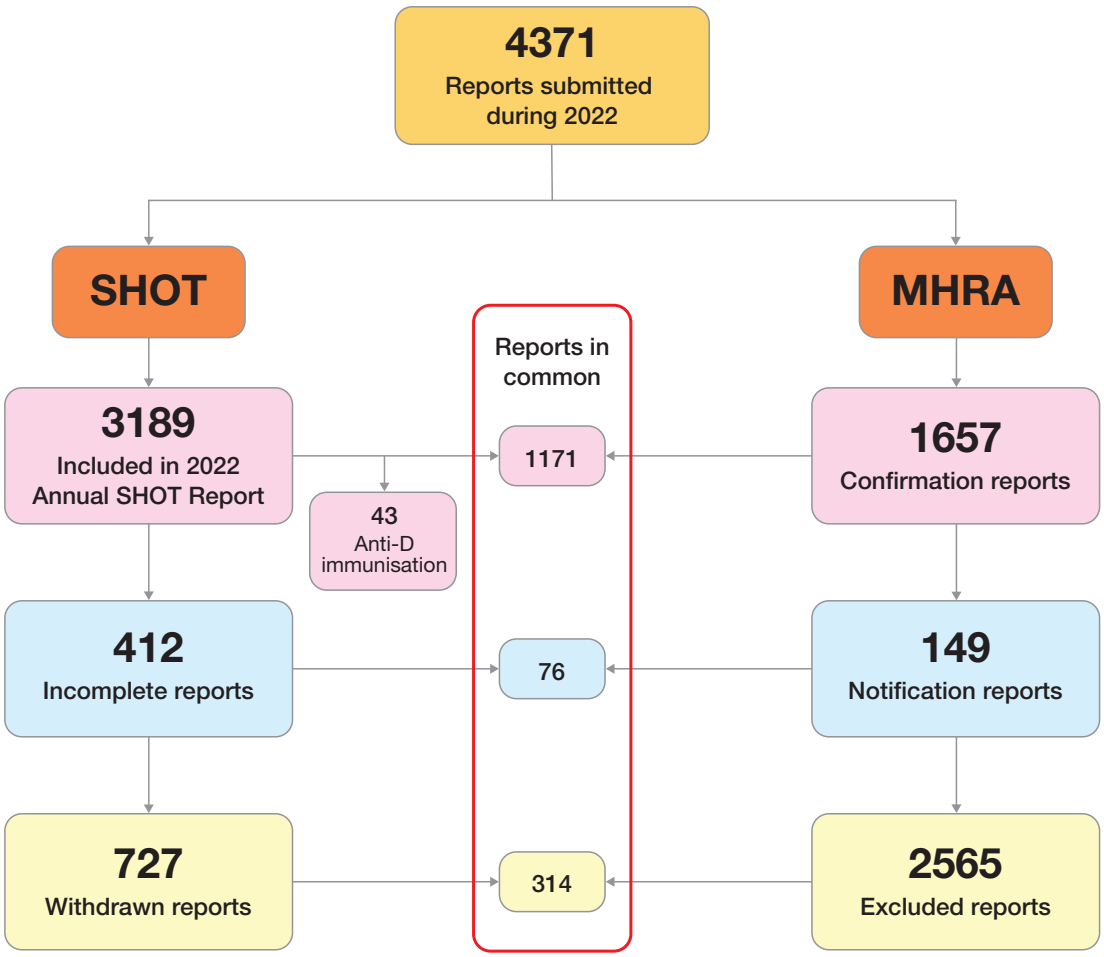


Figure 2.3: Reports submitted to SHOT and the MHRA in the calendar year 2022 (n=4371)

Withdrawn reports consist of reports that do not fit the SHOT reporting criteria but may still be MHRA-reportable (321), reports from Blood Services (127), reactions that were determined to be due to the underlying condition or unrelated to the transfusion (97), mild reactions (57) or duplicate reports (37). The remainder were due to various reasons, which included patient non-compliance, clinical decisions, no error following review etc.

Reporting organisations in 2022

For the first time in 2021, all UK NHS Trusts/Health Boards involved in transfusions submitted reports. This has not been repeated in 2022, as there were two NHS Trusts/Health Boards that did not submit any reports. Both these organisations were low blood users (1 issued with less than 1,500 components, and 1 less than 500 in 2022). Whilst there may have been other individual hospitals that did not submit reports, for participation purposes, SHOT consolidates reporting accounts into their respective Trust/ Health Board as a whole.

There were 19 non-NHS organisations that submitted 48 reports in 2022. This includes healthcare organisations situated in the Channel Islands who are not considered to be a part of the UK and therefore

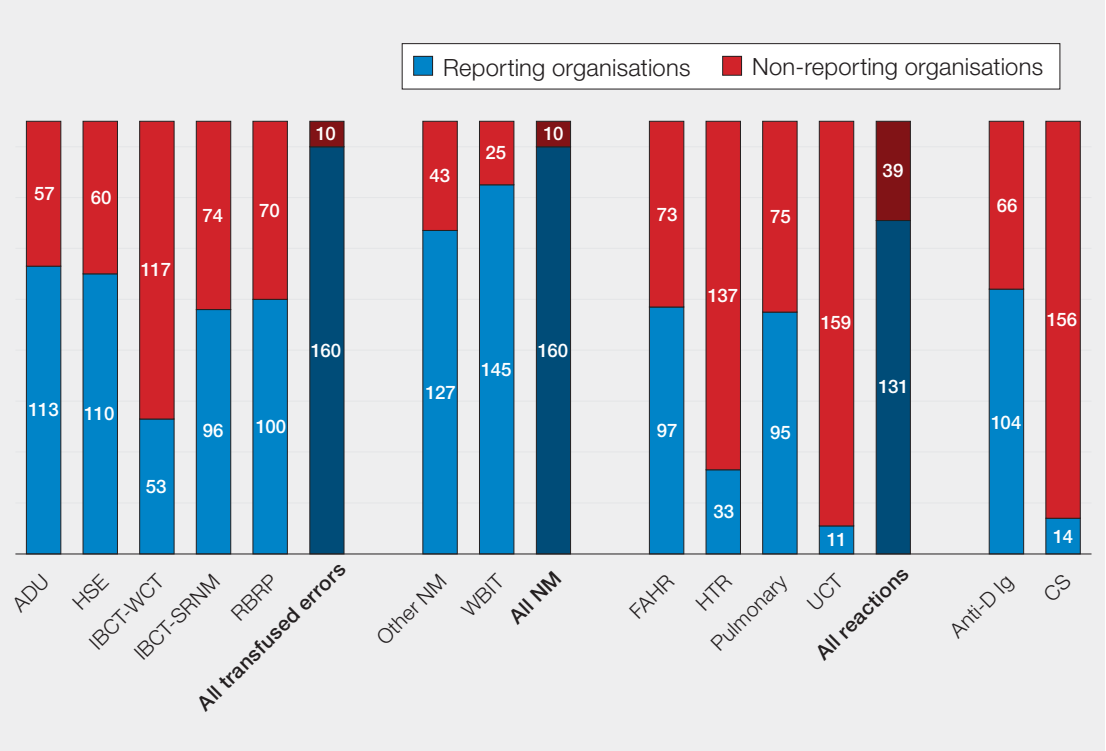
are not regulated by the MHRA. However, they still report to SHOT and incidents submitted are included in this Annual SHOT Report.

Further analysis has been carried out on the reports included in this year's Annual SHOT Report to determine how many NHS Trusts/Health Boards contributed to each reporting category, and overall type of report (Figure 2.4).

There was a slight increase in the proportion of NHS organisations that submitted error reports where a component was transfused,160/170 (94.1%). Of the 10 organisations that did not submit error reports, 1 was a very high user of blood, and 2 were medium users (according to the blood usage levels used for the 2021 participation benchmarking data https://www.shotuk.org/reporting/shot-participation-benchmarking/). Of the 10 reporting organisations that did not submit any type of near miss report, 1 was a high blood user, and 2 were medium users. There were a higher number of organisations that did not report any reaction reports, and 17/39 (43.6%) of these were medium, high, or very high usage organisations.

These data suggest that although in general participation is extremely good, there are still a small number of organisations that are likely to be under-reporting in certain areas. It is recommended that the participation data is reviewed by the hospital transfusion committee and appropriate actions taken if any concerns in trends or on comparison with similar organisations.

Figure 2.4: Number of NHS Trusts/Health Boards submitting reports by reporting category included in the 2022 Annual SHOT Report



ADU=avoidable, delayed and under/overtransfusion; HSE=handling and storage errors; IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; RBRP=right blood right patient; NM=near miss; WBIT=wrong blood in tube; FAHR=febrile, allergic and hypotensive reactions; HTR=haemolytic transfusion reactions; UCT=uncommon complications of transfusion; Ig=immunoglobulin; CS=cell salvage

Figure 2.5 demonstrates that reporting levels are extremely variable between different sized NHS organisations. There were 6 very high users (>19,000 components issued) that submitted fewer than 25 reports (1 only submitted 7 reports), compared to some low users (<6,000 components issues) that submitted more than 25 reports. The reasons for this are unknown but could indicate a poor reporting culture or staffing issues in some of the large organisations. These must be reviewed and addressed within each organisation to ensure learning from all patient safety incidents including near misses.

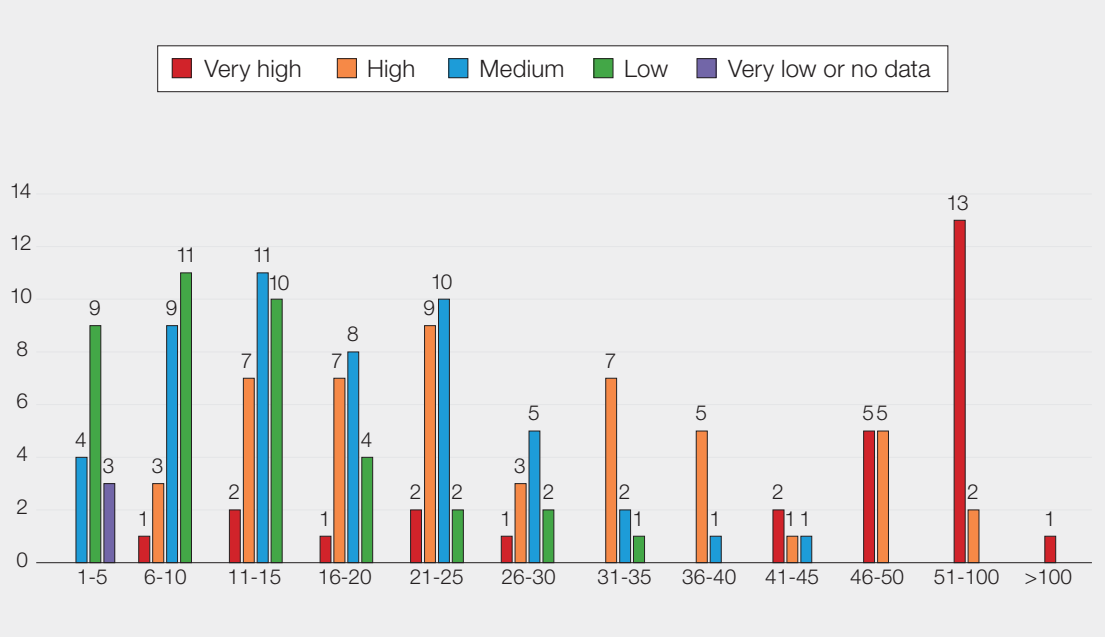


Figure 2.5: Number of reports by NHS reporting organisation and component usage level in 2022

Blood component issue data 2022

Table 2.1 lists the total number of blood components issued from the UK Blood Services in 2022.

	Red cells	Platelets	FFP	SD-FFP	MB-FFP	Cryo	Totals
NHS Blood and Transplant	1,361,676	248,360	173,134	66,400	404	40,166	**1,890,140**
Northern Ireland Blood Transfusion Service	41,622	8,108	4,305	3,120	1	882	**58,038**
Scottish National Blood Transfusion Service	136,633	24,313	15,350	2,450	0	3,384	**182,130**
Welsh Blood Service	74,840	9,426	7,930	1,865	-	465	**94,526**
Totals	**1,614,771**	**290,207**	**200,719**	**73,835**	**405**	**44,897**	**2,224,834**

FFP=fresh frozen plasma; SD=solvent detergent-sterilised; MB=methylene blue-treated; Cryo=cryoprecipitate

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

Paediatric/neonatal MB-FFP are expressed as single units; cryoprecipitate numbers are expressed as pools and single donations as issued; all other components are adult equivalent doses

Table 2.1: Total issues of blood components from the Blood Services of the UK in the calendar year 2022

Although blood component issues increased in 2022 compared to the previous 2 years, the larger reduction in 2020 was likely due to the pandemic, and Figure 2.6 demonstrates that the overall downward trend in blood component issue data is continuing.

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Serious Hazards of Transfusion

Figure 2.6a: Blood component issue data in the UK 2011-2022

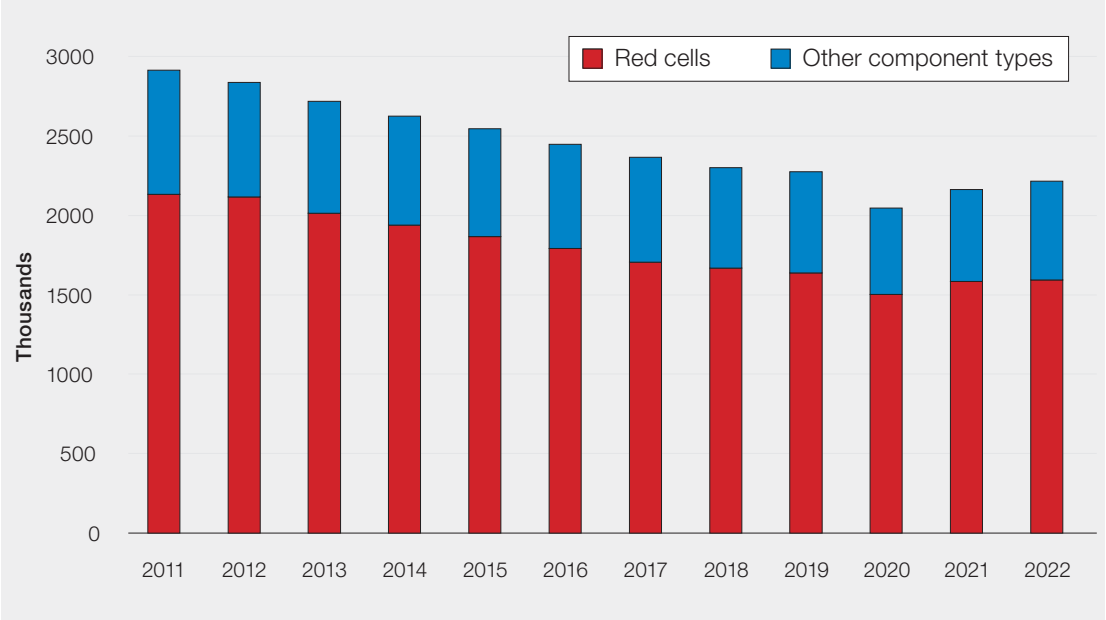
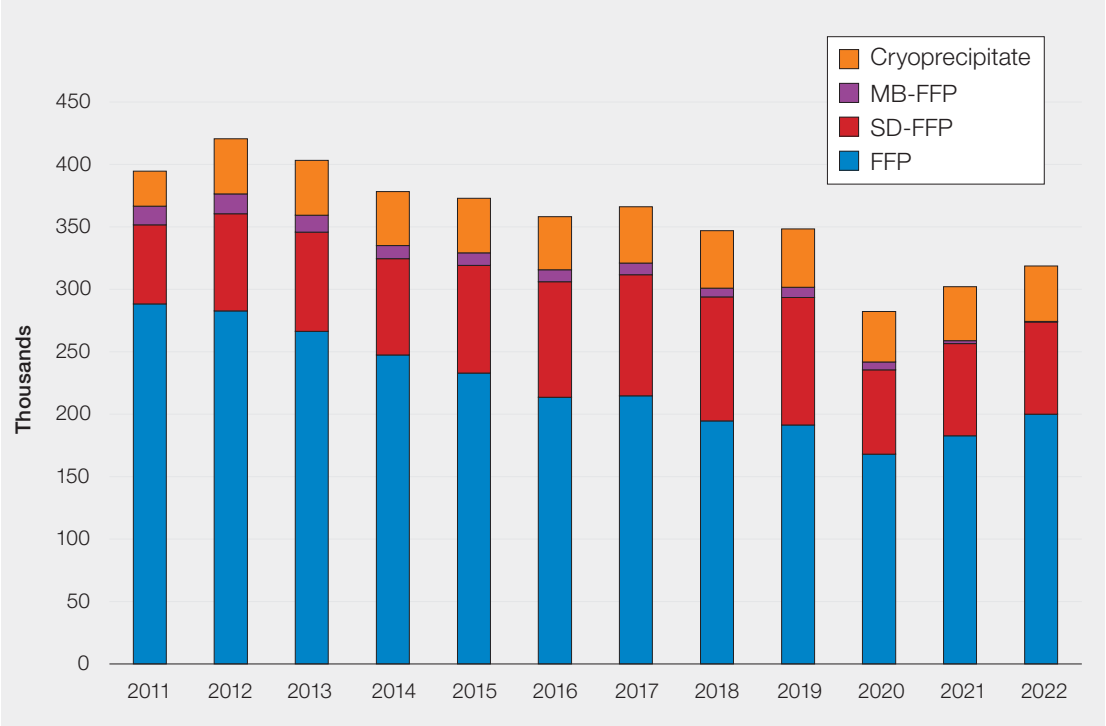


Figure 2.6b: Non-cellular component issue data in the UK 2011-2022



FFP=fresh frozen plasma; SD=solvent-detergent; MB=methylene blue

SHOT reporting by UK country

Full tables containing the breakdown of data from 2022 by UK country and previous years can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Cases included in the 2022 Annual SHOT Report n=3499

The total number of reports analysed and included in the 2022 Annual SHOT Report is 3499. This is an increase of 338 from the 3161 reports analysed in the 2021 Annual SHOT Report (Narayan et al. 2022).

In addition to these 3499 reports, there were 52 reports of immunisation against the D-antigen. These are counted separately as part of a stand-alone study.

The total number of 3499 is made up of the 3189 completed reports submitted in 2022 (Figure 2.3) plus 310 reports that were submitted in earlier years, but not finalised until 2022. Some of these reports may be related to historical transfusion incidents but incidentally discovered during audits and reported to SHOT.

The number of reports with potential for patient harm (excluding 'near miss' and 'right blood right patient') is 1869, a small increase of 79 from 2021 (n=1790).

Analysis of transfused errors by location

The number of incidents reported from the ED has increased substantially for the second year in a row and is now almost double the number reported in 2020. The large rise could be due to multiple factors including pandemic pressures, increasing workload, worsening staffing pressures and longer patient stays in the ED due to poor patient flow within organisations. The numbers of reports from other areas do not have such striking increases, and the trends as a percentage of transfused errors are mostly downwards.

Unfortunately, there are no denominator data available with regard to the number of transfusions undertaken in each of these areas, so it is difficult to draw any meaningful conclusions.

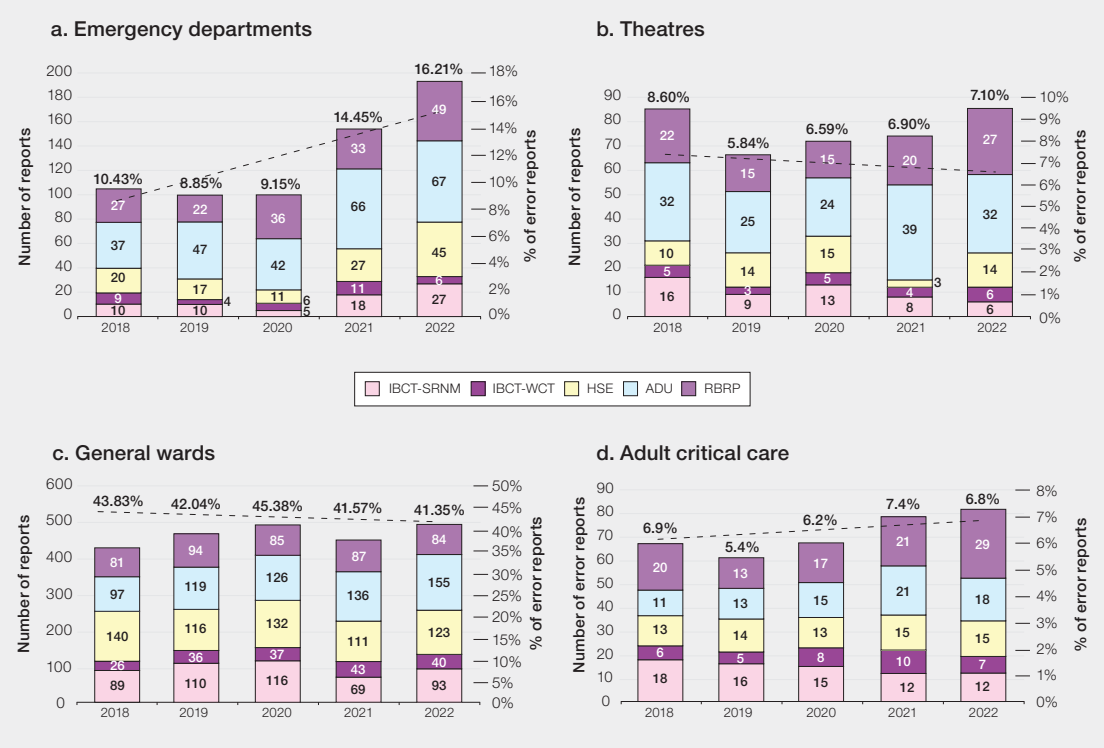


Figure 2.7: Five-year trend of error reports from different departments

ADU=avoidable, delayed and under/overtransfusion; HSE=handling and storage errors; IBCT-SRNM=incorrect blood component transfused-specific requirements not met; IBCT-WCT=IBCT-wrong component transfused; RBRP=right blood right patient

SHOT participation benchmarking data

SHOT participation data provides a useful benchmarking tool which is an integral part of continuous improvement in healthcare. Measuring, comparing to similar users, and identifying opportunities for tangible improvements will help improve patient safety. This supports local governance processes as well.

Data are collated and published annually in the autumn, and the 2022 participation data will be available on the SHOT website during October 2023.

SHOT also provides participation data on a monthly basis, which includes the number of reports submitted, and the number of reports completed in each category. However, these numbers are subject to change following review of the completed cases by the SHOT working expert group.

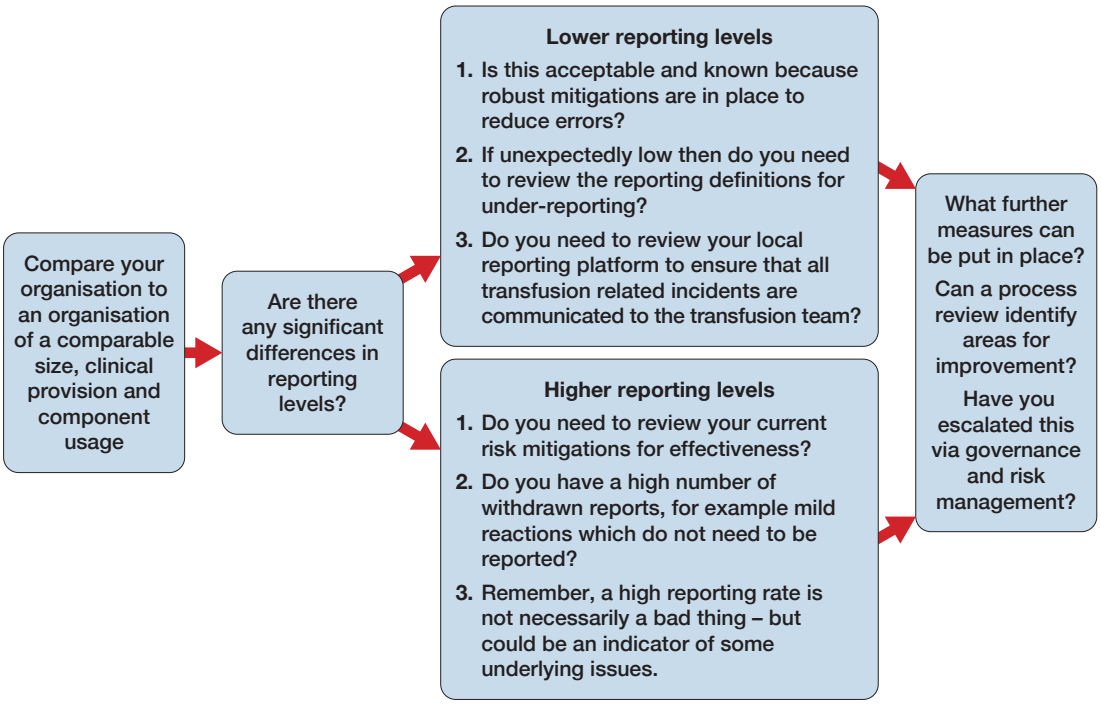
All reporters and local governance teams should access and use this participation data to inform local improvements. These discussions should be included in local and regional transfusion meetings.

Please see the links to the annual and monthly participation data on the SHOT website provided in the 'Recommended resources' section.

Conclusion

Reporting incidents is fundamental to error prevention and improving safety. Participation in UK haemovigilance is well supported, with a high level of engagement throughout the whole country, despite the ongoing pressures across the NHS. Reporting to SHOT and the MHRA across a broad range of reporting categories is essential to continue to learn from these incidents, and to embrace a culture of openness and sharing.

Figure 2.8: Using SHOT participation benchmarking data to drive improvements



Recommended resources

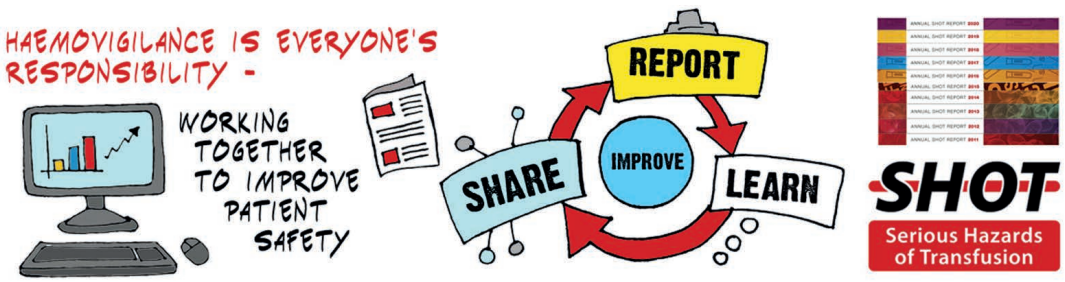
Definitions of current SHOT reporting categories & what to report
https://www.shotuk.org/resources/current-resources/

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

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

References

Narayan S (Ed), Poles D, et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2021 Annual SHOT Report (2022). https://www.shotuk.org/shot-reports/ [accessed 10 March 2023].



Headline Data: Deaths, Major Morbidity and ABO-Incompatible Transfusions 3

Authors: Shruthi Narayan and Debbi Poles

Key SHOT messages

- The risk of death related to transfusion in the UK is 1 in 63,537 (1.57 per 100,000) components issued and the risk of serious harm is 1 in 15,450 (6.47 per 100,000) components issued
- Errors (including near miss) continue to account for majority of the reports. In 2022, 2908/3499 (83.1%) of all reports were due to errors
- Near miss events continue to account for a large proportion, 1366/3499 (39.0%) of the incidents reported to SHOT
- Trends in pathological transfusion reactions, such as febrile, allergic, hypotensive, and haemolytic reactions are similar to previous years. All staff involved in transfusions must be competent and confident in recognising and appropriately managing transfusion reactions in recipients
- Transfusion delays and TACO continue to be the leading causes of transfusion-related deaths in the UK. These two categories together accounted for 21/35 deaths reported in 2022 (60.0%)
- ABO-incompatible red cell transfusions continue to occur and are the tip of the iceberg often resulting from failure to identify the patient at the time of blood sampling (wrong blood in tube) or administration to the wrong patient. Pre-transfusion administration safety checks using a patient side checklist can prevent incorrect transfusions in most cases

Abbreviations used in this chapter

ABOi	ABO-incompatible	**ISTARE**	International Surveillance of Transfusion Associated Reactions and Events
PAS	Platelet additive solution	**TACO**	Transfusion-associated circulatory overload
CAS	Central alerting system	**LIMS**	Laboratory information management system
RBRP	Right blood right patient	**UK**	United Kingdom
FFP	Fresh frozen plasma	**MB**	Methylene blue
SABTO	Advisory Committee on the Safety of Blood, Tissues and Organs	**vCJD**	Variant Creutzfeld Jakob Disease
HFE	Human factors and ergonomics	**NHS**	National Health Service
SCRIPT	SHOT Collaborative Reviewing and reforming IT Processes in Transfusion	**WBIT**	Wrong blood in tube
		NM	Near miss

The recommendation from last year remains pertinent and safety messages emerging from haemovigilance data must inform safety initiatives in all healthcare organisations not just for safer transfusions but for overall safer patient care.

Recommendation

- As in previous Annual SHOT Reports, NHS Trusts/Health Boards must use intelligence from all patient safety data including national haemovigilance data to inform changes in healthcare systems, policies, and practices to embed the lessons learnt and truly improve patient safety

Action: Hospital chief executives and medical directors, National Blood Transfusion Committee (or the equivalent for the devolved countries), hospital transfusion teams

Introduction

Haemovigilance helps identify and prevent occurrence or recurrence of transfusion-related adverse events, and increases the safety, efficacy, and efficiency of blood transfusion.

Haemovigilance data from 2022 show that while transfusions are generally safe in the UK, there are definite areas for concern where actions are urgently needed to improve transfusion safety. These are elaborated further in this chapter and throughout the Annual SHOT Report. The risk of death related to transfusion in the UK is 1 in 63,537 components issued, and the risk of serious harm is 1 in 15,450 components issued.

Transfusion-related serious adverse reactions and events are reported to SHOT and errors continue to account for most of the reports 2908/3499 (83.1%) (Figure 3.1). 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. The continuing trend of a high percentage of errors may reflect that systemic factors are not properly identified or rectified, leading to short term results rather than sustained improvement.

Figure 3.1: Errors account for most reports (n=2908/3499)

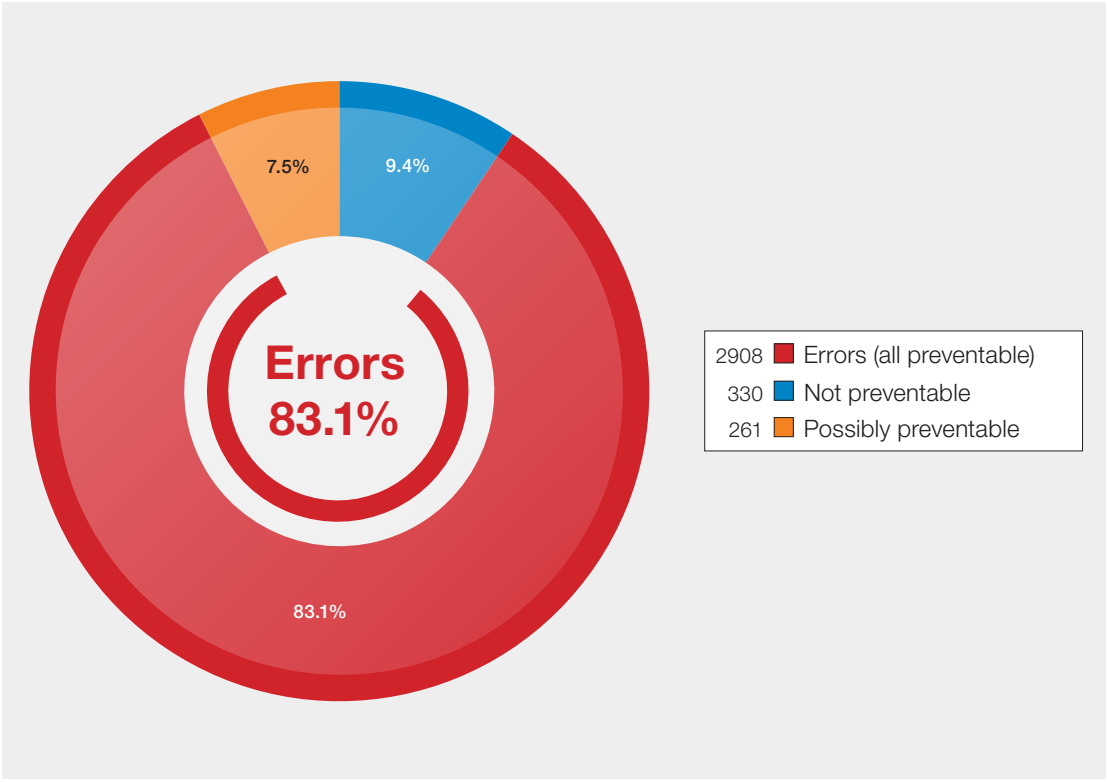


Figure 3.2 shows the trends in transfusion errors reported to SHOT as a percentage of total reports 2014-2022. Errors (including NM and RBRP) continue to account for >80% of reports analysed year on year. Learning from events and improving systems is vital. Analysis of errors is often limited and ineffective. Understanding what happened and how to prevent it from happening again requires a thorough, team-based discussion and analysis with application of human factors and ergonomics principles and systems thinking. Optimising learning from transfusion incidents, sharing lessons learnt widely, and periodically checking that the interventions have been effective, help move towards a learning system with enhanced transfusion safety.

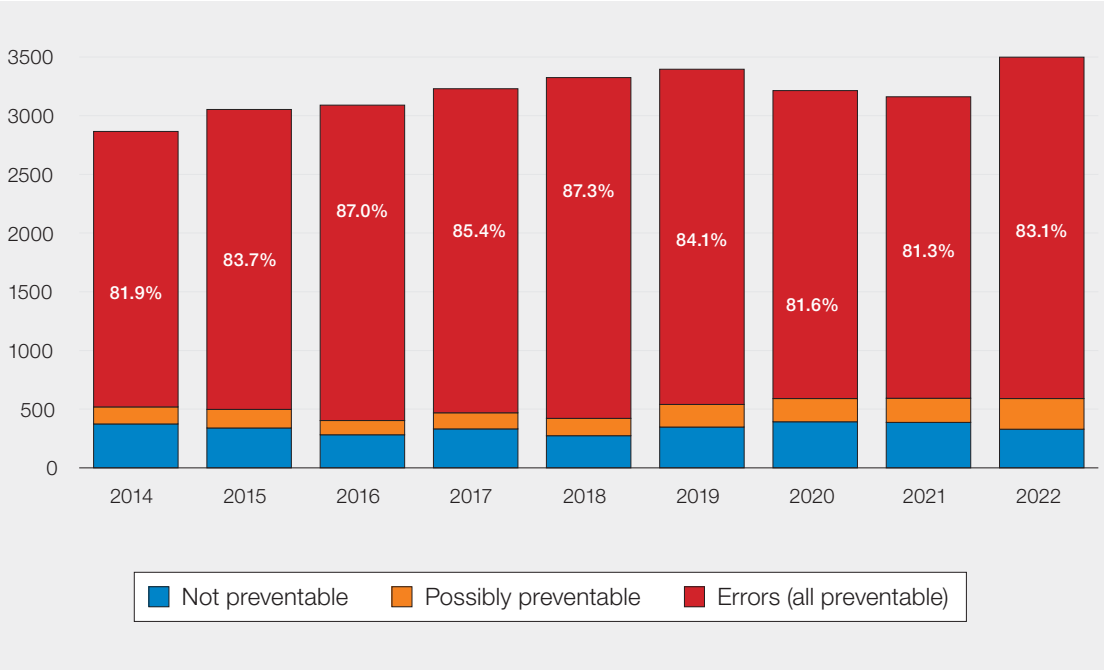


Figure 3.2: Errors as a percentage of total reports 2014-2022

Ensuring learning from transfusion incidents with effective, sustainable interventions means that the number of incidents resulting in or having the potential to harm patients fall over time with an expected corresponding increase in reports of no-harm incidents, so that learning can continue to be gained from near miss events. This is feasible with using HFE principles to build user-centric systems, application of human factors-based framework to investigate incidents with effective interventions addressing underlying factors. Figure 3.3 shows the percentage of no harm incidents reported to SHOT in recent years illustrating that there is still a lot of work to be done to improve safety.

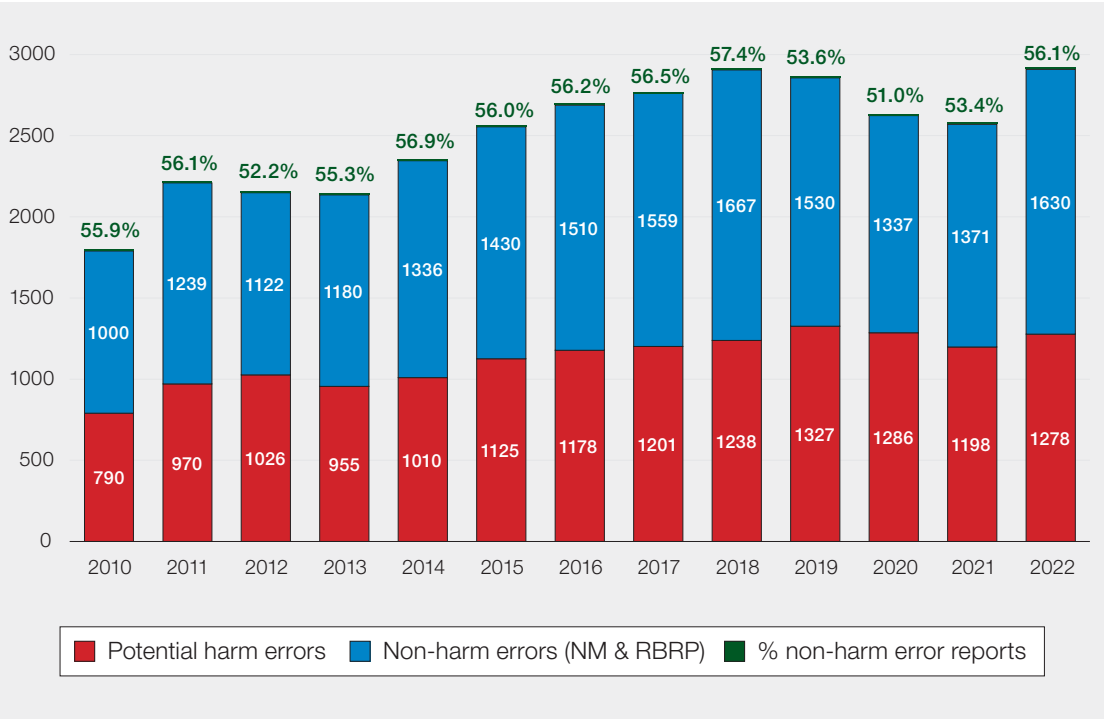


Figure 3.3: No patient-harm and potential patient-harm incidents 2010-2022

Potential harm incidents include incorrect blood component transfused (IBCT) errors, avoidable, delayed and under/overtransfusion (ADU) errors, handling and storage errors (HSE) and errors related to anti-D immunoglobulin administration

Deaths related to transfusion n=35

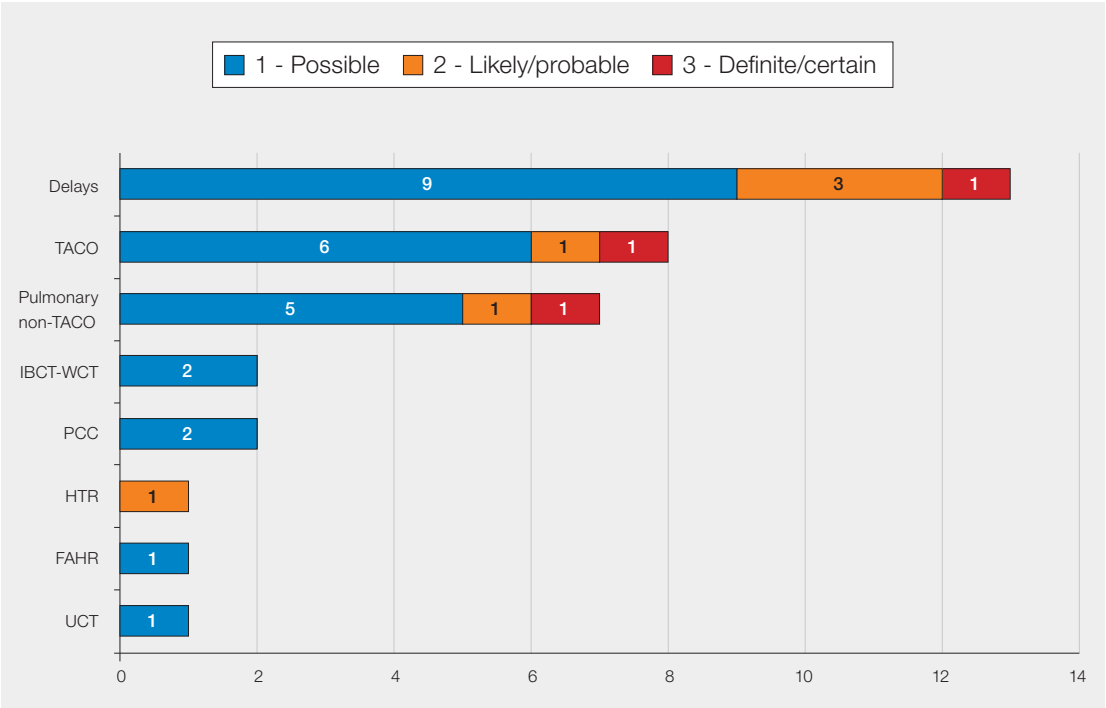
All serious reactions reported to SHOT are assessed for imputability i.e., the relationship of the blood transfusion to the reaction. The imputability criteria are detailed in the table below:

Table 3.1: Definition of imputability levels

Imputability		
N/A	Not assessable	When there is insufficient data for imputability assessment
0	Excluded or unlikely	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components or where the evidence is clearly in favour of alternative causes
1	Possible	When the evidence is indeterminate for attributing the adverse reaction either to the blood or blood component or where there may be alternative causes
2	Likely/probable	When the evidence is clearly in favour of attributing the adverse reactions to the blood or blood component
3	Definite/certain	When there is conclusive evidence beyond reasonable doubt

Transfusion delays (n=13) and TACO (n=8) were the most common causes of transfusion-related deaths reported to SHOT in 2022 accounting for 21/35 deaths reported (60.0%). This is the first year that transfusion delays have resulted in more deaths than TACO. Actions recommended in the SHOT CAS alert (SHOT 2022), if implemented effectively, help address preventable transfusion delays and improve safety. The impact of the alert is yet to be seen in trends of reports submitted to SHOT. Non-TACO pulmonary cases accounted for 7 patient deaths and other causes of transfusion-related deaths including imputabilities are shown in Figure 3.4. It is also important to note that there were 2 deaths following inadvertent ABO-incompatible red cell transfusions, both of which were totally preventable. Key factors identified in the transfusion-related deaths are discussed in the relevant chapters of this Annual SHOT Report.

Figure 3.4: Deaths related to transfusion with imputability reported in 2022 (n=35)



HTR=haemolytic transfusion reactions; FAHR=febrile, allergic and hypotensive reactions; UCT=uncommon complications of transfusion; TACO=transfusion-associated circulatory overload; IBCT-WCT=incorrect blood component transfused-wrong component transfused; PCC=prothrombin complex concentrates

A detailed review of the transfusion-related deaths in the UK from 2022 can be found in the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).

Major morbidity n=144

Febrile, allergic, or hypotensive transfusion reactions (77/144 (53.5%)) and pulmonary complications (TACO, 25/144 (17.4%)) continue to account for most of the cases with major morbidity. These are detailed further in the respective subject chapters in this report. Major morbidity was defined in the SHOT definitions document for 2022 as:

- Transfusion-induced coagulopathy in association with treatment for major haemorrhage (due to the dilution of haemostatic factors following unbalanced resuscitation or overuse of crystalloid/colloid)
- Evidence of acute intravascular haemolysis e.g., haemoglobinaemia, gross haemoglobinuria
- Life-threatening acute reaction requiring immediate medical intervention
- Persistent viral infection
- Acute symptomatic confirmed infection
- Sensitisation to D or K in a woman of childbearing potential
- Reaction resulting in a low or high haemoglobin (Hb) level of a degree sufficient enough to cause risk to life unless there is immediate medical intervention

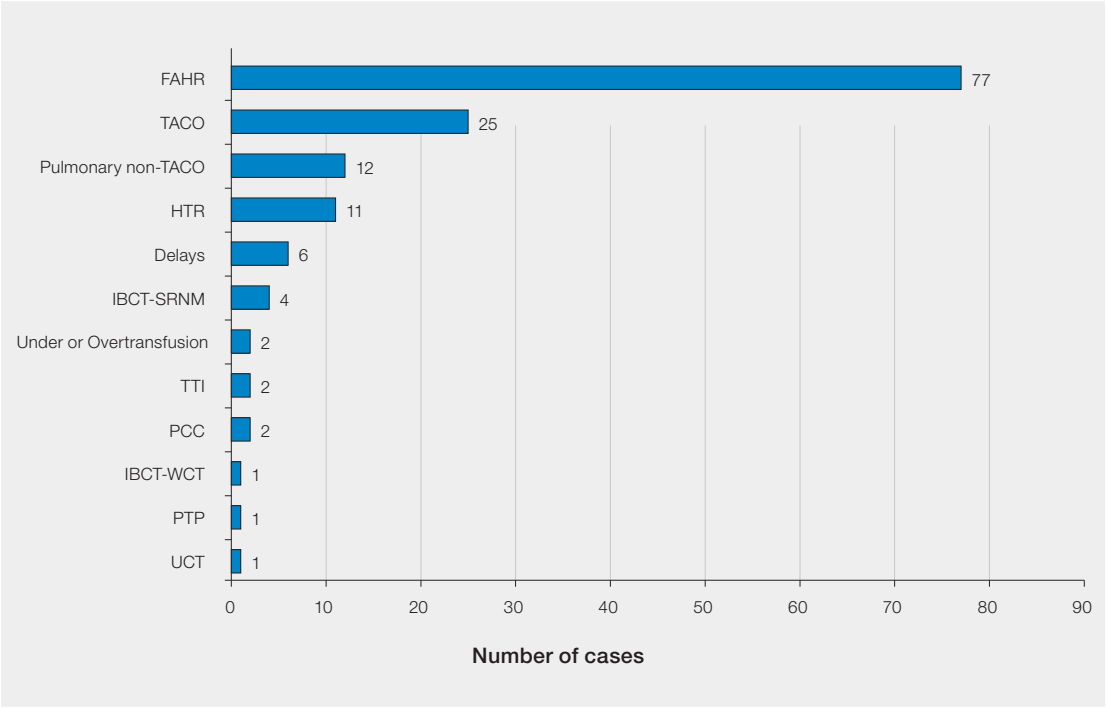


Figure 3.5: Ranking of categories to show number of serious reactions in 2022 (n=144)

FAHR=febrile allergic and hypotensive reactions; TACO=transfusion-associated circulatory overload; HTR=haemolytic transfusion reactions; IBCT-SRNM=incorrect blood component transfused-specific requirements not met; TTI=transfusion-transmitted infection; PCC=prothrombin complex concentrate; IBCT-WCT=IBCT-wrong component transfused; PTP=post-transfusion purpura; UCT=uncommon complications of transfusion

Summary data and risks associated with transfusion

Data collected in 2022 are shown in Figure 3.6. Near miss reports continue to account for most reports, 1366/3499 (39.0%). Reporting and investigating near misses help identify and control risks before actual harm results, providing valuable opportunities to improve transfusion safety. Cumulative haemovigilance data from SHOT between 1996-2022 are shown in Figure 3.7.

Figure 3.6: Summary data for 2022, all categories (includes RBRP and NM) (n=3499)

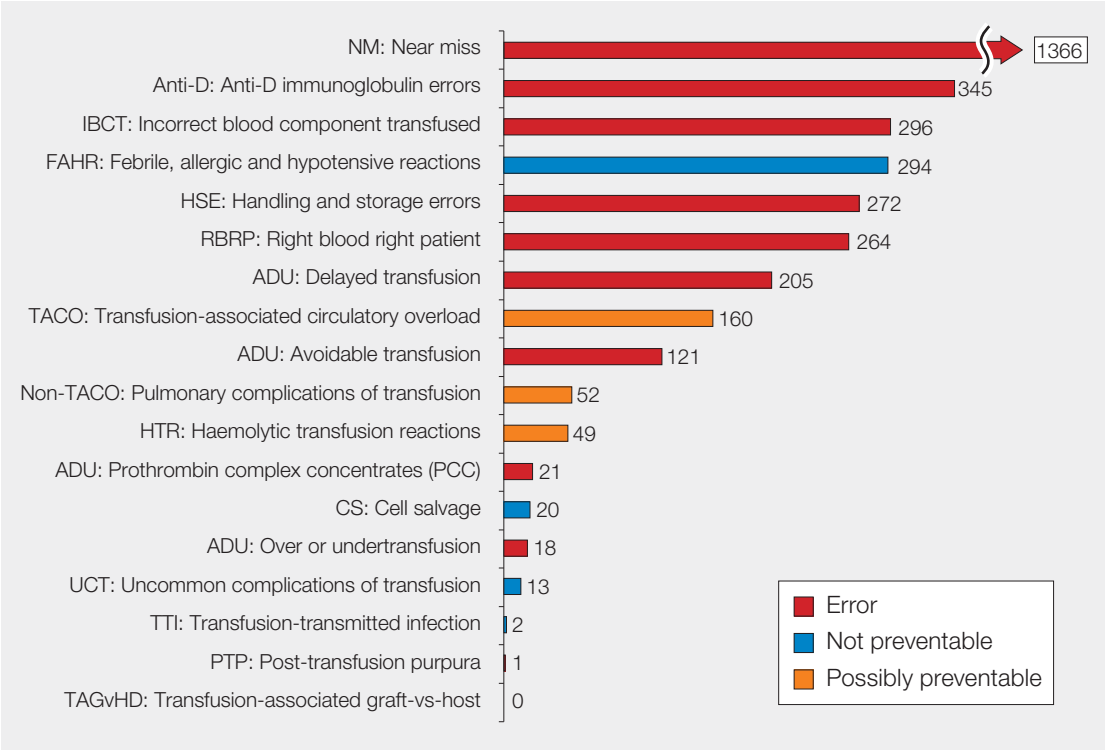
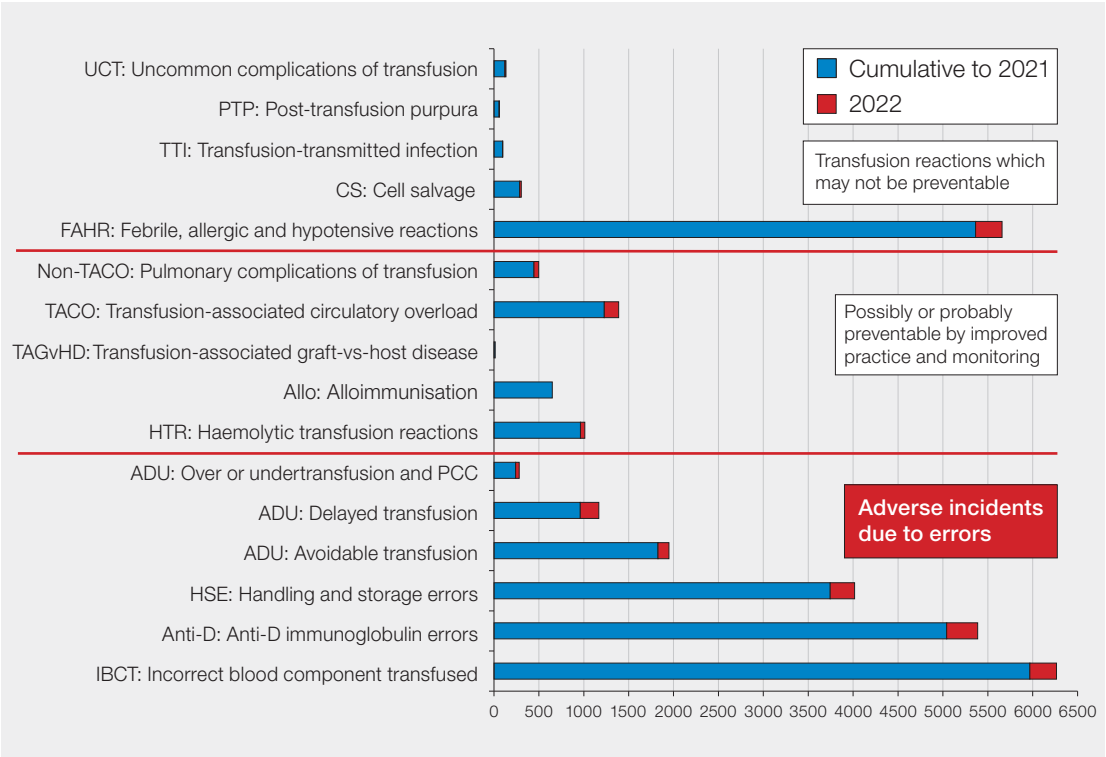


Figure 3.7: Cumulative data for SHOT categories 1996-2022 (n=28877)



**Data on alloimmunisation is no longer collected by SHOT since 2015*

Cumulative risk data from SHOT

Figure 3.8 shows the number of reactions reported per 10,000 blood components issued in the UK between 2010-2022. Although red cells are the most common blood component transfused, platelets account for the highest number of reactions reported per 10,000 components. Platelet transfusions are associated with a high frequency of febrile and anaphylactoid reactions (Kiefel 2008). The same pattern is seen in the cases reported to SHOT and these are further elaborated in Chapter 16, Febrile, Allergic and Hypotensive Reactions (FAHR). The incidence of allergic reactions is lower with pooled platelets (suspended

in PAS) than apheresis platelets and could most likely be associated with the reduction in plasma content. Reactions to platelets are at least in part caused by release of substances from the platelets themselves and therefore cannot be completely eliminated (Garraud et al. 2016, Maurer-Spurej et al. 2016).

It is also important to note that following the SaBTO recommendations (2019) that there is a reduction in the use of MB-FFP as it is no longer necessary for UK Blood Services to import plasma as a vCJD risk-reduction measure removing the selection of plasma components based on whether the patient was born before/after 1st January 1996. This reduction in use must be considered when interpreting the risk of reactions. A review of 7 years data from the ISTARE database had shown that pathogen-inactivated plasma was associated with fewer transfusion reactions than untreated plasma (Saadah et al. 2018).

Cryoprecipitate has similar risks to FFP for allergic and febrile reactions and has also been implicated in cases of TRALI (Green et al. 2018 and Bolton-Maggs et al. 2016).

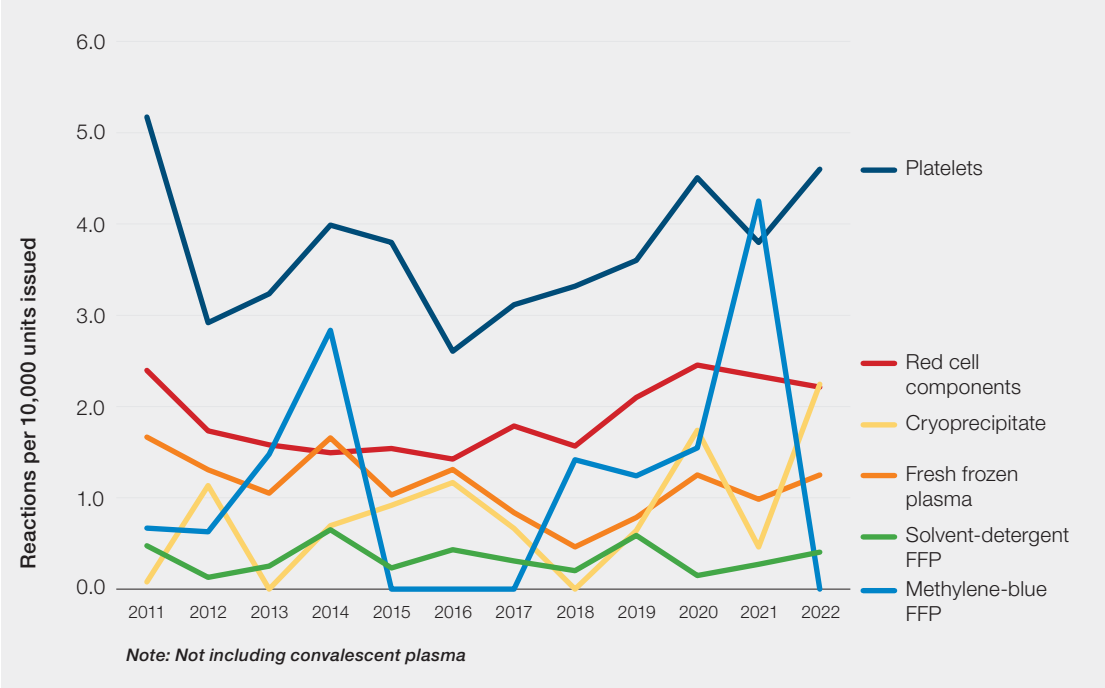


Figure 3.8: Reactions per 10,000 components, by component type 2010-2022

**The risks for blood components which are used infrequently such as cryoprecipitate and MB-FFP should be interpreted with caution due to the low numbers involved*

The following table shows the risk of transfusion reactions based on SHOT data 2013-2022. It is important to note that these are based on the number of blood components issued by the four UK Blood Services as accurate, reliable data regarding actual number of transfusions/transfused components is not easily available. Variations in reporting especially in certain categories over the years, changes in definitions, validation, and variation in practices should be considered when interpreting these data. Despite these limitations, the data are useful and provide valuable information about the risks for some of the common transfusion reactions reported to SHOT.

Table 3.2: Risk of transfusion reaction by reaction type 2013-2022

Transfusion reaction	Risk of transfusion reaction based on SHOT data 2013-2022
Febrile, allergic or hypotensive reactions	1 in 7,378
Transfusion-associated circulatory overload	1 in 19,075
Haemolytic transfusion reactions	1 in 48,023
Pulmonary non-TACO	1 in 93,976
Post-transfusion purpura	1 in 2,725,307
Transfusion-associated graft vs host disease	0 (none reported in the last 10 years)

ABO-incompatible (ABOi) transfusions n=6
ABOi patient deaths n=2

In 2022, there were 5 ABOi red cell transfusions reported and 1 ABOi plasma transfusion, with 2 preventable patient deaths and 1 major morbidity following ABOi red cell transfusion. There was no clinical reaction in the remaining 3 cases. Figure 3.9 shows the number of ABOi red cell transfusions reported to SHOT between 1996 and 2022 and Figure 3.10 shows the number of ABOi plasma transfusions reported from 2003 onwards. Figure 3.11 shows the outcome of ABOi red cell transfusions reported to SHOT since reporting began in 1996.

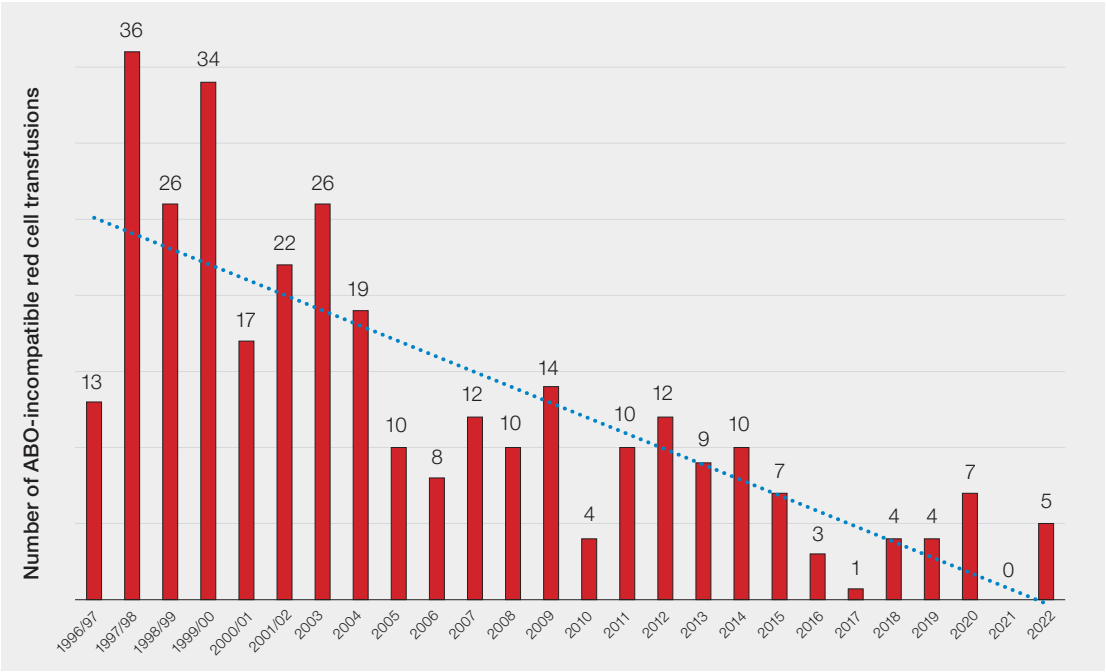
All 5 ABOi red cell cases reported in 2022 were in adult transfusion recipients and following primarily clinical errors. Two were related to blood collection errors, both of which resulted in patient fatalities. Of the remaining 3 ABOi red cell transfusions, 2 were due to primary administration errors and 1 was following a historical WBIT. Lack of pre-transfusion safety checks meant that these were not picked up prior to administration. Non-group O red cells were transfused to a group O patient in all but 1 of the ABOi red cell transfusions. The ABOi plasma component was due to a component selection error in the transfusion laboratory, with a group O plasma component being transfused to a group A recipient.

Lack of reliable, accurate patient identification was noted in the majority of these ABOi events. Other contributory factors included staffing issues with suboptimal skill mix, high workload, knowledge gaps, decision fatigue and assumption bias. These are explored in more detail in Chapter 9, Incorrect Blood Component Transfused (IBCT) and Chapter 14, Laboratory Errors.

ABO-compatibility for plasma components is different to that of red cells and group O FFP/cryoprecipitate must only be given to group O recipients. One of the key SHOT recommendations in the 2017 Annual SHOT Report was that training in ABO and D blood group principles is essential for all laboratory and clinical staff with any responsibility for the transfusion process and should form part of the competency-assessments (Bolton Maggs et al. 2018). This continues to be pertinent, and a compatibility check is an essential part of the pre-administration process. LIMS should be set up to prevent release of group O plasma components to any patients other than group O.

In the SCRIPT UK LIMS suppliers survey conducted, all 10 LIMS providers stated that ABO/D incompatibilities were controlled for issue of red cells and plasma. Override was configurable in 50% of LIMS, and 50% of the providers stated that ABOi was a ‘hard stop’. ABO/D compatibility rules for HSCT recipient transfusions were configurable in 8/10 LIMS yet reports where incorrect blood components were transfused in transplant recipients continue to be reported. Appropriately configured LIMS can reduce patient harm by preventing ABOi transfusions (Davies et al. 2022).

Figure 3.9: Number of ABO-incompatible red cell transfusions 1996-2022



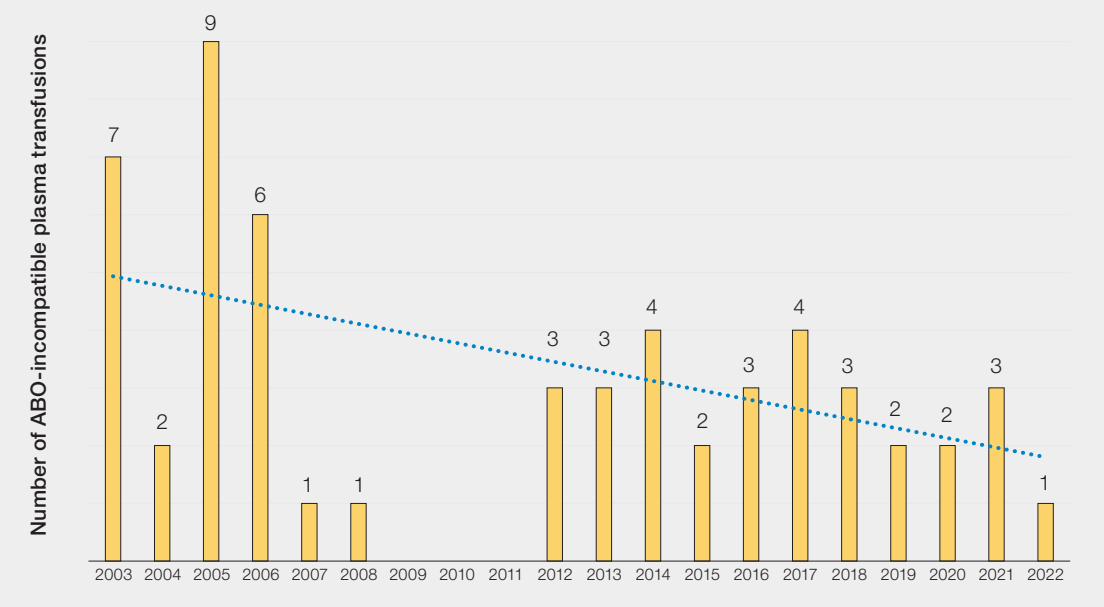


Figure 3.10: Number of ABO-incompatible plasma transfusions 2003-2022

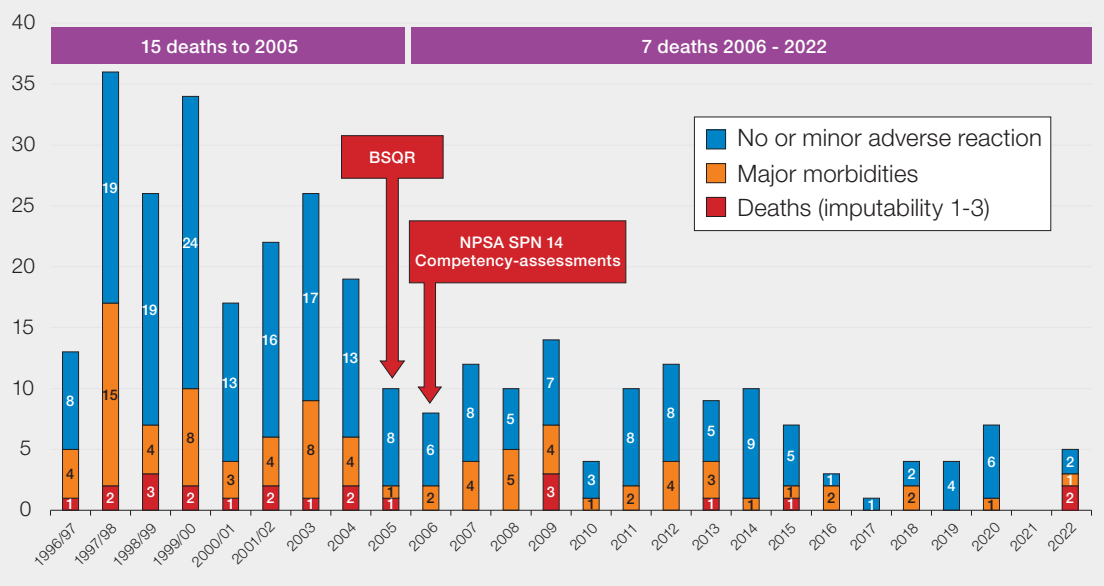


Figure 3.11: Outcome of ABO-incompatible red cell transfusions in 25 years of SHOT reporting

BSQR=Blood Safety and Quality Regulations; NPSA=National Patient Safety Agency; SPN=safer practice notice

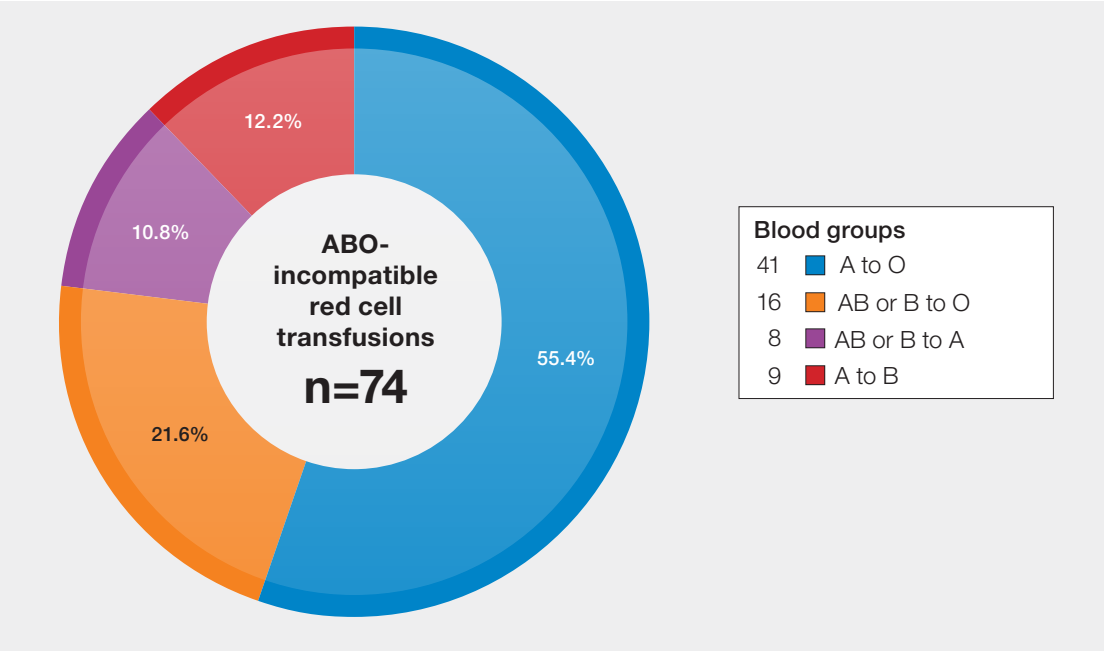
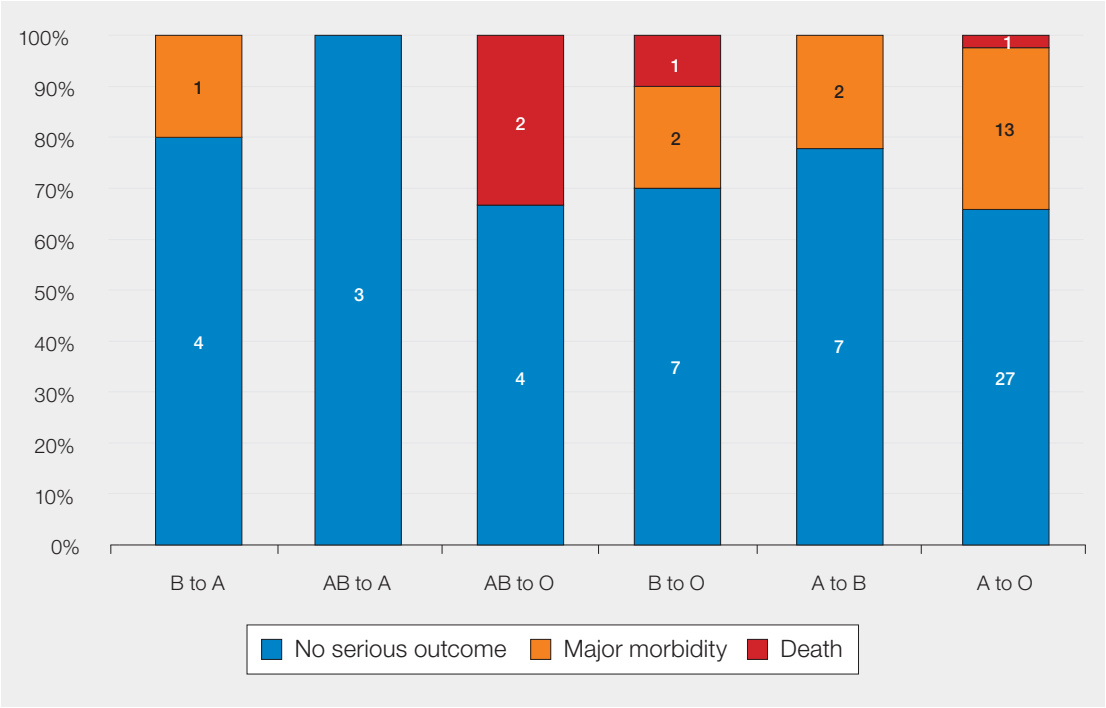


Figure 3.12: Combinations of groups in ABO-incompatible red cell transfusions 2010-2022 (n=74)

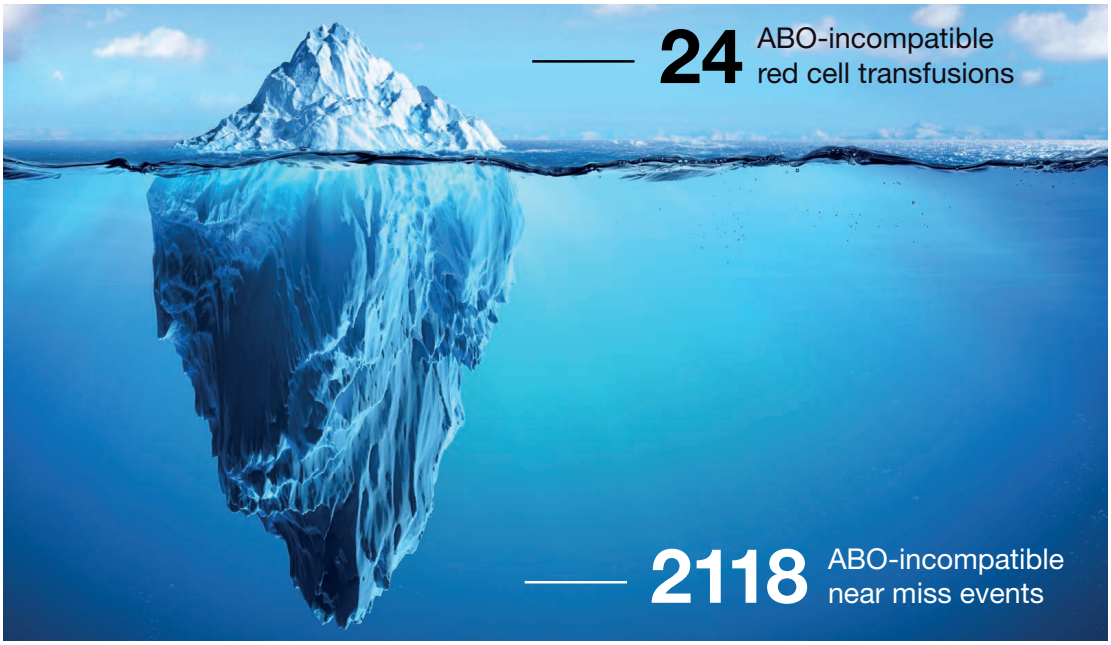
Transfusion of group A red cells to group O patients was associated with the greatest risk of major morbidity, 13/41 (31.7%), but deaths have occurred in group O patients receiving group AB red cells (2 deaths), B red cells (1 death) and A red cells (1 death). These are shown in Figure 3.13 below.

Figure 3.13: ABO-incompatible transfusions and outcome by groups 2010-2022 (n=74)



Data from 2016-2022 show that although there were 24 ABOi red cell transfusions, there were 2118 near misses where an ABOi transfusion could have resulted, the majority of these were WBIT incidents. WBIT constitute the largest subset of near miss cases reported to SHOT in 2022, 890/1366 (65.2%) of all NM events, and these are discussed separately. 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 (BSH Milkins et al. 2013). These errors, which could have lethal outcomes, demonstrate the importance of positive patient identification at the time of collecting and labelling pre-transfusion samples. As with all NM, WBIT incidents provide valuable opportunities to learn and improve systems. As is evident from the iceberg representation (Figure 3.14), these occur much more frequently and afford more opportunities to learn than the rarer serious adverse events. When they are not identified or investigated, they are missed opportunities that can contribute to future risks of potentially lethal ABOi.

Figure 3.14: ABO-incompatible red cell transfusions 2016-2022: few events (n=24) but many near misses (n=2118)

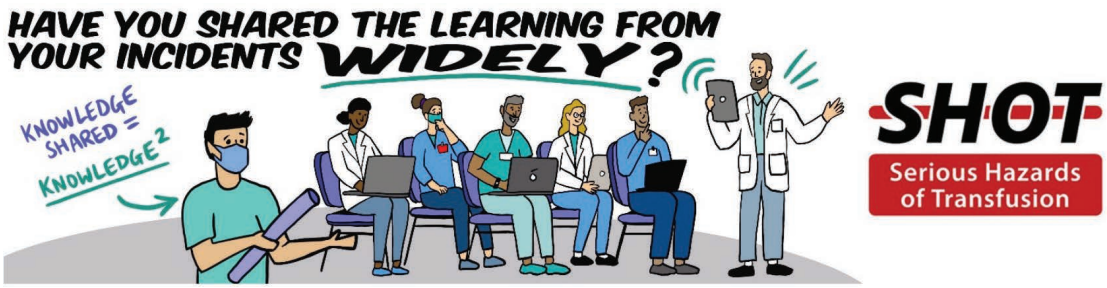


Trending and investigating WBIT, using human factors principles will help identify the causal and contributory factors; and will inform the corrective and preventative actions to improve patient safety and prevent future ABOi transfusions that could result in patient death.

Conclusion

Lessons learnt from incidents reported to SHOT must be used to improve and adapt healthcare systems, update transfusion policies and practices including training/education and investigation of incidents. These will help improve transfusion safety and can be evidenced by a reducing trend of such reports to SHOT in the future. Preventable errors and potentially preventable patient deaths continue to occur. With the NHS facing an unprecedented era of challenges with poor funding, lack of resources, staffing and IT issues and an ever-increasing workload, it is imperative that the gap between 'work as done' and 'work as imagined' is bridged. Application of human factors and ergonomics principles to design user-friendly systems, investigate and learn from incidents is vital in helping bridge this gap. Near misses also present valuable learning opportunities and should be trended, and investigated appropriately. System level changes are needed to ensure that healthcare is a robust, safe, and effective learning system with feedback loops.

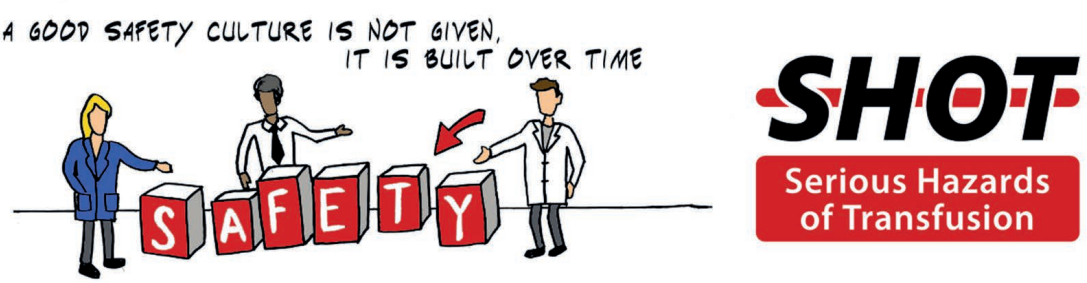
Further information and data can be found in the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).



Recommended resources

SHOT Bite No. 1a and 1b: Incident Investigation
SHOT Bite No. 17: Learning from Near Misses (NM)
SHOT Bite No. 20: IBCT-SRNM
https://www.shotuk.org/resources/current-resources/shot-bites/

Safety Notice relating to SRNM and gap analysis
https://www.shotuk.org/resources/current-resources/safety-notices/



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SaBTO (2019) Importation of plasma and use of apheresis platelets as risk reduction measures for variant CreutzfeldtJakob Disease. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/829906/SaBTO_PC_report.pdf [accessed 27 April 2023]

SHOT. Preventing transfusion delays in bleeding and critically anaemic patients SHOT/2022/001 (2022) https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103190 [accessed 04 April 2022]

Key Messages and Recommendations 4

Author: Shruthi Narayan

With contributions from the SHOT Steering Group

Key SHOT messages

- **Safe staffing:** Clinical and laboratory teams can function optimally only if adequately staffed and well-resourced. Staffing challenges in both clinical and laboratory areas are commonly cited as contributory in transfusion incidents and must be addressed urgently. 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
- **Well-resourced systems:** Healthcare leaders and management must ensure that staff have access to the correct IT equipment which is fit for purpose. Adequate financial resources are a must for safe and effective functioning of teams
- **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 contribute to poor decision-making so that these can be mitigated appropriately
- **Patient safety culture:** Fostering a strong and effective safety culture that is 'just and learning' is vital to ensure a reduction in transfusion incidents and errors, thus directly improving patient safety
- **Addressing transfusion delays:** Avoidable transfusion delays continue to contribute to patient deaths and measures recommended in the SHOT CAS alert (SHOT 2022) must be implemented to address these
- **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. Many of these are caused by poor communication and distraction. These must be investigated using human factors principles-based incident investigations and appropriate mitigating measures implemented
- **Learning from near misses:** Reporting and investigating near misses helps identify and control risks before actual harm occurs, providing valuable opportunities to improve transfusion safety
- **Shared care:** Clear, timely and comprehensive communication between all teams and hospitals involved in patient 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

SHOT
Serious Hazards of Transfusion

Abbreviations used in this chapter

ABOi	ABO-incompatible
AHSN	Academic Health Sciences Networks
AoMRC	Academy of Medical Royal Colleges
API	Application programming interface
CAS	Central alerting system
ESR	Electronic staff record
Hb	Haemoglobin
HSIB	Healthcare Safety Investigation Branch
ICS	Integrated care systems
IT	Information technology
LIMS	Laboratory information management systems
NCA	National comparative audit
NHS	National Health Service
NHSBT	NHS Blood and Transplant
TACO	Transfusion-associated circulatory overload
NICE	National Institute for Health and Care Excellence
UK	United Kingdom
WHO	World Health Organisation

The UK healthcare system is under unprecedented strain exacerbated by the COVID-19 pandemic resulting in extraordinary demands on the NHS and its workforce, with detrimental impacts on staff health and well-being. This is adversely impacting their capacity as well as motivation to continue working in healthcare.

A report into NHS workforce retention challenges and prospects, summarising headline findings from a series of large-scale UK-wide surveys of NHS employees has recently been published. This report highlights a rising trend in numbers of NHS staff applying for non-NHS jobs since the emergence of the COVID-19 pandemic (Weyman et al. 2023). It draws on three waves of survey data from over 17,000 NHS staff gathered between late 2020 and summer 2022. Key findings which are all sobering, highlight worsening morale, increased stress and workload amidst staffing shortages and disproportionate workload. More than a third of respondents reported 'tiredness' and 'low energy'; approximately one in four reported 'physical exhaustion', 'mental exhaustion' and 'feeling overwhelmed' most days or every day; of these about half attributed this completely to their job. 'Abnormally high staff shortages', 'Not enough time to do my job properly' and 'Impact of removing COVID-19 restrictions' were the highest ranked sources of worry amongst staff in April 2022. The proportion of staff applying for non-NHS jobs shows a rising trend, from one in ten (winter 2020-2021) to approximately one in seven (April 2022). The most frequently reported reasons why staff leave NHS employment are, in order of importance, stress, shortage of staff/resources and pay. Pay has become more salient since 2020. It was ranked 8th of the 15 variables explored at wave one of the surveys, rising to joint 4th at wave two and 3rd at wave three. Ratings of confidence in improvement to working conditions '…over the next 12 months' (beyond spring 2022) ranged from very low to modest across all the criteria explored.

The HSIB have published a third interim report in February 2023 on their investigation which focuses on staff well-being across the urgent and emergency care systems and impact on patient safety. The investigation concluded that whilst staff are trying their best to give good care, harm is happening and that affects the outcomes for patients and the ability for them to stay well. The report shows the strong link between patient safety and well-being and has emphasised that the two national plans overseeing both areas (in England) are not interlinked (The NHS People Plan 2020 and the NHS Patient Safety Strategy) as yet. NHS England have recognised this and to support this, HSIB have made a safety recommendation that they include staff health and well-being as a critical component of patient safety in the NHS Patient Safety Strategy.

The NHS staff survey from 2022 showed that the overall willingness of staff to recommend the NHS as a place to work has seen one of the biggest shifts, falling from 59.4% to 57.4%. There was lower staff confidence in the quality of care they felt able to deliver, compared with results from 2021 and staff willingness to recommend the NHS as a place to be cared for has fallen from 67.8% to 62.9%. Nearly 44.8% of staff reported feeling unwell as a result of work-related stress in the preceding 12/12 with 56.6% of staff reporting to have come to work despite not feeling well enough to perform their duties.

Shocking figures published by the Office for National Statistics show that overworked NHS staff are being driven to suicide, with one life lost every 3 days. In 2021, 144 healthcare workers (62 nurses, two midwives, six paramedics and 10 doctors) took their own lives, up by nearly 40% from 105 in 2011. Supporting mental health and well-being of staff must be a priority and should include psychological support and treatment as well as a national support service with more complex mental health needs brought about by issues such as trauma.

It is essential that we look at ways to support staff, optimise working efficiency, promote safety amidst challenges in the resource poor healthcare with a deepening workforce crisis – none of these challenges are likely to be resolved in the immediate future. If NHS is to meet its current and future operational challenges, it is imperative to look at innovative workforce solutions, improve resilience and mental well-being of our workforce, streamlining skills training and make jobs easier.

The following are the main recommendations prioritising digital innovations to support NHS staff, from the Health Innovation Network (HIN) which is a founding partner of DigitalHealth. London published in February 2023 (HIN 2023). DigitalHealth.London connects NHS staff, digital health companies and academics, to support them to improve the NHS and social care in London through digital technology.

- **Recommendation 1:** To allow time and 'head space' NHS organisations should prioritise and realise the return on investing in this important engagement. They can do this by providing protected time for frontline operational staff and clinical champions to co-design and implement digital workforce solutions. Maximising the support that AHSN can provide to reduce the time required for frontline staff to contribute and make the process efficient as possible
- **Recommendation 2:** Harness and legitimise the staff with an 'innovation mindset' who see opportunities for challenging the status quo and have the passion to drive innovation for patient and staff benefit. These internal innovators should be celebrated as pioneers and encourage wider digital champions across team
- **Recommendation 3:** NHS providers should maximise the opportunities that digital solutions provide to increase staff retention and attract clinicians by providing more flexibility of work patterns, overtime etc. through the use of technology
- **Recommendation 4:** Standardise and streamline the procurement process for commissioning digital solutions, to enable wider adoption at ICS level rather than in the piecemeal way that currently exists. Both NHS organisations and innovators should have the flexibility to enable faster and wider roll-out
- **Recommendation 5:** Companies need to identify and understand the financial pressures of NHS organisations and articulate better how their workforce solution will deliver efficiency savings
- **Recommendation 6:** NHS stakeholders and national policy makers at NHS England/NHS Digital should ensure that the systems such as ESR have open API. For example, the procurement of the replacement for the ESR should detail open API as a requirement in the specification
- **Recommendation 7:** Digital inclusion and time for digital skills training or onboarding needs to be embedded into rolling out solutions. This should take place alongside involving staff working at all levels in the development and testing of the solution to reduce the risks of failure that are normally associated with adoption of innovation within the NHS. To make solutions accessible for all staff provide bite-size or micro training that is embedded into their everyday work practices rather than taking clinicians away from frontline care

The publication from the Academy of Medical Royal Colleges, 'Fixing the NHS' (AoMRC 2022) highlights that a reformed system must centre on the needs of the whole person and of the whole population.

This requires:

- Expanding workforce numbers
- Improving patient access to care across all settings
- Reforming social care
- Embracing new ways of working
- Grasping the digital agenda
- Valuing our staff
- Modernising the NHS estate
- Revitalising primary care
- Greater focus on prevention and tackling health disparities
- Making better use of resources and ensuring there is adequate investment

This Annual SHOT Report highlights continuing error trends with 83.1% reports in 2022 related to preventable errors. Continuing reports of preventable ABO-incompatible transfusions resulting in patient deaths, increasing number of transfusion delays, avoidable transfusions and TACO are sobering to read. What is also evident is that the fundamental issues of staffing challenges, poorly resourced systems, with suboptimal implementation and use of IT solutions have not been addressed. Failing to identify and implement system-focused interventions reflects missed opportunities for enhancing safety and failure to optimally learn from incidents. It is also important to recognise that alongside examples of the failures of care, there are also eminent examples of innovation, staff working above and beyond striving to deliver safe care amidst all the challenges. These have also been highlighted throughout the Annual SHOT Report. It is encouraging to see a wider recognition of the importance of human factors principles but more needs to be done to use these in practice. An agenda for change with recommendations to enhance safety is covered in all the chapters. Without urgent interventions, the situation is only going to get worse. We must all act now and work together to improve systems and avoid normalising the unacceptable.

A driver diagram has been produced as a template for transfusion teams to use and adapt locally to identify tactical changes to help address the challenges and move towards a better and safer system. (see 'Recommended resources').

Key SHOT recommendations for 2022

The following main recommendations have been drafted to address the common themes identified as causal or contributory to adverse events that impact transfusion safety. Previous SHOT recommendations remain pertinent, and organisations must endeavour to progress implementation of the same if gaps are identified.

Appropriate management of anaemia and making safe transfusion decisions

Avoidable transfusions for haematinic deficiencies and reports of inappropriate management of anaemia continue to be reported to SHOT and the causes for these remain similar year-on-year. Information provided for several incidents demonstrates a lack of knowledge of basic haematology, particularly the characteristic features in the blood count in iron, B12 and folate deficiency. Avoidable transfusions can contribute to TACO which is evident in some cases reported to SHOT reinforcing the messages and recommendation for appropriate pre-transfusion assessment. Transfusions are a valuable and scarce resource, and every effort must be made to avoid unnecessary transfusions. This will also help ensure that patients are not put at unnecessary risk of exposure to blood components. Clinicians should be familiar with the 'Choosing Wisely' recommendations for transfusion and ensure that medical and nursing staff receive appropriate education and training about anaemia and its management. Haematinic deficiencies can be detected before severe anaemia develops and primary care teams can help address this before patients are admitted with severe symptomatic anaemia. The Evidence-Based Interventions Proposed List 2, drafted by the independent Expert Advisory Committee to the Evidence-Based Intervention programme and endorsed by the AoMRC (AoMRC 2020) supports the use of red cell transfusions only where indicated and then in single units, unless there are exceptional circumstances. While transfusions are safe there are inherent risks and unnecessary transfusions must be avoided wherever possible.

Appropriate laboratory tests should be performed in patients with suspected iron deficiency to help direct onward investigation and management based on national gastrointestinal and gynaecology guidelines and local pathways within individual healthcare settings (BSH Fletcher et al. 2022). The 2019 national comparative re-audit of the medical use of red cells showed significant numbers of asymptomatic or only mildly symptomatic patients being transfused when their Hb levels are above the recommended thresholds. In this audit, one in five patients were transfused because of iron-deficiency anaemia and nearly 5% of transfusions were documented as given because of B12 or folate deficiency or both (NCA 2019). The 2021 national comparative audit of NICE Quality Standard QS138 helped identify areas where there were gaps in implementing patient blood management measures and recommended that hospitals explore barriers to the implementation of the NICE Quality Statements for Blood Transfusion (NCA 2021) (NICE 2016). The NICE QS138 which is to be used in conjunction with the NICE guideline for Blood transfusion NG24, highlights four priority areas for improvement including iron supplementation, tranexamic acid for adults, reassessment after red blood cell transfusion and patient information. A quality improvement

benchmarking audit tool for hospitals to regularly self-assess their compliance to elements of the NICE QS138 Quality Standard has recently been introduced (NHSBT 2023). Decision-supporting tools such as the ABCDE approach to transfusions from SHOT, the Blood Assist App can support appropriate and safe transfusion decisions (see 'Recommended resources').

Main recommendation 1: Appropriate management of anaemia and making safe transfusion decisions

Patients should not be transfused with blood components where alternative and effective treatments are available. Patient blood management should be an established service within organisations. Cases of anaemia should be investigated and where haematinic deficiencies are identified, these should be corrected appropriately with minimal red cell transfusion. Identification and correction of anaemia should be standard in the assessment of patients for surgery where moderate blood loss is expected. The provision of an autologous cell salvage program supports surgery where transfusion is not an option and reduces the reliance on the allogeneic blood component resource.

Actions required:

Hospital management should:

- Ensure adequate support for clinical and laboratory teams with well-resourced services for treatment of anaemia, including haematinic deficiencies
- Ensure regular audits of blood usage, use of cell salvage and other patient blood management measures
- Provide services that support effective identification, assessment and management of pre-operative anaemia, including intravenous iron as appropriate in a timely manner. Patients scheduled for elective surgery should be screened for anaemia far enough in advance of surgery to allow appropriate correction of anaemia
- Ensure provision of a properly resourced cell salvage programme where the need is identified
- Ensure policies, procedures and training are in place to avoid delays in transfusion where this would cause patient harm
- Engage with primary care teams to facilitate early anaemia screening, investigations, referrals when relevant and appropriate management including support with haematinics

Clinical staff should:

- Be supported by training and tools that includes knowledge to identify, investigate and manage patients with anaemia following haematinic deficiencies
- Use decision-support tools, such as Blood Assist, to avoid unnecessary transfusions
- Proactively involve patients in their care (monitoring, follow up, making choices regarding treatment) with shared decision-making and provide leaflets, signpost videos and apps as relevant relating to transfusion support

Transfusion laboratory staff should:

- Have processes in place to question potentially unnecessary transfusions
- Have training and processes to avoid delays in provision of blood components in life threatening anaemia

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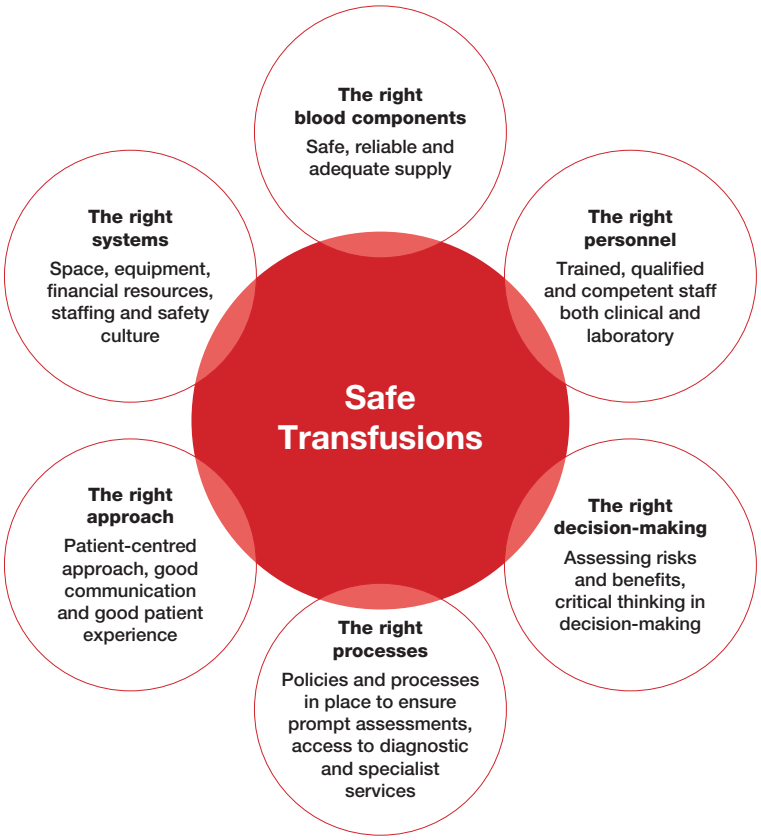
Safe systems to ensure safe transfusions

Having the right infrastructure is vital in promoting improved standards of care and well-being for all patients. This is a key pillar in ensuring safety and improving outcomes. Any health system needs adequate staff, funds, equipment including IT, information, supplies, transport, communications and overall guidance and direction to function. Strengthening and building safer health systems thus means addressing key constraints in each of these areas. Transfusion errors reported to SHOT are commonly errors caused by faulty systems, processes, and conditions that lead people to make mistakes. The key to eradicating transfusion errors and advancing patient safety is to create systems for reliable healthcare delivery. Improvements in safety do not occur unless there is commitment and support from senior executive managers. This has been reinforced repeatedly in the recent Annual SHOT Reports (Narayan et al. 2020, 2021 and 2022) and remain pertinent as they have not been addressed meaningfully.

While accepting that it may be impossible to eliminate error entirely, all error-related incidents are by definition preventable, so the aim of a haemovigilance programme should be to see a move from patient-harm to non-harm, i.e., we would expect an increase in near miss events compared to incidents in potential harm categories. An analysis of the last 5 years shows incidents with no patient-harm are between 51% and 57.4% of the total error events (Figure 3.3 in Chapter 3, Headline Data: Deaths, Major Morbidity and ABO-Incompatible Transfusions) meaning potential harm errors account for nearly half of all error incidents. The key to eradicating transfusion errors and advancing patient safety is to create systems for healthcare delivery that doctors, nurses, and others providing patient care can rely on. Actions needed are multifaceted and will need to ensure all the following at a macro-system level all the following aspects (Figure 4.1) for safe transfusions in healthcare

Figure 4.1: Framework for safe transfusions



Main recommendation 2: Safe systems to ensure safe transfusions

Transfusion of blood components is a multi-stage process, errors may occur at any step, from collection of the blood sample to administration of the blood component. Patient identification is paramount in transfusion safety, where patient identification bands are used in the transfusion process, they must be attached to the patient. Staff involved in the transfusion process must work within a system that supports safe practice, a system that makes it easier to do the right thing and harder to do the wrong thing. Systems should be designed with human factors and ergonomics at the forefront. Safety checks must be completed accurately to pick up any errors in the preceding steps and not be seen as a tick box exercise. Organisations should invest in effective information technology and automation, in the clinical and laboratory setting, that supports safe transfusion practice, each time and every time.

Actions required:

Hospital senior management should:

- Ensure adequate funding and resources are available for implementation and maintenance of effective IT and automation at all stages of the transfusion process
- Ensure adequate staffing levels, training and resources are available to support a systems-approach to safe practice, with emphasis on human factors and ergonomics
- Ensure that transfusion safety checks are embedded at all stages of transfusion practice, and where IT is not yet available, use SHOT or locally designed resources
- Ensure effective contingency plans are in place for IT downtimes, and staff have training in these processes
- Perform regular safety audits to assess work as imagined versus work as done. This will identify workarounds that may impact on patient safety and allow implementation of effective corrective and preventive actions

Clinical and transfusion laboratory staff should:

- Ensure they complete the NHS Patient Safety Syllabus training programme and local training and competency-assessment programs
- Have access to clear instructions for using IT and automation correctly, including escalation where key equipment does not function as expected or is not suitable for actual practice
- Perform safety checks at critical points in the transfusion pathway such as patient identification checks, collection of components, and administration including TACO risk assessment

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Effective implementation of appropriate interventions following incident investigations

Improvement in patient safety is a continuous cycle, including learning from Safety-I and Safety-II principles and adapting to change. Incident, and near miss, investigation should include a review of human factors that may have contributed to the event. It should look at every aspect of the system,

including training and competency-assessment, documentation, procedures, environment, equipment, staffing levels, workload, and leadership. The actions identified for improvement should be systems-based, not focused on the individual(s) involved in the event. Improvements require investment, this may be the purchase of equipment or information technology solutions, it may be staff training and education and it may be re-design of systems. Investments in reducing patient harm can lead to significant financial savings, and more importantly better patient outcomes (WHO 2019). Healthcare organisations should utilise processes for identification of risk, incorporate basic principles and innovations for safe design and use this knowledge in understanding the reasons for hazardous conditions and the ways to reduce vulnerabilities (Institute of Medicine 2000). Developing robust safety actions to address areas for improvement or system issues identified is one of the key aspects of the recently introduced Patient Safety Incident Response Framework (NHS England 2022).

Main recommendation 3: Effective implementation of appropriate interventions following incident investigations

Identification of actions to eliminate or control system hazards or vulnerabilities identified in the investigation of safety incidents is vital to improve safety. Teams should strive to identify effective actions that prevent the event from recurring and, if that is not possible, reduce the likelihood that it will occur or that the severity or consequences are reduced if it should recur. System-focused actions that provide effective and sustained system improvement must be identified and implemented. The success of any patient safety effort lies in its integration into the fabric of the organisation at all levels. This cannot happen without the active participation of leaders and managers at all levels.

Actions required:

Hospital senior management should:

- Have an oversight of the incident investigation process including management of near misses within their teams. This should be accomplished by supporting the process, approving and periodically reviewing the status of actions, understanding what a thorough incident investigation report should include, and acting when reviews do not meet minimum requirements
- Ensure they review the incident investigation process at least annually for effectiveness
- Ensure that staff are appropriately trained to carry out incident investigations and have access to the tools and resources for effective investigations. Staff should also have protected time during the normal work shift to lead or participate in these incident investigations
- Promote a just, learning safety culture with a collective, inclusive, and compassionate leadership
- Encourage patients to raise concerns, participate in incident investigations as appropriate and provide feedback on actions taken

Risk management departments should:

- Provide support and training for all staff involved in transfusion-related incident investigation
- Ensure procedures and templates are available that include consideration of human factors and a system-based approach to investigation, including plans for corrective and preventive safety actions and a process for reviewing the effectiveness of the actions
- Provide a platform to share learning from transfusion errors and near miss events across the whole organisation
- Provide opportunities for involved staff as well as involved patients/families to offer feedback of the findings of investigation process, and be given the opportunity to comment on whether the proposed actions make sense to them, where appropriate

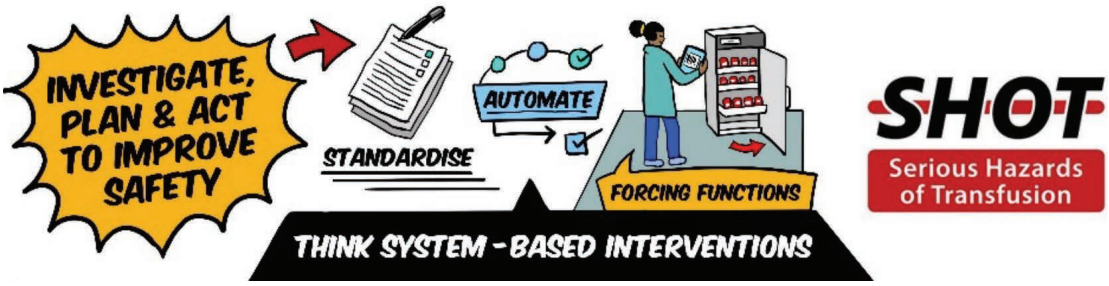
Clinical and pathology laboratory management should:

- Ensure capacity plans include provision of adequate staffing to support robust investigation of all transfusion-related incidents and near miss events
- Ensure that staff involved in incident investigation have received adequate training, including human factors and a system-based approach to investigation
- Provide support with implementation of effective corrective and preventive actions, ensuring that these are forcing functions* wherever possible
- Record unresolved residual safety risks identified that cannot be solved with short term measures in the organisational risk register and escalate appropriately

**A forcing function is an aspect of a design that prevents the user from taking an action without consciously considering information relevant to that action (e.g., a rule in the LIMS that does not allow issue of ABOi red cell units)*

Clinical and laboratory transfusion staff should:

- Be able to identify system-focused sustainable solutions, both short term and long term, if involved in incident investigations
- Identify solutions with effective and appropriate use of IT and automation with support from suppliers
- Review effectiveness of interventions/safety actions and share lessons learnt to optimise learning from safety incidents



Learning from excellence and day-to-day events

SHOT has been promoting a holistic approach to safety incorporating principles of Safety-I and Safety-II. This was one of the main recommendations in the 2019 Annual SHOT Report (Narayan et al. 2020). Safety-I practices are reactive; they are designed to retrospectively identify what went wrong after harm has occurred and are limited by ability to recall, inadequate reporting and hindsight bias affecting how the event is judged. Safety-II is a proactive approach that seeks to strengthen the ability of staff to prevent problems before they occur and ensure high quality care even when there are pressures and competing demands. Both Safety-I and Safety-II approaches are needed to build safer systems (Hollnagel 2015 and Braithwaite 2018). Safety-II does not replace Safety-I, instead both approaches complement each other. Resilience of any organisation is thought to involve four capacities: the ability to respond safely to problems as they occur, the ability to learn from experience and share that experience, the ability to monitor how things are going so that the need to respond can be identified as soon as possible, and the ability to anticipate future needs. Proactively and simultaneously seeking signals for improvement from unsafe, suboptimal and excellent care helps understand and build safer systems. Several recent publications have explored ways to operationalise Safety-II in practice (Bartman et al. 2021, Shorrock 2020 and Verhagen et al. 2022). Chapter 5. Acknowledging Continuing Excellence in Transfusion (ACE) explores a few of these approaches and paves the way for transfusion clinical and laboratory teams to embed these in day-to-day practices.

Main recommendation 4: Learning from excellence and day-to-day events

All healthcare organisations should incorporate the principles of both Safety-I and Safety-II approaches to improve patient care and safety. Healthcare leaders should proactively seek signals for improvement from unsafe, suboptimal as well as excellent care. Developing a proactive safety framework will help to better understand how staff adapt their everyday work and support a proactive approach to safety.

Actions required:

Hospital senior management should:

- Embed a proactive approach to safety within their teams across the organisation and learn not just from when things go wrong but from day-to-day events and excellence
- Regularly assess their organisation's safety culture using a safety assessment survey and take appropriate actions to address any concerns identified

Risk management departments should:

- Ensure local incident reporting systems also have the capability for excellence reporting
- Ensure staff are aware and are encouraged to report good practice

Clinical and transfusion laboratory staff should:

- Ensure they complete the NHS Patient Safety Syllabus training programme and are compliant with relevant current national legislation, guidelines, and recommendations
- Be familiar with human factors principles and application especially with designing user-friendly systems not just incident investigations
- Be able to engage with and promote a proactive safety framework by regularly using safety tools such as:
  - Proactive safety huddles bringing together an interdisciplinary team to plan, anticipate problems and identify actions that can help mitigate risks before an error occurs
  - Proactive safety observations with safety experts performing workflow observations/quality walkarounds, evaluate how work is done and proactively identify and address system weaknesses before an error occurs
  - Simulations with multidisciplinary teams to test systems and enhance process improvement
  - Observational audits such as vein-to-vein audit to help bridge the gap between 'work as done' and 'work as imagined' and learning from near misses to understand effectiveness of controls in place
  - Appreciative inquiry so that teams can learn from 'what went well' and utilising successful cases to investigate, identify strengths and behaviours that lead to positive patient outcomes to promote learning
- Escalate any safety concerns identified to leaders and help identify/implement appropriate mitigating actions, ensure feedback loops in place

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We need to rethink strategy, consider the people involved and support them, promote a just and learning safety culture; ensure resources are in place, including adequate financial support with a well-trained, well-informed, resilient and competent workforce. Using technology to automate processes and reduce human intervention is vital. Clinical and laboratory practices need to be evidence-based with robust governance processes and a safety culture that promotes learning from experience including instances of unsafe, suboptimal and excellent care. The long term aims of an incident reporting system, such as SHOT, are to help reduce incidents that result in harm while moving towards increased reporting of near miss events for future learning. Facilitating system-wide changes is a step in the right direction.

Recommended resources

A-E decision tree to facilitate decision making in transfusion
Driver diagram to help identify tactical change ideas to improve transfusion safety
Safe Transfusion Checklist
https://www.shotuk.org/resources/current-resources/

Patient Blood Management - Hospitals and Science – NHSBT
https://hospital.blood.co.uk/patient-services/patient-blood-management/

E-learning modules on e-learning for health includes modules such as 'Anaemia - the only introduction you need', 'Anaemia in primary care patients' and 'Anaemia in hospital patients'
https://hospital.blood.co.uk/training/clinical-courses/

Blood component use in major haemorrhage
https://www.e-lfh.org.uk/programmes/blood-component-use-in-major-haemorrhage/

The NHSBT O D-negative toolkit
https://hospital.blood.co.uk/patient-services/patient-blood-management/o-d-negative-red-cell-toolkit/

Royal College of Pathologists - Choosing Wisely
https://www.rcpath.org/profession/patient-safety-and-quality-improvement/patient-safety-resources/choosing-wisely/recommendations-for-transfusion-medicine.html

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/)

National Comparative Audit – Vein to Vein audit – contact details
https://hospital.blood.co.uk/audits/national-comparative-audit/

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Acknowledging Continuing Excellence in Transfusion (ACE) n=8

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Definition:

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

Abbreviations used in this chapter

ACE	Acknowledging continuing excellence in transfusion	**HCA**	Healthcare assistant
BMS	Biomedical scientist	**HTL**	Hospital transfusion laboratory
ED	Emergency department	**MHP**	Major haemorrhage protocol
FMH	Fetomaternal haemorrhage	**PACE**	Probe, alert, challenge, and escalate
		RTC	Regional transfusion committee

Key SHOT messages

- Learning from ACE is equally as valuable as learning from errors
- There are many ways to identify and recognise excellence which can be embedded within existing processes and day-to-day practice
- Excellence occurs within everyday practice and in response to unforeseen events

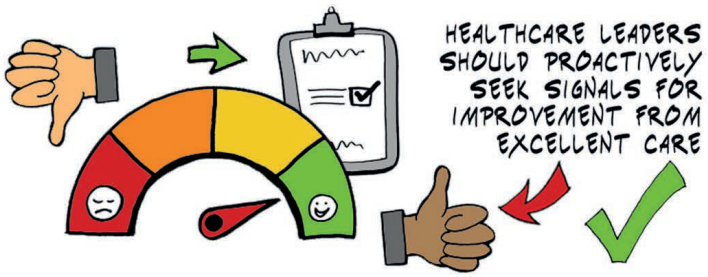
Recommendations

- Formal systems to recognise excellence should be implemented and engaged with wherever possible

Action: All hospital staff

- The light of excellence dims when it is not shared. Where excellent practice is identified this should be shared locally and within regional/national networks so that widest possible group of staff and patients can benefit

Action: All management levels, department and national



SHOT
Serious Hazards of Transfusion

Introduction

This is the 3rd year of including the ACE chapter within the Annual SHOT Report, and the 2nd year of data collection. In 2022, 8 reports were accepted under a wide range of ACE sub-categories and it has been encouraging to receive reports of the innovative work taking place within the transfusion community. Taking inspiration from these submitted reports, this year's ACE chapter takes a practical focus and explores how the transfusion community can continue to acknowledge and celebrate excellence.

The theories of Safety-I and Safety-II (Hollnagel et al. 2015), civility in the workplace (Johnson and Indvik 2001 and Porath and Pearson 2013), appreciative inquiry (Cooperrider and Whitney 2000 and Ludema et al. 2021) and psychological safety (Edmonson 2002 and Lagace 2018) remain extremely pertinent to the purpose of ACE. These theories have been well detailed in the 2020 and 2021 Annual SHOT Reports (Narayan et al. 2021 and Narayan et al. 2022). Resources related to these are available in the recommended resources and references for this chapter.

ACE cases 2022

Table 5.1 shows a summary of cases accepted under the ACE category in 2022, and the key themes identified. Two cases are discussed in detail in this chapter, and full case descriptions for the remaining cases can be found in the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).

Table 5.1: Acknowledging continuing excellence (ACE) case summaries 2022

ACE category	Case number	Summary	ACE themes
Transfusion practice - laboratory	**1**	Introduction of 'improvement and development lead' role. Expedited many of the service improvements and transformational needs of the service	Innovation Positive change
Transfusion practice - laboratory	**2***	BMS recognised potential FMH in mixed field result of maternal sample. Initiated prompt detection and treatment of large volume foetal bleed	Collaboration Communication Patient focus
Teamwork and collaboration	**3**	Major haemorrhage at a district general hospital. Excellent multidisciplinary communication, rapid issue of fibrinogen concentrate, and cold chain maintained despite blood refrigerator difficulties	Collaboration Communication Patient focus
Teamwork and collaboration	**4**	Large scale cold storage failure. Excellent communication between all teams to rectify issue within time constraints	Collaboration Communication
Transfusion practice - clinical	**5**	Excellent teamwork and communication between clinical area and laboratory during MHP activation. All cold chain maintained and MHP stood down	Collaboration Communication Patient focus
Transfusion practice - clinical	**6**	A healthcare assistant questioned a nurse not following the 2-sample policy correctly and corrected the situation. This case has been included in the organisation's training	Patient focus Education
Patient or public engagement	**7****	An innovative project to rectify incidents of transfusion >5 hours was undertaken. This resulted in successful development and trial of 'transfusion take down tag' which has been shared regionally	Innovation Collaboration Communication Patient focus Positive change
Education and research	**8**	An innovative e-learning module was developed which has been used as the basis for other organisation's training	Innovation Collaboration Education

**This case is described in Case 14.3 in Chapter 14, Laboratory Errors*

***This case is described in Case 10.2 in Chapter 10, Handling and Storage Errors (HSE)*

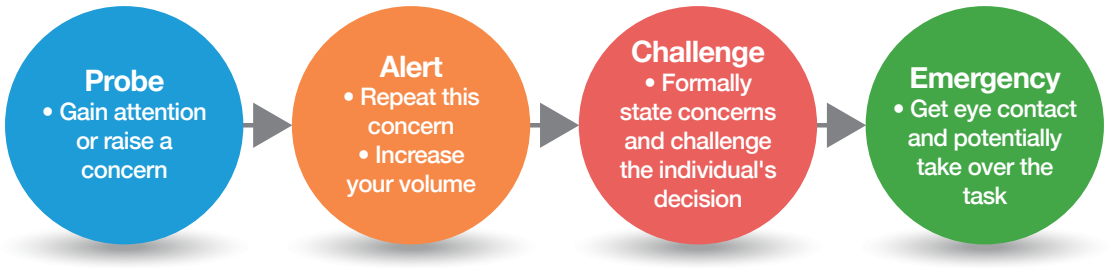
Case 5.1: Speaking up for patient safety despite hierarchical barriers

A HCA noticed a registered agency nurse taking two samples for a group and screen at the same time. The HCA challenged the process as this was against the organisations policy, however the nurse stated that they were going to put a different time on one sample. The HCA reiterated safe practice and local policy (that samples must be taken at different times by different people), removed and disposed of duplicate sample, and raised a near miss incident on the local reporting system. A repeat sample was taken and sent to the laboratory. The patient in question had no previous blood group on the system. The transfusion practitioner provided positive feedback to the HCA and escalated the incident to the organisation's central safety team. They have also incorporated this scenario into mandatory transfusion training.

This case demonstrates excellent patient care from an unregistered member of staff who felt empowered to challenge unsafe practice by a registered nurse. They were not swayed by hierarchical influence when an incorrect justification for the unsafe practice was given.

The probe, alert, challenge and escalate (PACE) model to improve patient safety, or 'graded assertiveness' describes the ability to speak up as a key safety behaviour, and integration of this model in healthcare culture can allow 'any health or care professional of any type or seniority to use graded assertiveness to challenge any action or behaviour they may feel is inappropriate or unsafe' (Royal College of Obstetricians and Gynaecologists n.d.).

Figure 5.1: PACE model



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Case 5.2: Excellent teamwork and communication during a MHP activation

The MHP was activated for a patient in the ED of a medium sized hospital. The clinical staff on duty followed all procedures correctly, and the communication between the clinical area and laboratory was excellent. The BMS on duty was informed when the patient was expected, a single person for communication was established and all components taken out of the refrigerator or requested from the HTL were communicated clearly in a timely manner. The MHP was stood down at the end of incident.

Good communication between the clinical area and the HTL allowed for a very smooth running of the MHP with one person allocated to form that line of communication. Learning from this event was shared via email with the matron in the ED for them to disseminate to members of the team.

Learning from everyday events may be incorporated into incident trend and analysis to recognise areas where processes are working well and how similar workflows can be adapted in other areas of concern.

The benefits of learning from everyday work have been described as (Sharrock 2020):

- **Learning from everyday work helps to improve all aspects of performance and well-being –** this helps to improve all aspects of working and learning from one area can be applied to many without additional resource

- **Learning from everyday work does not require unwanted events –** when ordinary work is focused upon, it does not require adverse events and patient harm to occur to drive improvement
- **Learning from everyday work helps to see and build on what's strong -** looking at everyday work can recognise areas of strength and use these to build on elsewhere
- **Learning from everyday work helps to see slow changes –** the process of 'practical drift' explains how work can slowly move away from the expected, this can occur in both positive and negative ways and if day-to-day practice is examined this drift can be identified
- **Learning from everyday work can involve everyone –** by learning from everyday work, those involved in routine practices must be involved and can therefore have more ownership and engagement with any change necessary

Safety-II and ACE in practice

Safety-II in practice

Safety-II is learning from situations where safety is present. There is a challenge to implementing this in practice. The benefits have been discussed earlier, but how can this be achieved or operationalised? Suggested approaches could be (Verhagen et al. 2022):

- Using a Safety-II mind-set when looking at a problem area identified by Safety-I. If the whole process is examined there will be certain aspects which are functioning well
- Looking at Safety-I events and asking 'what was so ordinary' not just 'what went wrong' during incident investigation
- Areas where staff have raised conflicting priorities, work can be examined to determine how the people are maintaining a balance and still delivering safe care despite these conflicts
- Reframing certain tasks can alter the outlook of those undertaking them and encourage active engagement (e.g., using a checklist isn't just to prevent errors but to recognise what has been achieved and how to further improve care for the patient)
- Discussing and reviewing unusual events and not just adverse events allows learning from success in situations with additional risks and challenges

ACE in practice

ACE can take many forms and does not necessarily mean additional activities or time/resource. Occurrences that are excellent within healthcare often occur during everyday activities and may only improve care for a single individual or within a single area. However, the power of identifying these events and sharing learning can have a widespread impact. On the opposite end of the spectrum, ACE can influence regional and national practice and can cause a huge wave of change when they are shared on a larger scale. Figure 5.2 shows the range of interventions.

Figure 5.2: Range of ways to acknowledge continuing excellence (ACE) and potential impact

ACE=acknowledging continuing excellence; RTC=Regional transfusion committee

The following are examples of how ACE can take place and have been inspired by the cases submitted to SHOT in 2022.

- **Individual feedback**: In 3 cases excellent communication was identified within the ACE event itself. Learning from, and gratitude, about these events was fed-back to those involved as well as line management. Feedback can be as simple as an email following an event, a team debrief, communication in person or submitting local good practice reports. One case acknowledged excellent communication within major haemorrhage despite unexpected circumstances at a site that rarely encountered major bleeds. Learning from this case was shared by email, and at anaesthetic team meetings, hospital transfusion team and hospital transfusion committee meetings
- **Departmental action and influence**: In 2 cases feedback resulted in departmental change. Feedback can be discussed at departmental meetings and initiate changes to policies and procedures, trigger reviews of contingency plans, and evaluate whether the area would benefit from additional resources (e.g., implementing a quality improvement lead)
- **Hospital-wide action and influence:** In 2 cases ACE contributed to hospital-wide change which mainly centred around transfusion training. Learning from ACE can be used to influence the content of transfusion training, make updates to transfusion policy and involve teams outside of transfusion. This can lead to positive impact in other areas of patient care. In 1 case an event where an individual challenged dangerous practice has been included as a case study in local transfusion training.

Interaction and collaboration between departments can impact upon culture. This cooperation has been seen within several ACE cases and one study has shown the use of transfusion practitioners during large scale emergencies to improve sample labelling (Chowdry et al. 2021)

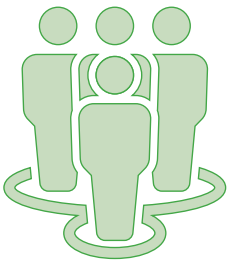
- **Regional/network action and influence:** In 2 cases ACE contributed to positive patient outcomes throughout a region or network. Presenting particular cases or projects of merit outside of individual hospitals stops innovative practice being limited and allows others to benefit. In 1 case (Case 7 in Table 5.1), an increase in error reports led to an intervention and improvement project within the organisation. The hugely positive outcome from this project was shared within the RTC and the organisations are now collaborating to implement the intervention regionally
- **National/international action and influence:** In 1 case a newly developed e-learning module has been used as a basis for other organisations. This illustrates the collective power of sharing good ideas and resources, which improve the care of patients. By submitting ACE reports to SHOT, learning can be captured and considered nationally and internationally

ACE tools

The following are suggested tools hospitals may wish to consider, to assist in the practice of ACE. Some of these are easily implemented and some may be longer term aspirational goals.

'Quick wins'

- ✓ Consistent positive feedback to staff within day-to-day communication style and debriefs
- ✓ Raising positive 'compliments' or reports of excellent practice
- ✓ Reporting to SHOT ACE



Medium term departmental actions

- ✓ Sharing of positive events as well as incidents at departmental meetings
- ✓ Using change request tools to record excellent innovations or solutions to problems, allowing these to be incorporated into future document versions
- ✓ Allocation of time for ACE or improvement projects within job descriptions and capacity planning
- ✓ Audit and audit tools such as the NCA vein-to-vein (see 'Recommended resources')
- ✓ Extracting the learning from ACE reports to enhance safety

Longer term goals

- ✓ Presentations to RTC or other regional network meetings
- ✓ Submitting abstracts to national meetings
- ✓ Submitting research papers
- ✓ Sharing resources

Conclusion

There is room for more than one viewpoint and approach to improving patient safety and by embracing all angles patients can only benefit. ACE data collection within SHOT allows organisations to share learning on a national and international basis. Recognising that persistent challenges exist in healthcare, it is the people within the systems who can be innovative, resilient and achieve excellence in the face of increasing pressures. People should be celebrated regularly for the difference they make within their everyday work as the excellence that occurs during routine work is often unacknowledged. This should be commended as well as the standout events. By sharing these experiences of ACE, it is hoped that these will inspire further improvements for patient and staff benefit.

Focus on ACE in emergencies

Just under half of all ACE reports received in 2022 involved excellent work during emergencies, 2/8 in MHP activation and 1/8 in a widespread cold storage failure. This illustrates the human resilience to pull together and make real-time beneficial decisions in face of the unexpected.

ACE has considerable value in emergency planning where learning from incidents provides a valuable opportunity to use many of the approaches above. Disaster may be rare or recurrent, depending on where you work in the world. Each event provides an opportunity to learn and improve. Lessons identified should be captured during 'hot debriefs' as soon as practical after the incident. Formal debrief may be held later using additional material. Methodology varies between organisations but may include one-to-one interviews, questionnaires, and responses to 'hot debrief postcards.' Debriefing should be used to thank staff and recognise achievements (Doughty et al. 2022).

Recommended resources

ACE reporting – SHOT Definitions and ACE Examples
https://www.shotuk.org/reporting/ace-reporting/

Civility saves lives (2022)
https://www.civilitysaveslives.com/

Learning from Excellence
https://learningfromexcellence.com/

National Comparative Audit – Vein to Vein audit - contact details
https://hospital.blood.co.uk/audits/national-comparative-audit/

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Donor Haemovigilance

6

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Definitions:

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).

Key messages

- Donor complications can occur despite best care, and some may have serious impact on donors
- While donor selection criteria help in ensuring donor and donation safety, decision-making depends on whether the condition was known, disclosed or evident before blood donation
- Delayed bleeding and bruising are the most commonly noted complications in donors >70 years and these donors have lower rates of vasovagal events compared to younger donors
- Staff dealing with blood donors should have adequate knowledge about potential complications and be able to identify and manage them promptly on session
- Improving donor experience with measures to reduce risk of complications related to blood donation along with prompt recognition and management of complications is vital

Abbreviations used in this chapter

AABB	Association for the Advancement of Blood & Biotherapies
ADL	Activities of daily living
BSQR	Blood Safety and Quality Regulations
DAE	Donor adverse event
EBA	European Blood Alliance
ISBT	International Society of Blood Transfusion
IHN	International Haemovigilance Network
JPAC	Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee
NHSBT	NHS Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
OMC	Outside medical care
RTC	Road traffic collision
SAED	Serious adverse event of donation
SNBTS	Scottish National Blood Transfusion Service
UK	United Kingdom
VVR	Vasovagal reactions
WBS	Welsh Blood Service

Recommendations

- All UK Blood Services should implement the 'Severity Grading Tool for Blood Donor Adverse Events' developed in 2020 by the AABB Donor Haemovigilance Working Group and endorsed by ISBT, IHN and EBA
- All UK Blood Services should benchmark donor haemovigilance data to improve practices and policies

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

Introduction

Blood transfusions save lives and improve health. An adequate and reliable supply of safe blood needs a stable base of regular, voluntary, non-remunerated blood donors. The four UK Blood Services rely wholly on donations given by voluntary blood donors gifting their time and donations altruistically. Blood donation is an uneventful experience for most donors, but as with any clinical intervention, there are risks associated with it. Complications related to blood donations are adverse reactions and events with a temporal relation to a blood donation. Complications are broadly classified into two main categories: those with predominantly local symptoms and those with predominantly generalised symptoms. These are usually minor adverse events but, on occasion, may have lifelong consequences for the donor.

Good donor care not only involves the implementation of measures to minimise the risks to donors and the subsequent management of any adverse reactions, but it also requires informing donors of the material risks of blood donation.

The SAED reported by the four UK Blood Services are covered here. This year, adverse events in blood donors >70 years are discussed with further detail in the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).

Serious adverse events of donation

The UK Blood Services have implemented the 'Standard Surveillance of Complications Relating to Blood Donations' (Goldman et al. 2016). Each Blood Service records and monitors their own adverse events, including any SAED. SAED are those complications or events which result in a significant disability/ incapacity persisting for >1-year post donation, hospitalisation, interventions or rarely death. There are 10 SAED reporting categories, which are listed in Table 6.2. Assigning severity rating and imputability scoring (the strength of relation between donation and complication) is challenging, especially when information is incomplete. History taking and assessment are subjective and vary between clinicians. 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).

Recording imputability status for donor events, whilst not a mandatory requirement under BSQR (2005), is assessed and recorded for every SAED as follows:

3. Definite or certain link to donation
2. Probable or likely link to donation
1. Possible link to donation
0a. Link to donation unlikely
0b. Link to donation excluded

Occasionally, the reported complication is clearly unrelated, or very unlikely to be related, to the donation event itself; for example, a donor developing abdominal pain relating to ovarian torsion requiring admission within 24 hours of donation.

Data

A total of 1,816,191 whole blood and component donations were collected by the 4 UK Blood Services in 2022. This is summarised in the Table 6.1.

Donations from 2022		NHSBT	SNBTS	WBS	NIBTS
Whole blood	Donations from male donors	714,557	69,432	38,760	20,261
	Donations from female donors	738,152	79,963	43,918	19,661
	Donations from new donors	117,716	8,531	10,449	2,697
	Donations from repeat donors	1,334,993	140,864	72,229	37,225
Apheresis	Donations from male donors	68,478	7,204	2,300	3,298
	Donations from female donors	9,177	344	365	321
	Donations from new donors	6,017	0	56	0
	Donations from repeat donors	71,638	7,548	2,609	3,619
Total number of donations in 2022		**1,530,364**	**156,943**	**85,343**	**43,541**

***Total number of donations in the UK from all the four UK Blood Services in 2022* = 1,816,191**

Table 6.1: Cumulative donation data from the four UK Blood Services in 2022

Table 6.2 summarises the number of SAED by category for all four UK Blood Services combined for period January 2022 – December 2022.

SAED category ***All cases reported to the UK Blood Services included here irrespective of imputability or causality in relation to blood donation***	**Total number (from all UK Blood Services)**	**NHSBT**	**SNBTS**	**WBS**
01. Death within 7 days of donation	2	2	0	0
02. Hospital admission within 24 hours of donation	11	9	1	1
03. Injury resulting in a fracture within 24 hours of donation (including fractured teeth)	8	6	1	1
04. Road traffic collision (RTC) within 24 hours of donation	4	3	1	0
05a – Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries)	24	18	6	0
05b – Problems relating to needle insertion requiring hospitalisation/intervention (this mainly includes vascular complications)	0	0	0	0
06. Acute coronary syndrome (ACS) diagnosed within 24 hours of donation	5	3	1	1
07. Anaphylaxis	0	0	0	0
08. Haemolysis	0	0	0	0
09. Air embolism	0	0	0	0
10. Other event	1	0	1	0
Total reported SAED in 2022* ***No SAED were reported from NIBTS in 2022**	**55**	41	11	3

Table 6.2: SAED by category in 2022 (all SAED included here irrespective of imputability)

The 2 deaths reported following blood donation were due to coronary artery disease and were deemed to be unrelated to blood donation. One donor was in his late 60s and the other was >70 years old and both had donated several times before uneventfully and had not declared any underlying cardiac

problems or recent anginal symptoms. Ascherio et al. (2001) showed that there was no evidence of association between a history of blood donation and risk of coronary heart disease in a large cohort. Donors developing symptoms of cardiovascular disease contributed to 5 cases reported in 2022. None of these donors had declared any cardiovascular disease at screening. All these donors have been withdrawn from donating.

Table 6.3 details the total number of whole blood and component donations and the total number of SAED reported for each of the four UK Blood Services for period January 2022 - December 2022. This equates to 0.30 SAED per 10,000 donations or 1 SAED per 33,022 donations (irrespective of imputability). Table 6.3 also gives a summary of total number of SAED excluding imputability scores of 0a, 0b for 2022. This equates to 0.24 per 10,000 donations or 1 SAED per 42,237 donations.

Table 6.3: Summary of total donations for the four UK Blood Services and total numbers of SAED for 2022

	NHSBT	SNBTS	WBS	NIBTS
Whole blood donations	1,452,709	149,395	82,678	39,922
Apheresis donations	77,655	7,548	2,665	3,619
Total donations	**1,530,364**	**156,943**	**85,343**	**43,541**
Total number of SAED in the calendar year 2022	41	11	3	0
Total number of SAED excluding those scored with an imputability of 'unlikely' or 'not related to blood donation'	33	9	1	0
Rate of total SAED per 10,000 donations in UK for 2022 (all submitted reports irrespective of imputability)		0.30		
Rate of SAED per 10,000 donations in UK for 2022 excluding those with imputability of 'unlikely' or 'not related to donation'		**0.24**		

Comparison of trends with previous years

The four UK Blood Services have produced an annual summary report to SHOT of SAED recorded since 2015.

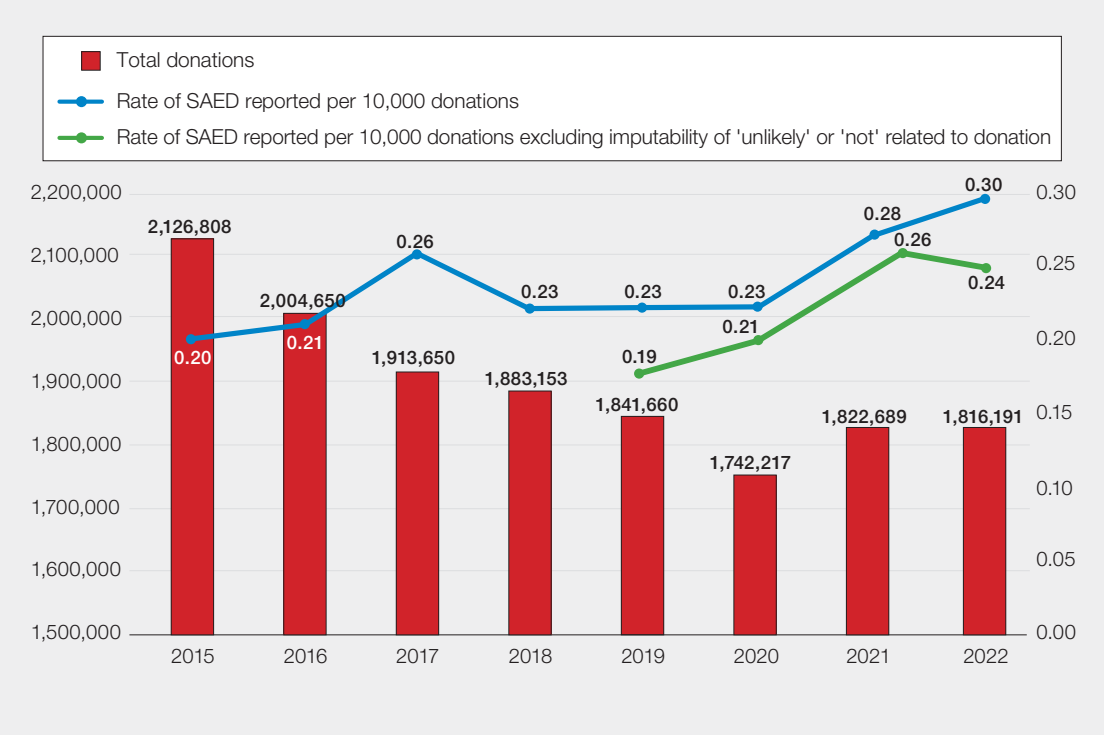

Figure 6.1
Rate of SAED reported per 10,000 donations in the UK from 2015-2022

SAED=serious adverse event of donation

Since 2015 there has been an overall upward trend in the rate of SAED. Improved reporting by better informed donors who are now reporting SAED that occurred in years prior to 2022 (these are included in the 2022 figures), and improved recording by UK Blood Services are key factors. There are additional factors that need to be considered such as staff turnover, training challenges, and effectiveness of measures implemented to reduce these severe events.

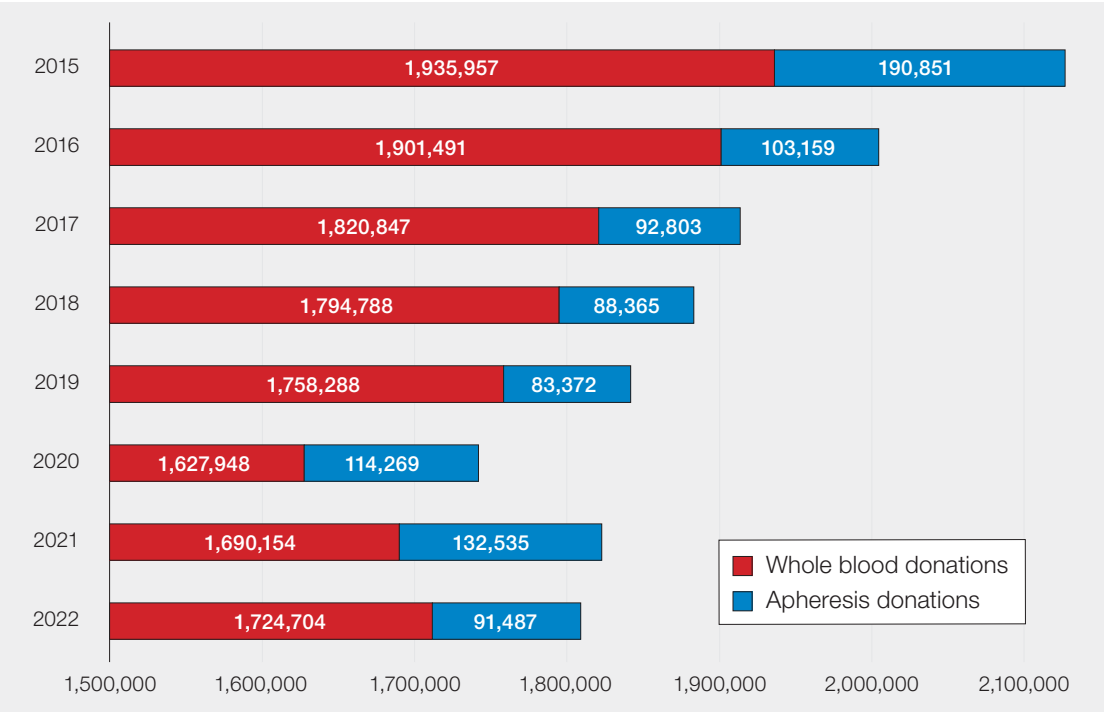

Figure 6.2
Trends in the number of donations collected across the UK 2015-2022

Donor adverse event severity grading

The UK Blood Services have agreed to implement in 2023/24, the validated donor severity grading criteria developed by the AABB Donor Haemovigilance Working Group and endorsed by ISBT, IHN and EBA

(Link to document provided under 'Recommended resources') (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 6.4 below. SAED will be recorded according to the new grading criteria and will render the current categories, as outlined in Table 6.2, obsolete. This will lead to an increase in the number of SAED recorded in the UK once implemented.

Table 6.4: 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)

Donors >70

Since 2009, UK donors aged 70 and over have been able to donate blood, provided they have given a donation in the preceding two years. UK Blood Services are assessing adverse events data for this cohort, as part of a review of the age criteria within the JPAC Whole Blood and Component Donor Selection Guidelines. Among regular whole blood donors, the reported incidence of bruising and rebleeds was higher in donors aged over 70 years compared to those aged 25-70 years; however, vasovagal events and all types of arm pain occurred less often. Younger donors (aged under 25 years) were more likely to experience vasovagal events or arm pain, but less likely to rebleed. Further information regarding donor adverse events among donors of different age groups reported to all the UK Blood Services can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Illustrative cases

Case 6.1: Donor had a syncopal episode on session and later diagnosed to have Brugada syndrome

A young male whole blood donor, in his 30s, experienced a syncopal episode which was thought to be an immediate vasovagal reaction following his first donation. He was suspected to have sustained a minor head injury following this syncope. He recovered sufficiently at session to be able to go home with family but had attended hospital since and following further investigations, was diagnosed with Brugada syndrome. The donor was withdrawn from future donations. The donor had commented he was grateful that due to his donation, his unidentified condition had been diagnosed.

Syncope is a sudden temporary loss of consciousness associated with a loss of postural tone with spontaneous recovery. Syncope has a large differential diagnosis, is difficult to evaluate, and can be disabling. There are subsets of syncopal patients with a high risk of sudden death. Establishing the cause of syncope, deciding whether the patient needs to be admitted, and treating the causes of syncope effectively to reduce recurrences and potentially improve patient outcomes are the key issues to be addressed when managing patients with syncope. While vasovagal reactions are one of the common causes of syncope, other causes such as situational (micturition related, cough related, etc.), orthostatic hypotension, medications, cardiac and neurological causes can also cause syncope (Kapoor 2002; Grossman and Badireddy 2022).

VVR are among the most common complications of whole blood donation (Seheult et al. 2016). VVR is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness. Donors can experience VVR due to several physiological reasons or due to underlying pathology which often comes to light during investigations of VVR. Syncope, or transient loss of consciousness, is the major cause of immediate morbidity of medical significance during blood donation and is the most severe of a spectrum of VVR, which range from mild pre-syncopal symptoms to severe reactions involving syncope. The overall prevalence of VVR in whole blood donors is estimated to be between 1.4 and 7% (moderate reactions) and between 0.1 and 0.5% (severe reactions) (Amrein et al. 2012). VVR have significant implications not only for the welfare of donors but also staff time and training, the management of donor sessions and perhaps more crucially on the retention of donors and security of the blood supply (France et al. 2004).

Brugada syndrome is a rare genetic disorder, affecting about 5 of every 10,000 people worldwide (Johns Hopkins Medicine n.d.). The condition can cause a very fast, abnormal heartbeat, but many people are unaware they have the syndrome, although some may experience syncope or a blackout, as illustrated by this donor (BHF 2022).

While neurally mediated syncope are frequent in patients with this syndrome similar to the general population, patients can have an arrhythmic syncope typically resulting from a self-terminating sustained ventricular tachycardia or paroxysmal ventricular fibrillation, potentially leading to sudden cardiac death. Distinguishing syncope due to malignant arrhythmias from a benign form is often difficult in these patients unless an electrocardiogram is recorded during the episode (Mascia et al. 2021).

Had the donor known of his condition prior to donation and reported to staff, he would have been deferred (JPAC 2019). However, as illustrated by this case, the donor was unaware of his underlying condition, and therefore could only be managed once he presented with the syncope at session, and subsequently with his hospital admission.

Case 6.2: Delayed vasovagal reaction leading to a road traffic accident

A female donor in her late 60s, gave a unit of whole blood at a community session. Donation was unremarkable. She left immediately after receiving a post-donation drink on the bed and drove away from the session. At some point she lost consciousness. A passer-by observed that her car drifted to the side and then scraped along a wall bordering the street, before coming to a gradual stop. The donor came round shortly afterwards and was unharmed. No one else was involved. After being assessed by paramedics the donor was allowed home.

The donor had successfully given many times with only one minor vasovagal episode at session several years earlier. She was not on any medication and had no recent medical treatment apart

from a COVID-19 booster four weeks earlier. On reflection, she noted that although she had not felt unwell after donation, she would have benefitted from taking longer to recover. In total she had been at the session for less than 30 minutes. In view of the severe delayed vasovagal reaction, she was deferred from future donation.

Risk factors for delayed faints include being a new donor, female, young age and smaller stature (Kamel et al. 2010; Narbey et al. 2016). Increased risk has also been documented in older female donors (Narbey et al. 2016). Delayed vasovagal reactions carry a higher risk of injury to the donor and to those around them (Kamel et al. 2010; Narbey et al. 2016). Blood Services should ensure that all donors are aware of the risks and have the opportunity to wait at session after donation if needed.

Case 6.3: Myocardial infarction within 24 hours of donation

A regular female donor in her 70s, had given 62 donations previously. She donated whole blood uneventfully following her health screen when no concerns were reported. The donor then called the Blood Service and reported that she had a myocardial infarction requiring two stents within 24 hours of donating. Prior to donating, the donor had noticed an increasing sense of heartburn type symptoms, the donor assumed this was related to her acid reflux so did not mention this to session staff as she felt well at the time of donation. Upon investigation the donor did have a family history of cardiovascular disease, but she was not known to have any cardiovascular disease. This donor has since been withdrawn from donating.

Around 11.3% of the UK's population have cardiovascular disease, therefore a portion of blood donors may have underlying coronary artery disease (BHF 2021).

Current blood donor selection guidelines in the UK state that donors with ischaemic heart disease or angina, regardless of cause, must not donate (JPAC n.d.). Careful donor selection, thorough donor education and robust pre-donation assessment are critical to identify risk factors.

This case highlights the importance of educating blood donors to ensure they are aware to inform session staff of any change in health or new symptoms before donation, so that appropriate decisions can be made. This donor would not have been accepted if she had disclosed a recent increase in heartburn type symptoms.

Conclusion

Blood Services should encourage donors to make early contact with the Blood Service if they experience any complications so that they can be appropriately investigated and managed. Post-donation information must be provided to all donors. This should include the risk of delayed reactions, when to seek medical advice and guidance on prevention. 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 resources

Severity grading tool for donor adverse events developed by AABB Donor Hemovigilance Working Group and endorsed by ISBT, IHN and EBA
https://www.ihn-org.com/wp-content/uploads/2020/06/Tool_brochure_all_logos.pdf

STRategies to Improve Donor ExperienceS (STRIDES) study (ISRCTN10412338)
http://www.donorhealth-btru.nihr.ac.uk/studies/strides-study/

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BHF. UK CVD Factsheet - British Heart Foundation (2021). https://www.bhf.org.uk/what-we-do/our-research/heart-statistics [accessed: 01 May 2023].

BHF. Brugada syndrome – British Heart Foundation (2022). https://www.bhf.org.uk/informationsupport/conditions/brugada-syndrome [accessed 27 April 2023].

BSQR (2005) The Blood Safety and Quality Regulations ISBN 0110990412; http://www.legislation.gov.uk/uksi/2005/50/contents/made [accessed 01 March 2023].

EU directives: https://ec.europa.eu/health/blood_tissues_organs/blood_en [accessed 30 March 2023] then click Blood Legislation and guidelines to expand list and select the option below:

Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC OJ L 33, 8.2.2003. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002L0098 [accessed 30 March 2023].

Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events (Text with EEA relevance)

OJ L 287M, 18.10.2006, p. 350–358 (MT) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32005L0061&qid=1648656281267

Mascia G, Della Bona R, Ameri P, et al. Brugada syndrome and syncope: a practical approach for diagnosis and treatment, *EP Europace*, 2021;**23(7)**:996-1002, https://doi.org/10.1093/europace/euaa370 [accessed 27 April 2023].

Goldman M, Land K, Robillard P, et al. Development of standard definitions for surveillance of complications related to blood donation. *Vox Sang*. 2016;**110(2)**:185-8. doi: 10.1111/vox.12323. Epub 2015 Sep 11. PMID: 26361365.

Grossman SA, Badireddy M. Syncope.2022. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; https://www.ncbi.nlm.nih.gov/books/NBK442006/ [accessed 27 April 2023].

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Kamel H, Tomasulo P, Bravo M et al. Delayed adverse reactions to blood donation. *Transfusion*. 2010;**50(3)**:556-65.

Land K, Townsend M, Goldman, et al. (2018) International validation of harmonized definitions of complications of blood donations. *Transfusion* 2018:**58(11**)2589-2595.

Narbey D, Fillet, A-M, Jbilou S et al. Case–control study of immediate and delayed vasovagal reactions in blood donors. *Vox Sang*. 2016;**111**:257-265.

Seheult JN, Lund EL, Yazer MH, et al. Factors associated with vasovagal reactions in apheresis plasma and whole blood donors: a statistical-epidemiological study in a European donor cohort. *Blood Research* 2016; **51(4)**:293-296.

Townsend M, Kamel H, Van Buren N, et al. Development and validation of donor adverse reaction severity grading tool: enhancing objective grade assignment to donor adverse events. *Transfusion*. 2020;**60(6)**:1231-1242. https://doi.org/10.1111/trf.15830. [accessed 27 April 2023].

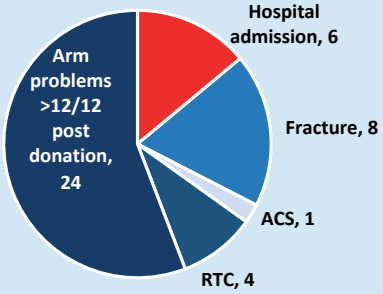
Serious Adverse Events following Blood Donation reported to the UK Blood Services in 2022

In 2022 the UK Blood Services collected approximately 1.8 million donations (whole blood and apheresis)- this includes plasma collected for fractionation at NHSBT. Fifty five serious adverse events of donation (SAED) have been reported last year (this includes all categories of imputability and equates to 1 in 33,022 donations). Of the fifty five cases reported, 12 were not related to blood donation. The remaining forty three cases are described below. Serious adverse events are very rare but do occur and can have a significant impact on donor health and donor retention. UKBTS are planning implementation of the internationally validated donor adverse events severity grading criteria over the next year.

Breakdown of Serious Adverse Events in 2022

SAED Categories

Excluding SAED's with an imputability of 0a and 0b.



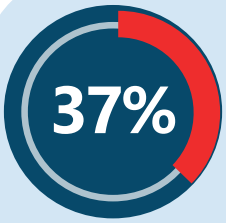
RTC=road traffic collision
ACS= Acute coronary syndrome

SAED were seen in both female (23/43, 53.49 %) and male donors (20/43, 46.51%).

Five SAED were reported in first time donors, 3/5 of these being whole blood donors.

There were no reports of anaphylaxis, haemolysis or suspected air embolism due to component donation reported in 2022.

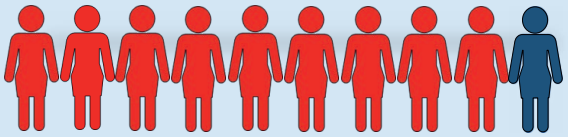
All 8 fractures were related to delayed vasovagal reactions (DVVR). Female donors accounted for 6/8 of these cases. None of these cases were in first time donors.



16/43 SAED were as a direct result of a delayed vasovagal reaction. The break down of these cases include 4 RTC, 4 hospital admissions and 8 fractures.

24/43 SAED reported were related to persistent arm problems more than one year post donation.
Three were in component donors while all others were whole blood donors.

In general 9/10 donors who suffer an SAED are withdrawn from future donations



Key Messages

Blood Services must ensure that blood donors are aware of any 'material risks' involved in donating blood and the measures that need to be taken to reduce risk of these complications.

More than 1/3 of SAED's during 2022 were due to a delayed vasovagal event.

Whole blood and component donation is safe but complications do sometimes occur. The overall incidence of serious adverse events of donation (SAED) remains low. The rate of SAED in UK for 2022 is 0.24 per 10,000 donations taking into account the SAED where blood donation was deemed to have potentially contributed to the donor adverse event.

ERROR REPORTS

7 Human Factors and Ergonomics in SHOT Error Incidents n=2908

Authors: Alison Watt and Emma Milser

Definition

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

Abbreviations used in this chapter

BMS	Biomedical scientist	**BSQR**	Blood Safety and Quality Regulations
CAPA	Corrective and preventative actions	**CIEHF**	Chartered Institute of Ergonomics and Human Factors
HFACS	Human Factors Analysis and Classification System	**HFE**	Human factors and ergonomics
HFIT	Human factors investigation tool	**IT**	Information technology
MHP	Major haemorrhage protocol	**MHRA**	Medicines and Healthcare products Regulatory Agency
NHSE	NHS England	**PACE**	Probe, alert, challenge, and escalate
PSIRF	Patient Safety Incident Response Framework	**RCA**	Root cause analysis
SAE	Serious adverse event	**SEIPS**	Systems Engineering Initiative for Patient Safety
SMART	Specific, maeasurable, achievable, realistic, and timely	**YCFF**	Yorkshire Contributory Factors Framework

Key SHOT messages

- It is encouraging to see an upward trend in the use of HFE frameworks for incident investigations and consideration of systemic factors, and not blaming staff involved
- It is essential that incident investigators recognise that lack of attention to HFE can lead to adverse events. When an error is made, or a process fails, it is often consequential of inadequate system design leading to hazards

SHOT
Serious Hazards of Transfusion

Recommendations

- To improve transfusion safety, effective and sustainable improvement interventions that address all the factors recognised during incident investigations must be implemented. Identifying and implementing appropriate actions are the most important aspect of incident investigations
- Reflective learning by an individual staff member should not be used as a stand-alone action from incidents. This is a weak corrective action in relation to the hierarchy of intervention effectiveness and has potential to be perceived as punitive by the individual. Future incidents of a similar nature may be likely unless more robust preventative actions are also taken
- Where incident investigations demonstrate ongoing risks such as insufficient staffing or poor skill mix, inadequate or outdated resources, lack of IT solutions, these should be highlighted and recorded in the CAPA every time it is relevant, even if they cannot be readily corrected. Such risks should be documented on risk registers and reviewed regularly

Action: Hospital risk departments, hospital transfusion committees, hospital transfusion teams, all staff investigating transfusion incidents

Introduction

Understanding HFE continues to be important when investigating adverse incidents so that system and organisational changes can be made to improve the likelihood of future error incidents being detected before patients are put at harm. Current and previous SHOT recommendations and learning points related to HFE should be heeded throughout investigations to improve patient safety. The CIEHF, the professional body for HFE, has recently published three chapters on HFE in health and social care, based on the institute's professional competencies (CIEHF 2023) and incident investigators may find these to be useful resources.

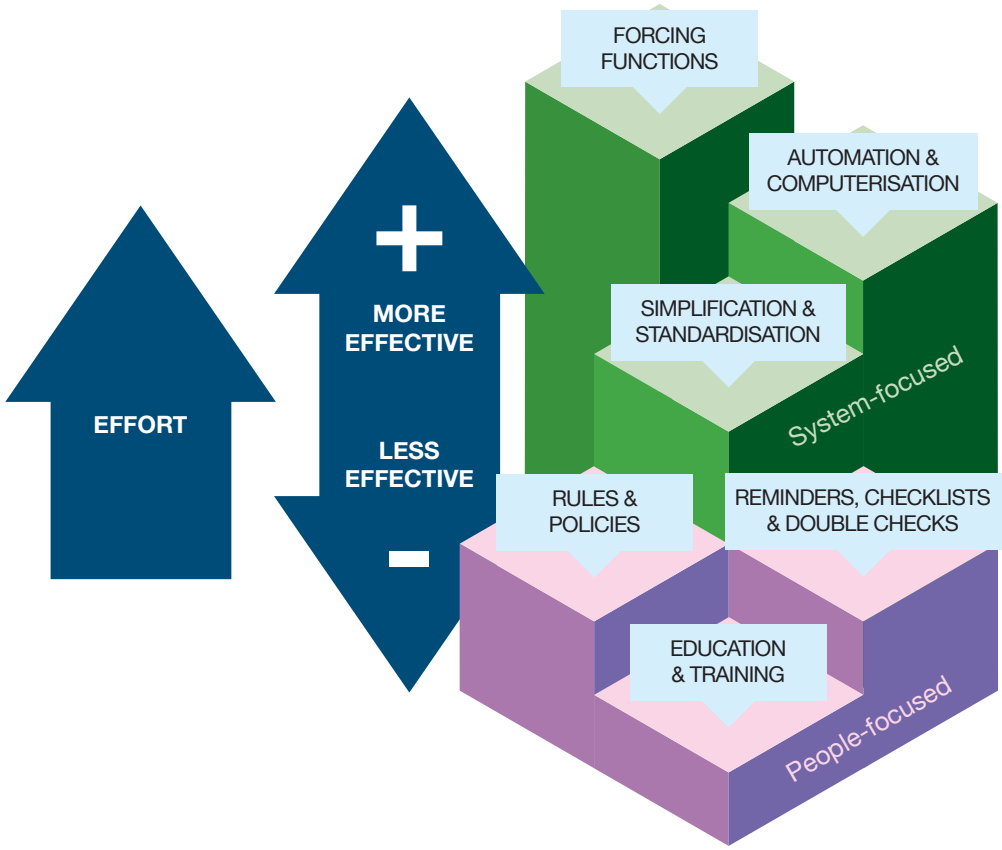


Figure 7.1: Hierarchy of intervention effectiveness

Adapted from the figure in 'From Discovery to Design: The Evolution of Human Factors in Healthcare' by Joseph A. Cafazzo and Olivier St-Cyr in the Healthcare Quarterly 15 (Special Issue) April 2012: 24-29.doi:10.12927/hcq.2012.22845

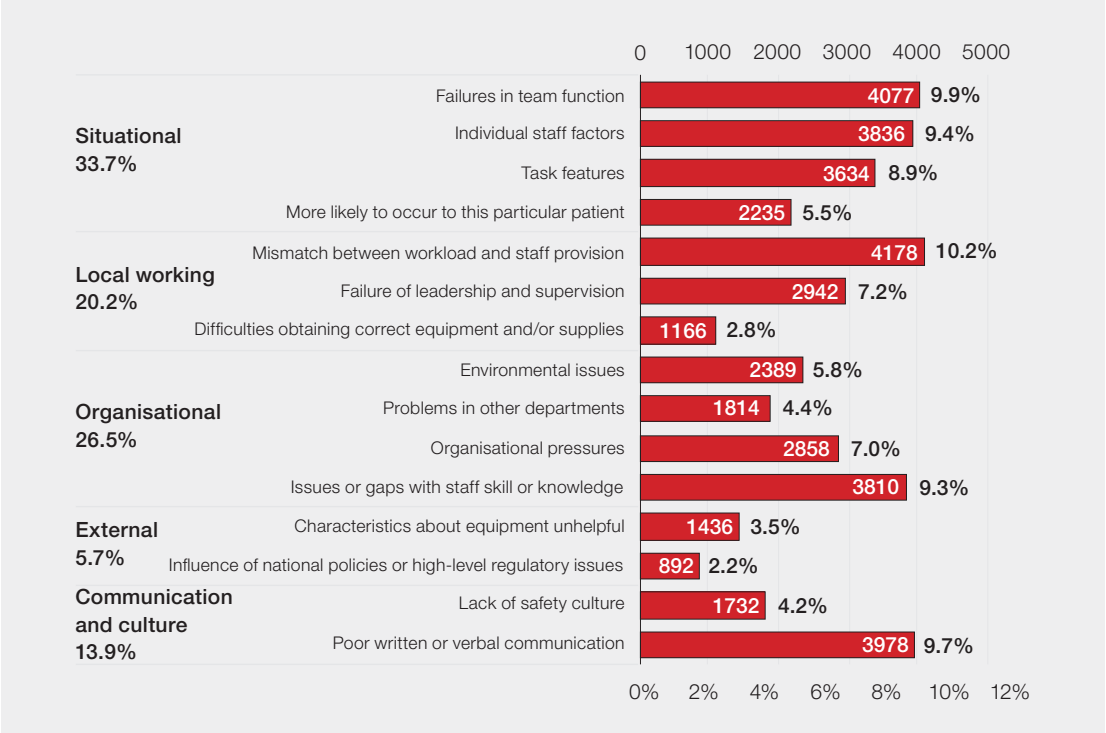
The hierarchy of intervention effectiveness (Figure 7.1) depicts a framework for ranking corrective actions by their effectiveness and deems person-based approaches, such as the use of checklists, policies, and reflection, as weaker than those targeted at the system level (Trbovich and Shojania 2017). Lower ranked interventions may have some value in mitigating errors, but with less impact than more robust systemic solutions, and this can be magnified if human-based interventions are used in isolation. For example, an IT system that forces functions to prevent an incorrect blood component being issued may feature high up on the hierarchy compared to human-based interventions. A multifactorial approach is often required to ensure a holistic approach to incident prevention.

Analysis of the SHOT HFIT

A total of 2908 error cases were included in 2022, which is a considerable increase in the error cases reported in 2021 (n=2569). Throughout SHOT's analysis of human factors, dating back to 2016, there has been evidence of an over-emphasis on individual behaviours, but 2022 has seen a move towards an improved appreciation of system and organisational factor (Figure 7.2).

Figure 7.2 shows an even spread of scoring across the breadth of factors, which is to be expected if all the factors contributing to SAE are examined during incident investigations. This supports the evidence that trying to assign a single root cause is not appropriate (Peerally et al. 2017).

Figure 7.2: Comparative total scores assigned for different system factors



SHOT HFIT has been updated in January 2023 and the need for scoring the factors has been removed. Further details comparing the scores assigned for each factor in 2022 and discussion can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

A recommendation was made in the 2021 Annual SHOT Report that 'a tried and tested human factors-based framework should be applied to incident investigations.' In 2022, 1947/2908 (67.0%) cases specified that HFE principles or a framework/model was used to investigate incidents and a further 428/2908 (14.7%) indicated they were planning to in the future. This is comparable to 2021 (70.0% used and 12.8% planning) but these figures therefore indicate approximately a third of cases might be investigated without a formal process to consider human factors. In 2022 an additional question asked which type of HFE framework/model was used and 1717/1947 (88.2%) of those using a framework/model provided some data. All ten answer options in the SHOT HFIT elicited at least one response,

but by far the biggest majority used the SHOT questions as a framework. The SHOT HFIT was not introduced as a validated incident investigation tool, but it was adapted from the YCFF (Improvement Academy 2023) which is an evidence-based framework, developed following a systematic review of 83 research studies about the causes of patient safety incidents (Lawton et al. 2012).

The top five frameworks/models can be seen in Figure 7.3, which shows that apart from using SHOT questions, in house methods including RCA, are the most commonly used, while specific human factors frameworks/models such as SEIPS (n=30/1717, 1.7%) and HFACS (n=1/1717, 0.1%) were rarely used. SEIPS is a model particularly well-suited to healthcare investigations (Holden et al. 2013) and forms the basis of the recently introduced PSIRF (NHSE 2022). HFACS has been shown to allow important insights into what investigators view as contributory factors (Peerally et al. 2022).

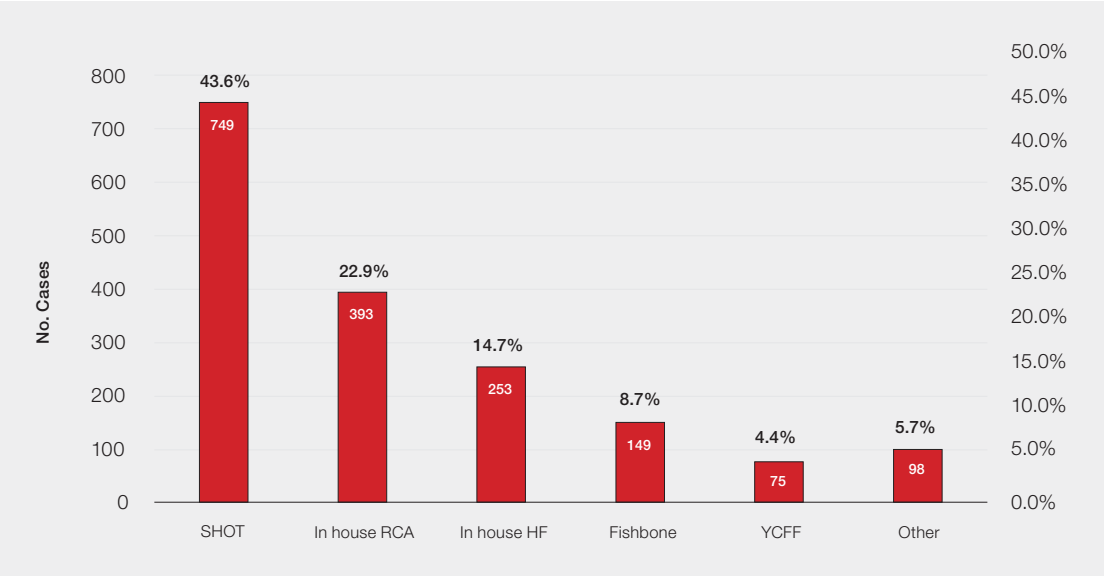


Figure 7.3: Top five human factors frameworks/ models used for incident investigation as submitted by SHOT reporters

RCA=root cause analysis; HF=human factors; YCFF=Yorkshire Contributory Factors Framework
Please note that this relates to individual reports and not organisations

The PSIRF has only recently been introduced, but this framework was selected as the model used in a handful of investigations (n=14/1717, 0.8%). This number is likely to increase as organisations transition from the previous NHSE Serious Incident Framework to PSIRF. A document has recently been released to answer questions regarding the recording, reporting and investigation of transfusion related adverse incidents in England following the introduction of PSIRF (see 'Recommended resources'). It remains important that SHOT-reportable incidents are fully investigated and in the case of MHRA-reportable incidents the BSQR requires an investigation of factors leading to the incident and appropriate CAPA (BSQR 2005). Further details can be found in Chapter 27, MHRA Report on Blood Safety and Quality Regulations (BSQR) in 2022.

Case 7.1: Incorrectly labelled sample used for urgent crossmatch during MHP

A patient with acute bleeding required an urgent red cell transfusion and the sample was accepted out-of-hours by BMS 1 who missed an incorrect date of birth. The sample was used for crossmatch during an MHP activation by BMS 2. The red cell units were issued and transfused to the patient. A second MHP activation was triggered for the patient and the same sample was attempted to be used by BMS 1 who noticed the sample discrepancy during the final check so repeat samples were requested.

The incident investigation identified multiple contributory factors: only one transfusion BMS was on duty out-of-hours, with increased workload pressures over recent months; staff sickness meant the laboratory was short staffed; a senior haematology BMS was covering the late shift; the BMS had covered numerous out-of-hours shifts in close proximity and was carrying out multiple duties in different departments. The incident occurred toward the end of a late shift when staff were tired. As part of the

HFIT on the SHOT database (Dendrite) reporters are asked: 'If you could change one thing to make this incident less likely to happen again, what would it be?' In this case the one thing stated was to increase staffing in the laboratory.

While all the contributory factors were identified including staffing issues, the CAPA actions identified were all at the lower end of the hierarchy of intervention effectiveness and centred around BMS 1 and BMS 2 undertaking reflection. If the staff member(s) made an error due to lack of understanding, that is a training issue and should not be resolved by 'reflection'. If there was no misunderstanding, then individual reflective learning is unlikely to prevent future incidents by the staff involved and may feel punitive. A review of staffing, rostering and recruitment was an additional action, but there were no higher-level escalation processes stated that could help with increasing staff in the laboratory, e.g., inclusion on the risk register, involvement of risk and governance departments or any mitigation for understaffing, such as restricting leave, altering workflow, or modelling how recruiting extra staff could affect managing the workload.

Learning point

- Close the loop by identifying all system and organisational factors that have contributed to an incident and ensuring appropriate CAPA are implemented promptly where possible, or recorded for continuous monitoring where resolutions are not immediately possible

Case 7.2: Incident action plan demonstrates a holistic approach

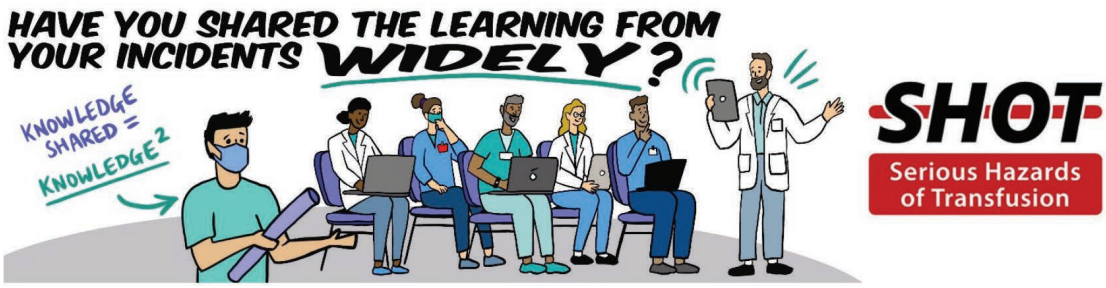
A unit of B D-negative red cells was transfused to the wrong recipient who was group O D-positive. Nurse 2 was asked by Nurse 1 to request collection of a unit of red cells. Nurse 2 requested a unit of red cells for Patient 2, but it was Patient 1 that required the transfusion. The unit arrived in the clinical area and was checked by two nurses outside of the single person room remotely from the bedside. It was then administered to Patient 1 without verbal confirmation. Patient 1's identification band had been cut off earlier in the shift to remove an arterial line. The nurses involved noted that after the COVID-19 pandemic more checks were being performed outside rooms, although at the time of this incident, neither patient was COVID-19 positive. The patient did not have any observable reaction nor evidence of haemolysis and the error was detected by laboratory staff who noticed mixed field reactions in ABO and D grouping tests post transfusion.

There were multiple contributory factors identified in the investigation report for this case. Staff were distracted by other tasks that were deemed to be of greater priority at the time. Nurse 1 was due their break and Nurse 2, who called the laboratory, was more familiar with Patient 2 whom they had been looking after. The incident report recognised that clinical handover with the potential for lost or misinformation, poses a risk. Patient 1 had had previous transfusions earlier in the week and Patient 2 also had blood available in the laboratory. Nurse 1 was familiar with Patient 1 and their familiarity resulted in a confidence that they knew the patient without having to check the ID band, unaware of the errors that had already occurred, because the red cell unit had not been checked at the patient's bedside. It was noted that COVID-19 changes had led to process drift and a culture of checking remotely from the patient had become accepted practice.

The investigation and action plan were comprehensive with a clear escalation process outside the local departments and plans for wider learning to take place. Completion dates were identified and person(s) responsible for each action. The focus was on wider preventative actions rather than the individual staff involved. In comparison to Case 7.1 there was no inclusion of reflection, but there were many SMART actions with clear description of how learning would be shared and fed back to the staff involved.

Learning point

- CAPA is enhanced if actions are SMART and demonstrate escalation beyond the local department



Conclusion

This chapter has highlighted the aim to see a reduction in adverse events that lead to patient harm, with an expected corresponding increase in reports of no-harm incidents, so that learning can continue to be gained from near miss events. See Figure 3.3 in Chapter 3, Headline Data. This outcome should be possible by using a tried and tested human factors-based framework to investigate incidents and thus using HFE principles to introduce CAPA that are at the more effective end of the hierarchy of intervention effectiveness (Figure 7.2).

Case 7.2 highlighted the problem of process drift due to changes introduced during the COVID-19 pandemic. Such drift can gradually become the norm, with systems drifting into failure (Dekker 2016). If the culture of departments is open-minded, this can be monitored actively by colleague observations, with associated discussion, about small changes from normal practice. In Chapter 5, Acknowledging Continuing Excellence in Transfusion (ACE), the concept of PACE is introduced, which can aid staff in communicating deviations from normal practice, especially if faced with a steep hierarchical gradient (see Figure 5.1).

It is constructive to see that there was a fairly even spread of scoring across the breadth of factors, which justifies the decision taken to remove the need for scoring since January 2023. A continued move towards investigating system and organisational factors, with an accompanying reduction in emphasis on staff blame would be welcomed.

Recommended resources

SHOT Videos: Human factors videos
https://www.shotuk.org/resources/current-resources/videos/

SHOT Bite No. 1(a) and 1(b): Incident Investigation
SHOT Bite No. 12: Cognitive Bias
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOTcast: Human Factors
https://www.shotuk.org/resources/current-resources/shot-casts/

SHOT Webinar: Human Factors
https://www.youtube.com/watch?v=ie0UK9R5IbM

Yorkshire Contributory Factors Framework
https://improvementacademy.org/resource/yorkshire-contributory-factors-framework/

Human Factors in Healthcare AI
https://ergonomics.org.uk/resource/human-factors-in-healthcare-ai.html

Patient Safety Incident Response Framework (PSIRF)
https://www.england.nhs.uk/patient-safety/incident-response-framework/

NHS HEE Patient Safety Syllabus
https://www.hee.nhs.uk/our-work/patient-safety

NHS Patient Safety Syllabus training programme
https://www.e-lfh.org.uk/programmes/patient-safety-syllabus-training/

NHSE: A just culture guide
https://www.england.nhs.uk/wp-content/uploads/2021/02/NHS_0932_JC_Poster_A3.pdf

Case Study reworked using updated HFIT and SEIPS framework
https://www.shotuk.org/wp-content/uploads/myimages/HFIT-and-SEIPS-Supplementary-material-2020-.pdf

SHOT Human Factors Tuition Package
https://www.shotuk.org/reporting/human-factors-tuition-package/

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Adverse Events Related to Anti-D Immunoglobulin (Ig) n=345

8

Authors: Jennifer Davies and Simon Carter-Graham

Definition:

Events relating to the requesting and administration of anti-D immunoglobulin (Ig) to women of childbearing potential and events relating to the administration of anti-D Ig following transfusion of D-mismatched platelets.

Abbreviations used in this chapter

BSH	British Society for Haematology	**LIMS**	Laboratory information management system
cffDNA	Cell-free fetal deoxyribonucleic acid	**NICE**	National Institute for Health and Care Excellence
FMH	Fetomaternal haemorrhage	**PCR**	Polymerase chain reaction
HFIT	Human factors investigation toolkit	**PSE**	Potentially sensitising event
Ig	Immunoglobulin	**RAADP**	Routine antenatal anti-D Ig prophylaxis
IT	Information technology	**RPRP**	Right product right patient

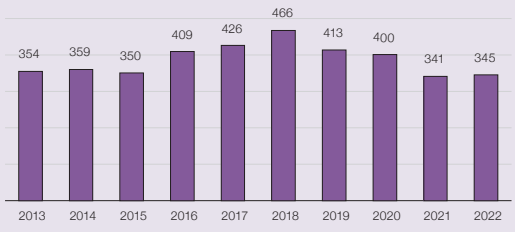
Key SHOT messages

- Omission or late administration of anti-D Ig or RAADP accounted for most cases analysed, 232/345 (67.2%)
- Errors in the clinical setting, 273/345 (79.1%) accounted for most cases
- Use of non-invasive cffDNA screening reduces unnecessary exposure to mothers carrying D-negative fetuses and protects supplies of the product. Staff need to be aware of false-positive and false-negative results that impact on patient care, and these should be investigated appropriately

Headline data 2022

Number of reports n=345
Deaths n=0
Major morbidity n=0

Anti-D Ig reports by year



Demographic data

Male n=0
Female n=345
Adults n=335
Paediatric n=2
Unknown n=8

Potential for major morbidity n=232

Late/omitted RAADP n=75
Late/omitted anti-D Ig following a PSE (including delivery) n=156
Unknown n=1

Recommendations

- Where the D-type of the mother is equivocal and not confirmed this must be clearly reported through the LIMS
- Cases where the cord D-type is discrepant with the D-type predicted by cffDNA should be investigated in a timely manner to ensure appropriate administration of anti-D Ig
- Laboratories should have processes for follow up of anti-D Ig that has not been collected from blood refrigerators to support administration within the 72-hour window

Action: Laboratory management

- Confirmation that anti-D Ig has been administered prior to discharge must be included in the discharge pathway to prevent delays and omissions
- Where mothers have been unable to attend appointments for RAADP, there should be processes to pursue alternative dates and clear communication of the risks with delays and omissions

Action: Maternity and gynaecology services

- Development of IT, including interoperability between laboratory and clinical IT systems, to support appropriate management of D-negative pregnancies must be considered a priority and supported with adequate resourcing to prevent transcription errors

Action: Trust/Health Board IT services, laboratory management

Introduction

Guidelines for safe and appropriate administration of anti-D Ig post sensitising events and RAADP have now been in place for many years (BSH Qureshi et al. 2014; NICE TA156; NICE NG140; NICE NG126). It is essential that these guidelines are reflected in local policies and systems are in place that support compliance in all healthcare settings. Anti-D Ig is also important in reducing the risk of developing immune anti-D in D-negative patients with childbearing potential (including paediatric patients) following transfusion of D-positive blood components. In this chapter 345 cases have been analysed, all related to anti-D Ig management during pregnancy.

Deaths related to anti-D Ig n=0

There were no deaths reported in the cases analysed for 2022 related to anti-D Ig errors.

Major morbidity n=0

No cases related to major morbidity were noted as a direct result of anti-D Ig errors. It is important to recognise that delays, omissions, under-dosing and failures to perform follow up testing after an FMH of more than 4mL have the potential to result in development of immune anti-D and haemolytic disease of the fetus and newborn in future pregnancies. More information regarding the clinical outcomes resulting from past failures in anti-D Ig and RAADP management can be seen in Chapter 26, Immune Anti-D in Pregnancy. The impact of anti-D Ig and RAADP errors should not be underestimated.

Overview of cases n=345

Errors in the clinical setting, 273/345 (79.1%) accounted for most cases, and 72/345 (20.9%) errors occurred in the laboratory setting.

Where information regarding the reason for anti-D Ig was available, errors occurred post-delivery, 127/345 (36.8%), RAADP, 113/345 (32.8%) and PSE, 103/345 (29.9%).

Errors in the clinical setting were seen in a variety of settings including delivery suites, 84/273 (30.8%), community, 40/273 (14.7%), antenatal clinic, 37/273 (13.6%), maternity wards, 11/273 (4.0%) emergency

departments, 5/273 (1.8%) and gynaecology wards, 3/273 (1.1%), however, in 38 cases the location was not recorded. Anti-D Ig was given unnecessarily in 87/345 (25.2%) of cases.

Good practice was noted in 4 cases, where routine laboratory practice included a review of uncollected anti-D Ig in blood refrigerators, facilitating communication with the clinical team. Unfortunately, in each of these cases it was still not possible to administer the product within the time frame, but it is suggestive that this practice does have the ability to prevent omissions and delays and should be adopted widely.

Figure 8.1 shows the distribution of anti-D Ig related error reports in 2022 (n=345).

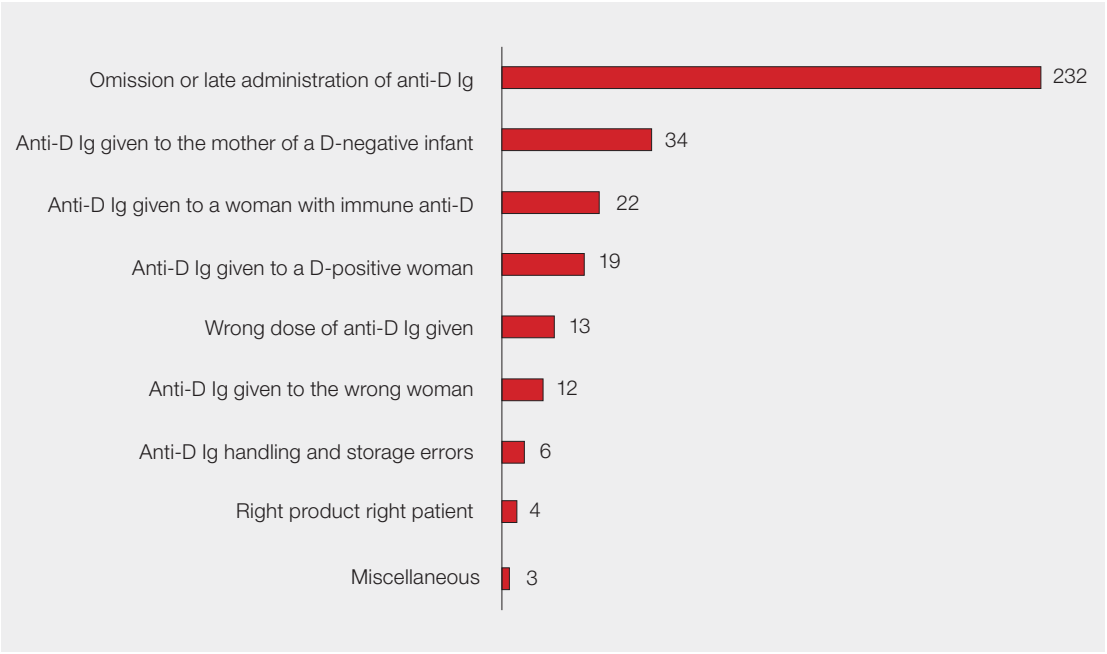


Figure 8.1: Distribution of anti-D Ig related error reports in 2022 (n=345)

Omission or late administration of anti-D Ig errors n=232

Omission or late administration of anti-D Ig or RAADP accounted for most cases analysed 232/345, (67.2%); 51/232 (22.0%) related to patient discharge prior to administration and 26/232 (11.2%) related to flawed decision-making.

Case 8.1: Failure to attend appointment and no follow up

A D-negative mother did not receive RAADP at 28 weeks in the community setting. The mother did not attend the clinic appointment at 28 weeks, and this was not followed up by the clinical team. The omission was noticed later in the pregnancy by the laboratory team.

The incident was reviewed, and improvement actions identified. It was agreed that the community clinic would be included in the hospital patient booking system so that non-compliance could be managed electronically by sending reminders to both mother and clinic staff.

Failure to attend appointments is a challenge across the whole of healthcare. Omission or delay resulting from patient non-compliance is not SHOT-reportable, however, it was unclear in this case whether the mother made a conscious and informed decision not to attend for anti-D Ig administration but there was no evidence of follow up by the clinical team. It is encouraging to see in this case that the improvement action has included using IT systems to provide an effective process for follow up where appointments have been missed.

Learning point

- Systems should be in place to ensure that, where mothers have not attended an appointment, there is a follow up and effective communication of the risks of not having anti-D Ig administered

Case 8.2: Discharge prior to administration leading to delay

A D-negative patient had a termination of pregnancy at 12+1 weeks. Anti-D Ig was issued but not administered before the patient was discharged. The ward staff realised the patient required the anti-D Ig and arranged for it to be administered 2 days after the procedure. The patient then informed the clinical team that they a positive lateral flow COVID-19 test and so were unable to attend for the appointment. Confirmatory COVID-19 PCR testing was negative 2 days later and the patient attended for the anti-D Ig injection, 4 days post procedure.

Discharge prior to administration of anti-D Ig is a common reason for delays and omissions. This case demonstrates good communication between the clinical team and the patient, with every effort being made to attempt to administer the anti-D Ig within 72-hours. The delay could have been prevented by ensuring that anti-D Ig is always administered prior to discharge. Other cases reported highlight the challenges with administration of anti-D Ig post-discharge; cost of living pressure impacting on travel to appointments, conflicting advice on requirement for anti-D Ig, lack of understanding of the potential risks of delay or omission.

Due to the retrospective nature of anti-D Ig submissions, COVID-19 pandemic themes continue to resonate in the 2022 reports (Almozain et al. 2022). Contributory factors to omissions and delays included changes in policies for anti-D Ig administration to reduce hospital appointments, staff re-deployment, mothers moved to COVID-19 wards where staff were unfamiliar with anti-D Ig, inability to attend appointments due to self-isolation. Whilst these reasons may diminish as the world learns to 'live with COVID-19', there are important messages within these themes that will remain. Unfamiliarity with the use of anti-D Ig is a recurrent theme in SHOT reports, particularly where mothers are seen outside of the maternity or gynaecology setting.

Learning points

- It is essential that anti-D Ig is administered prior to discharge, this should be supported by effective processes in maternity and gynaecology service, with confirmation of administration included within the discharge checklist and summary
- It is important that all staff have a basic understanding of management of D-negative pregnancies, this should be included in the regular transfusion training programs. SHOT provide educational videos that can be incorporated into local training packages

Other anti-D Ig errors n=113

Administration to a mother carrying a D-negative infant accounted for 34/345 (9.9%) of cases, 9/34 due to failure to check cffDNA or cord blood D-types and 11/34 due to false positive D-types predicted by cffDNA screening.

Anti-D Ig was administered to mothers with immune anti-D in 22/345 (6.4%) cases, 8/22 resulted from failures to check records.

D-positive mothers received anti-D Ig inappropriately in 19/345 (5.5%) cases, 7/19 of these were weak D-types, other errors included failure to check results and transcription errors.

There were 13/345 (3.8%) cases that involved administration of incorrect doses, 5/13 related to failure to perform Kleihauer testing, cases of under-dosing related to cell salvage and miscalculation of FMH, over-dosing resulting from miscalculation of FMH and challenges around appropriate administration following frequent PSE. Failures in FMH estimation should be investigated. Whilst under-dosing has a real risk for development of immune anti-D, there are no patient safety risks associated with perceived over-dosing.

Anti-D Ig was administered to the wrong woman in 12/345 (3.5%) cases, all resulted from failures in positive patient identification.

Errors in the handling and storage of anti-D Ig accounted for 6/345 (1.7%) of cases, 2/6 cases of administration of expired products, 2/6 storage errors and 2/6 administered without prescription. Finally, 3 cases were classified as miscellaneous, and 4 RPRP cases related to errors in labelling of anti-D Ig.

From the information available related to incident investigations, it is encouraging to see the increase in cases being formally investigated and reviewed and less emphasis placed on individual staff members. A human factors and systems-based approach supports identification of true causes of error and implementation of effective interventions to reduce risk of recurrence.

Involvement of information technology

IT was noted as being involved in errors in 54/345 (15.7%) of cases, the majority of these related to omission or delay (28/54) and anti-D Ig administered to a mother with a D-negative infant (14/54). The involvement of IT was varied but the main theme was transcription errors due to lack of interoperability of laboratory and clinical systems. It is interesting to note that IT is being seen as involved in only a small number of cases and mainly associated with lack of interoperability. IT systems are now prevalent in healthcare, these should be developed and configured to support safe and appropriate practice across the whole of anti-D Ig management, not just transfer of laboratory results.

Non-invasive prenatal testing n=23

Fetal D-typing using cffDNA screening is a highly accurate non-invasive method supporting the appropriate use of anti-D Ig and RAADP, reducing exposure to blood products for D-negative women carrying D-negative fetuses (NICE 2016). The assay has limitations, with sensitivity of 99.3% (95% CI 0.982-0.997) and specificity of 98.4% (95% CI 0.964-0.993) (Mackie et al. 2017), leading to a small risk of false positive or false negative results. Anti-D Ig should be given when results are inconclusive.

A total of 23 cases were reported relating to cffDNA screening. Of these, 11/23 were false positive and 8/23 were false negative screening results, these are described in the laboratory errors chapter. The remainder comprised of failures to check cffDNA results prior to order, release or administration of anti-D Ig and a laboratory failure to report the results which led to them not being visible to the clinical team.

The limitations of the screening assay include a low risk that predicted D-types may be discrepant with cord D-types (Narayan et al. 2022). The false negative rate (where women would not be offered anti-D-Ig and so be at risk of sensitisation) is very low at 0.34% (95% CI 0.15 to 0.76) and the false positive rate 1.26% (95% CI 0.87 to 1.83) (Yang et al. 2019). It is important that discrepant results are followed up to ensure that anti-D Ig is provided appropriately. A checklist for investigation of discrepant results is now available on the SHOT website that can be used for local investigations (see ‘Recommended resources’).

Near miss anti-D Ig cases n=37

There were 37 near miss cases analysed in 2022, which is an increase from 15 in 2021. Errors were detected by laboratory staff in 22/37 (59.5%) of cases, and by a registered nurse or midwife in 15/37 (40.5%).

Conclusion

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. The implementation of non-invasive cffDNA screening has undoubtedly improved practice by targeting administration of this blood product to those who need it, both reducing unnecessary exposure to mothers carrying D-negative fetuses and protecting supplies of the product. Access to the screening program should now be an accepted standard in all maternity services.

In the 2021 Annual SHOT Report (Narayan et al. 2022), this chapter stressed the importance of harnessing the power of IT to support the safe and appropriate management of anti-D Ig. This message is becoming more vital as the healthcare service struggles with current challenges of staffing, workload and post-pandemic backlogs. IT provides an opportunity for clinical decision support, checklists, fail-safes and user alerts within patient records in both the clinical and laboratory settings. IT is not dependent on staff knowledge, memory or familiarity with tasks. IT can pull different aspects of the clinical record, including pregnancy status, D-type, cffDNA result, together to support flags and alerts for anti-D Ig administration, and reminders for appointments. It is incumbent on IT providers, clinical users and patient groups to work together to configure and design IT systems that support good practice. SHOT resources are available to guide how IT systems can support good practice in the management of anti-D Ig. The SHOT anti-D aide-memoire provides a checklist that can be used in the absence of IT support, but also as resource for designing IT systems to support safe practice.

SHOT provide a variety of resources that can be used as training aides for healthcare staff and are open access for patients and carers. Mothers are often well informed on their pregnancies and should be included in discussions relating to requirement for anti-D Ig, the importance of timings for administration and the risk of delays and omissions in administration. Healthcare services are now promoting patient-centred care, where patients are not only involved in decisions about their own treatment, but encouraged to become involved in incident investigation, suggesting improvements in care and system design. The management of anti-D Ig should be integral in this initiative. It is only by working together, with buy in from all stakeholders, that we can truly improve practice and reduce risk of error.

Recommended resources

Anti-D Immunoglobulin (Ig) Administration to avoid sensitisation in pregnancy - an aide memoire SHOT 2020
IT supports anti-D Ig management
Template for investigation of discrepant cffDNA results in hospitals
https://www.shotuk.org/resources/current-resources/

SHOT Bite No 2: Anti-D Ig Administration
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT video Anti-D Ig and Immune anti-D (part 1 and part 2)
https://www.shotuk.org/resources/current-resources/videos/

cffDNA testing centres
Exeter Genomics Laboratory https://www.exeterlaboratory.com/genetics/non-invasive-cell-free-fetal-rhesus-d-rhd-genotyping/
IBGRL (NHSBT) https://ibgrl.blood.co.uk/services/molecular-diagnostics/fetal-rhd-screen/

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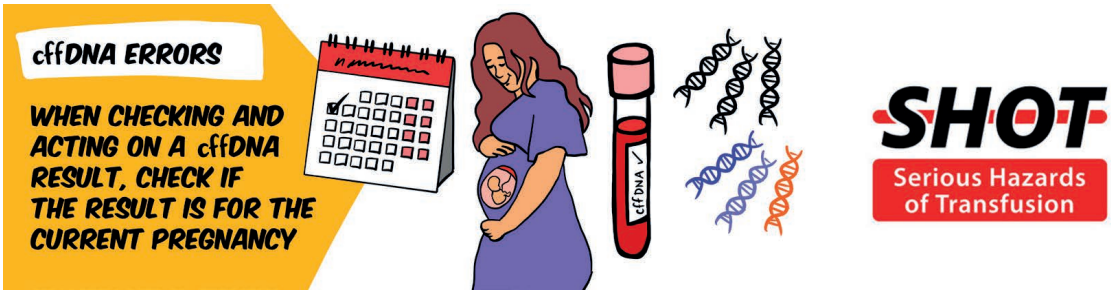
NICE (DG25). High-throughput non-invasive prenatal testing for fetal RHD genotype (2016). https://www.nice.org.uk/guidance/dg25 [accessed 28 April 2023].

NICE (NG126). Ectopic pregnancy and miscarriage: diagnosis and initial management (2019). https://www.nice.org.uk/guidance/ng126/chapter/Recommendations#anti-d-rhesus-prophylaxis [accessed 28 April 2023].

NICE (NG140). Abortion care (2019) https://www.nice.org.uk/guidance/ng140/chapter/Recommendations#anti-d-prophylaxis [accessed 28 April 2023].

Yang H, Llewellyn A, Walker R, et al. High-throughput, non-invasive prenatal testing for fetal rhesus D status in RhD-negative women: a systematic review and meta-analysis. *BMC Med.* 2019;**17**:37. https://doi.org/10.1186/s12916-019-1254-4 [accessed 28 April 2023].



9 Incorrect Blood Component Transfused (IBCT) n=296

Authors: Simon Carter-Graham, Nicola Swarbrick, Victoria Tuckley, Caryn Hughes, Debbi Poles and Shruthi Narayan

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).

Key SHOT messages

- Accurate patient pre-administration checks are critical to transfusion safety – lack of proper patient identification could lead to a fatality. PPID does not only apply to blood transfusion; confirming patient identity is vital at every point of patient care
- Disparities between competency-assessment, knowledge and skills impact on transfusion safety. These gaps lead to basic errors which can cause significant negative impact in patients
- Electronic systems should act as an additional barrier. Staff must not become reliant on IT systems providing a fail-safe in place of scientific and clinical knowledge
- Understaffing, staff sickness, recruitment and retention issues, and use of agency staff can add to pressures already existing in both the clinical and laboratory setting, including placing a training burden on the remaining staff. Where this impacts on transfusion safety this should be escalated
- IT alerts should be relevant, understandable to the user, not easily overridden and have associated actions. These should be regularly reviewed and updated where appropriate

Abbreviations used in this chapter

ABOi	ABO-incompatible	**HDU**	High dependency unit
BMS	Biomedical scientist	**HLA**	Human leucocyte antigen
BSH	British Society for Haematology	**HSCT**	Haemopoietic stem cell transplant
CAS	Central alerting system	**ICU**	Intensive care unit
CMV	Cytomegalovirus	**IBCT**	Incorrect blood component transfused
DHTR	Delayed haemolytic transfusion reaction	**ID**	Identification

FFP	Fresh frozen plasma
LIMS	Laboratory information management system
MH	Major haemorrhage
MHP	Major haemorrhage protocol
MHRA	Medicines and Healthcare products Regulatory Agency
NM	Near miss
PPID	Positive patient identification
IT	Information technology
SOP	Standard operating procedure
SRNM	Specific requirements not met
UKTLC	United Kingdom Transfusion Laboratory Collaborative
WBIT	Wrong blood in tube
WCT	Wrong component transfused

Recommendations

- If staff are interrupted and/or distracted during the final pre-administration check, they must re-start the process from the beginning (BSH Robinson et al. 2018)

Action: All staff in transfusion, ward managers

- Collection is a critical step in the transfusion process – barriers such as collection checks and smart refrigerators must be in place to reduce errors

Action: Transfusion service managers, hospital transfusion teams and risk management teams

- Ensure that competency and training is effective and robust. Competency-assessment must be of value, rather than a tick box exercise

Action: Training leads

- Laboratory staff providing training should have knowledge of transfusion to ensure training is of sufficient standard, in line with UKTLC standards (see 'Recommended resources')

Action: Transfusion laboratory managers

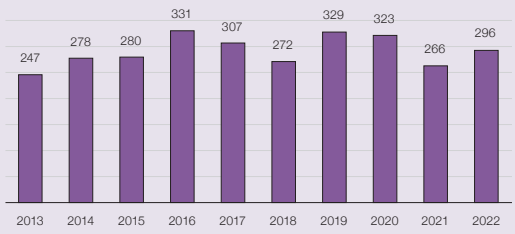
- LIMS must be used to their full potential to ensure the correct component is issued to the patient which meets all requirements for their clinical picture

Action: LIMS suppliers, transfusion service manager

Headline data 2022

Number of reports n=296
Deaths n=2
Major morbidity n=5

IBCT reports by year



Demographic data

Male n=137
Female n=144
Unknown n=15

Adults n=242
Paediatric n=37
Unknown n=17

Blood component data

Red cells n=241
Platelets n=30
Plasma n=7
Multiple components n=15
Granulocytes n=1
Cryoprecipitate=1
Unknown n=1

Introduction

Incorrect blood component transfused (IBCT) events have the potential to cause major morbidity or patient death, as evident in the 2022 Annual SHOT Report data. These errors accounted for 296/3499 (8.5%) of all reports analysed by SHOT in 2022. The proportion of IBCT cases in 2022 is similar to data from 2021, 266/3161 (8.4%). The total number of IBCT-WCT reports has slightly decreased in 2022 to 87 from 93 in 2021, with an increase in the number of IBCT-SRNM reports to 209 from 173 in 2021. Figure 9.1 provides an overview of reports submitted to SHOT in 2022 where an incorrect blood component was transfused. This category includes instances where wrong components were transfused, and/or specific requirements were missed.

Figure 9.1: Overview of reports where an incorrect blood component was transfused in 2022 (n=296)

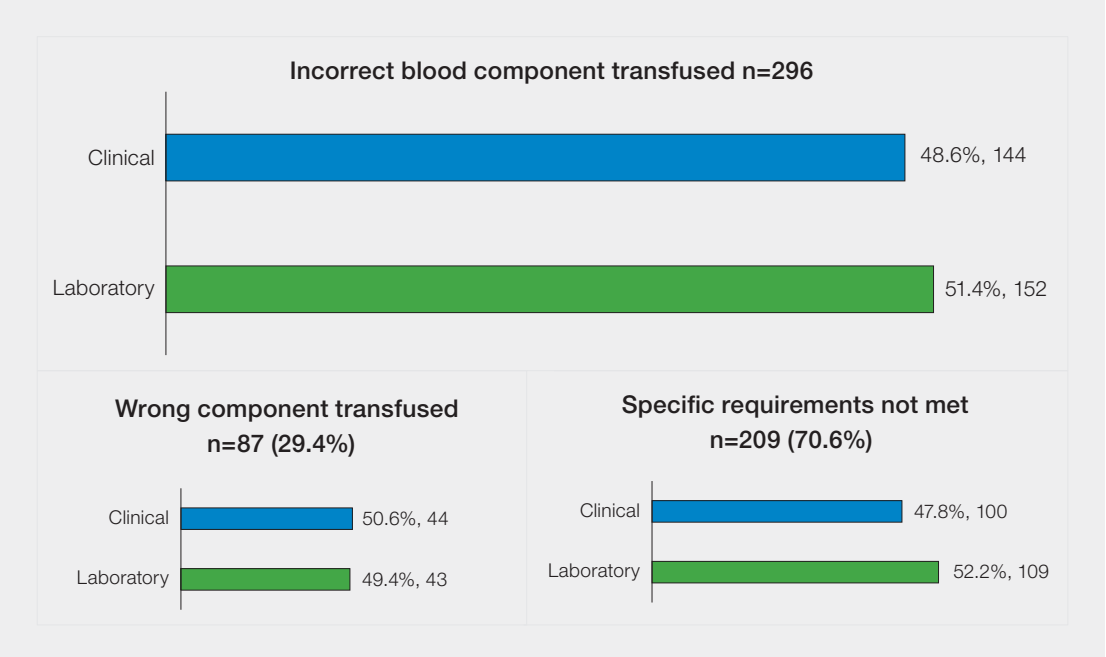
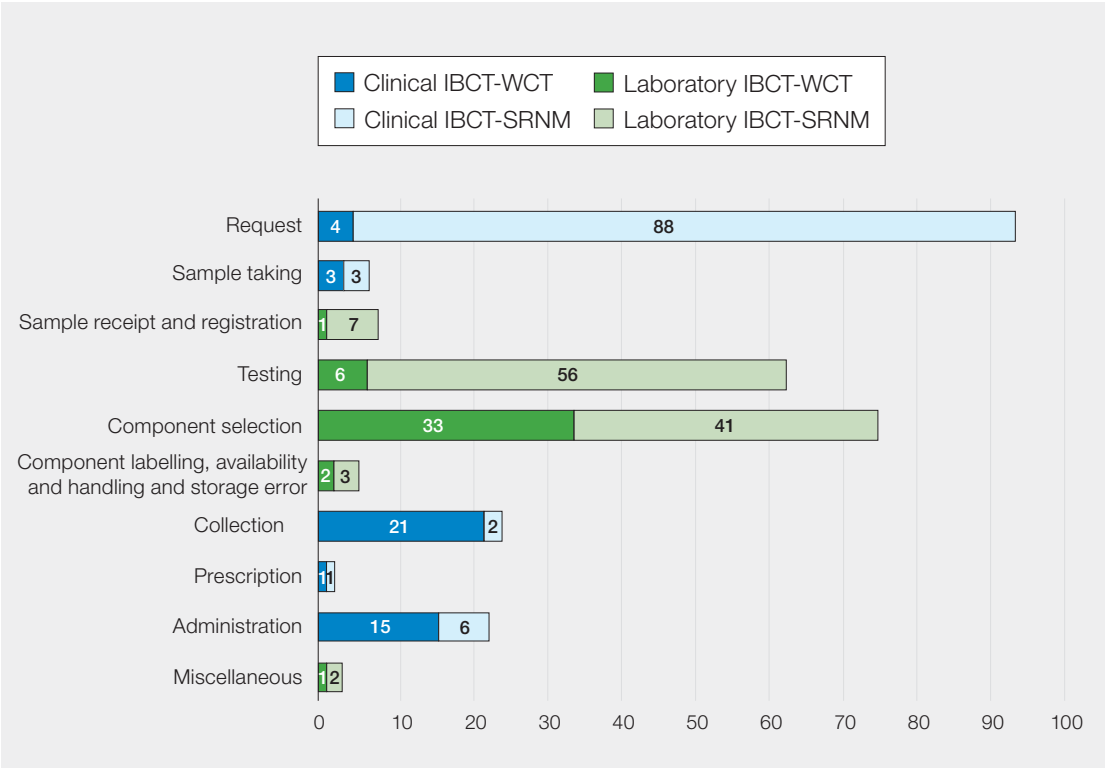


Figure 9.2: Total IBCT errors categorised by the step where the error occurred (n=296)



IBCT-SRNM=incorrect blood component transfused-specific requirements not met; IBCT-WCT=IBCT-wrong component transfused

Most clinical errors occurred at the request step of the transfusion process with 92/144 (63.9%) reports, followed by 23/144 (16.0%) at collection and 21/144 (14.6%) at administration. In the laboratory the majority of errors occurred at the component selection 74/152 (48.7%) and testing, 62/152 (40.8%) stages.

Deaths related to transfusion n=2

There were 2 patient deaths in 2022 due to IBCT-WCT errors (each assigned imputability of 1, possible). Both were the result of ABOi red cell transfusions with the primary error in both occurring at the collection step. These are discussed as Cases 9.1 and 9.2.

Case 9.1: Collection error and lack of pre-administration PPID leads to an ABOi transfusion

Following cardiac surgery, a female in her 70s received an ABOi transfusion during a MH. The patient was group O D-negative and was inadvertently given B D-positive. A unit of red cells was collected by a porter from the issue refrigerator, but this was for another patient on a different ward. None of the details on the issue label/compatibility label were checked. Soon after, the porter realised the error and reported to laboratory staff, but the red cell unit had already been transfused. BloodTrack® was available but not utilised and ward staff did not carry out any pre-administration checks. The emergency response team were not trained to use BloodTrack®. The ward staff were inexperienced in dealing with MH and this event was very unusual and traumatic for those involved. The patient died on return to theatre and the death was attributed to complications of cardiac surgery.

Investigation of this incident found that the porter was already dealing with multiple tasks when the MHP was activated. The porter did not take the BloodTrack® collection slip to the refrigerator. Had they collected the appropriate blood transfusion slip before going to the transfusion laboratory refrigerator, they would have scanned in the BloodTrack® code for the correct patient, and it would not have been possible to remove the blood component intended for another patient. The ward nurse did not verbally confirm the patient's details with the porter, nor did they check the unit itself to confirm it was for the correct patient before handing the blood component over to a colleague who was directly involved in the emergency. Pre-transfusion administration safety checks to ensure the correct unit of blood was being given to the correct patient were not carried out. The organisational policy stipulated the use of the BloodTrack® system to perform pre-transfusion safety checks. As per their policy, if the BloodTrack® system was not available for any reason, a manual, two-person check should have been performed prior to administering each unit of blood. The staff involved in this incident were compliant with blood transfusion training and were up to date with competency-assessments.

Case 9.2: Collection error and incomplete pre-administration checks lead to a haemolytic reaction

A patient with blood group O D-positive was admitted to the HDU following a surgical procedure associated with a history of life-threatening sepsis on the background of poorly controlled diabetes. The patient was transfused A D-positive red cells as part of a routine transfusion. The collector transported the red cells from the transfusion laboratory for two patients in two different clinical areas and accidentally mixed the two blood boxes up, therefore the wrong blood component went to the wrong location. In the clinical area the pre-transfusion checking procedure was significantly disrupted as the patient would not permit the nurses to check their identification band, was displaying challenging behaviour and was demanding that staff use their chosen name (the patient was known by a chosen name that did not bear any resemblance to their formal name). There was a determined effort by staff to undertake the usual pre-transfusion checks, but this was unsuccessful.

The error was detected when the other clinical area phoned the transfusion laboratory to ask where the red cell unit was that was intended for their patient. This was 45 minutes after the blood components had been delivered to each location. Laboratory staff phoned the clinical area to explain the error, asking for the unit to be returned immediately but staff confirmed the transfusion was almost complete. The remainder of the transfusion (10-15mL) was stopped immediately. Senior medical staff

were informed, and emergency treatment was commenced. The patient required plasma exchange and renal replacement therapy. The patient died one week after the ABOi transfusion.

Whilst the case has been submitted to SHOT and the MHRA, the full incident investigation report is still awaited, and an update will be provided in the next Annual SHOT Report. Details of the case as submitted on SABRE have been included here for information.

Major morbidity n=5

One clinical case of major morbidity resulted in the admission of a patient with sickle cell disease to the HDU following an ABOi red cell transfusion (Case 9.3).

Case 9.3: Distractions, familiarity and assumptions lead to an ABOi transfusion

A male patient in his 40s (patient 1) with sickle cell disease was due to receive a routine exchange transfusion as an out-patient. The patient was O D-positive but was given B D-positive red cells. The nurse was about to administer a unit of red cells to patient 2. They became distracted because patient 1's infusion alarm sounded. The nurse, still holding the unit, addressed the alarm and then connected the unit to patient 1 in error. The patient was not wearing an ID band, PPID was not carried out as the nurse was familiar with patient 1, and no other pre-administration checks were completed.

The patient consequently experienced chest and groin pain with a feeling of impending doom and was admitted to the HDU for additional observations and monitoring. This gentleman recovered but is consequently very anxious about future treatments.

The investigation into this incident found that staff reported being overwhelmed by their workload and multiple alarms sounding at the same time. There was a lack of appropriately trained staff due to sickness at short notice. There were no effective bedside red cell exchange guidelines, and the SOP was described as 'unworkable'. Local 'workarounds' were in place for when the department was busy and there was anecdotal evidence of an under-supported, under-developed specialist service with inadequate staff numbers and skill mix.

Other cases resulting in major morbidity

The 4 laboratory cases of major morbidity resulted in sensitisation to the K antigen in patients of childbearing potential due to component selection errors as discussed in Chapter 14, Laboratory Errors. All patients were females under the age of 34, and in 3/4 cases the transfusion was required for acute bleeding directly related to pregnancy.

A further patient required admission to the ICU following a DHTR. This occurred in a patient with sickle cell anaemia who received a non-phenotype matched transfusion. The patient subsequently formed an anti-C. This case is included in the figures and commentary for Chapter 18, Haemolytic Transfusion Reactions (HTR).

ABO-incompatible (ABOi) transfusions n=6

ABOi transfusions are entirely preventable and have the potential to cause severe clinical consequences including patient death. Despite this, 6 ABOi occurred in 2022. A summary of ABOi transfusions can be seen in Table 9.1.

Five ABOi transfusions were as a result of clinical errors (collection and administration errors) and led to 2 deaths and 1 case of major morbidity. One laboratory error (component selection error) resulted in an ABOi transfusion of group O FFP to a group A patient. The error was detected by laboratory staff prior to issuing however due to the emergency, the FFP was approved for transfusion by the clinician.

Figure 9.3: ABOi cases reported in 2022 (n=6)

ABOi=ABO-incompatible; FFP=fresh frozen plasma. Note: case numbers refer to the cases in Table 9.1

Table 9.1: ABO-incompatible transfusions in 2022 (n=6)

Case number	Case 1	Case 2	Case 3
Component transfused	Red cells group B 	Red cells group A 	Red cells group B 
Patient group	Group O	Group O	Group O
Volume transfused	>50mL	>50mL	>50mL
Primary error	**Collection** Porter delivered unit to the wrong ward and Patient ID checks not carried out fully	**Collection** Porter delivered unit to the wrong ward and Patient ID checks not carried out fully	**Administration** Patient ID checks not carried out
When was error detected	Porter realised error and informed laboratory	Other ward rang laboratory to ask where their unit was	Acute adverse reaction in patient
Patient impact	**Death**	**Death**	**Major morbidity**
Imputability	1 - possible	1 - possible	3 - definite
Urgency	Emergency	Routine	Routine
MHP	Yes	No	No
Department	Ward	Ward	Haematology day unit
Adult/paediatric	Adult	Adult	Adult
Administration checklist used. Patient ID	No 1-person check	No 2-person check	No 1-person check
ID band in place	Yes	Yes	No

Case number	Case 4	Case 5	Case 6
Component transfused	Red cells group B 	Red cells group B 	FFP group O 
Patient group	Group O	Group A	Group A
Volume transfused	>50mL	2 units	>50mL
Primary error	**Administration** Patient ID checks not carried out	**Sample taking** Unable to establish further details due to passage of time	**Component selection** Lapse in concentration when selecting FFP from freezer prior to defrosting
When was error detected	When further group sample was sent to laboratory	On current sample testing (historical WBIT, 2016)	At point of thawing but due to urgency of request clinician decided to continue and transfuse
Patient impact	**No clinical reaction**	**No clinical reaction**	**No clinical reaction**
Imputability	n/a	n/a	n/a
Urgency	Routine	Urgent	Emergency
MHP	No	No	Yes
Department	Ward	Ward	Laboratory
Adult/paediatric	Adult	Adult	Adult
Administration checklist used. Patient ID	No 1-person check	Unknown	Yes 2-person check
ID band in place	No	Unknown	Yes

The remaining ABOi cases are described in full in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Commentary

It is disappointing to see 5 ABOi red cell transfusions, of which 2 resulted in patient death. The last ABOi-related death occurred in 2015, and there were no reports of red cell ABOi transfusions in 2021. Levels of harm following ABOi red cell transfusions are difficult to predict, and as such must be prevented. There are currently a number of pressures on healthcare staff above and beyond that which is seen as normal. The consequences of these additional pressures are evident in the increase of serious, and fundamental errors occurring. In 4 of the ABOi cases there was a failure to complete PPID prior to administration. This is a basic process in healthcare and justification for not properly identifying patients is difficult to come by. The use of a pre-administration checklist has been promoted by SHOT recommendations over the past 6 years and stipulated as a necessity by the CAS alert: 'Safe Transfusion Practice: Use a bedside checklist' (Department of Health 2017).

Two deaths occurred in 2022 due to safety checks not being performed during collection, and then subsequently not performed at the pre-administration check, however in different circumstances many more patients could have suffered the same fate. Figure 9.4 shows a summary of potential outcomes resulting from errors in the transfusion pathway and that while there were 2 deaths following ABOi, there were several errors with the potential to cause serious patient morbidity and mortality.

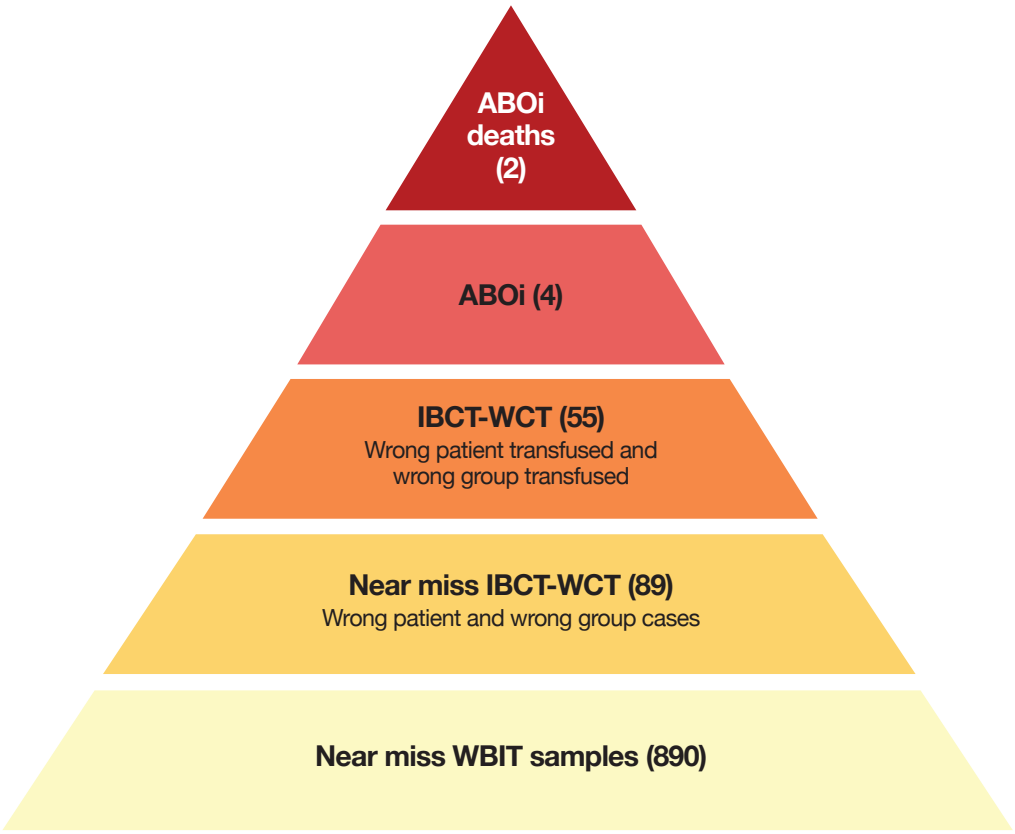


Figure 9.4: ABO-incompatible (ABOi) transfusions and events that had the potential to lead to ABOi in 2022

ABOi=ABO-incompatible; IBCT-WCT=incorrect blood component transfused-wrong component transfused; WBIT=wrong blood in tube

Many errors were detected and prevented by robust processes being employed (e.g., laboratory zero tolerance policy), however in several occurrences harm was prevented fortuitously (e.g., wrong patient transfusions where the component was ABO-compatible). In 2022 a total 19/87 (21.8%) IBCT-WCT events were due to lack of patient identification and resulted in a patient receiving a blood component which was labelled and intended for another patient. In 2/19 PID errors, the error occurred in the laboratory when handing over components to the clinical staff and 17/19 occurred in the clinical area with errors at collection and administration. These incidents need to be investigated thoroughly as any of these could have potentially resulted in ABOi and patient death. It is crucial not to simply attribute fault to the staff member for the omission, but to investigate system factors and processes, for instance ineffective transfusion policies, inability to print an ID band in a timely manner, suboptimal staff training and staffing issues.

Other factors that have been noted to be contributory include information technology available but not used, policies in place for two-person independent checking but not undertaken, untrained staff collecting blood components, and LIMS alerts either not configurable or overridden. Errors can occur at several stages of the transfusion pathway and can be cumulative. Cognitive bias including assumptions, rushing to complete work, multitasking and gaps in knowledge are recognised as contributory factors (Swarbrick et al. 2022).

Clinical IBCT events n=144

There were 144 cases reported in 2022 which is an increase from the 119 in the 2021 Annual SHOT Report.

Clinical IBCT-WCT events n=44

This is a slight increase in cases from 40 in the 2021 Annual SHOT Report.

There was a total of 15/44 (34.1%) transfusions of the wrong component type, 12/44 (27.3%) of the wrong group and 17/44 (38.6%) to the wrong patient.

Most of the IBCT-WCT errors 21/44 (47.7%) occurred at the point of collection of the component from the storage area. Of these, 4 involved staff members collecting the component/s without relevant training and were not formally assessed for this competency. Collection of blood components must only be carried out by a trained and competency-assessed healthcare worker (BSH Robinson et al. 2018). Collection as the primary error resulted in 11 wrong type of components transfused, 4 wrong blood group transfused and 6 where components were administered to the wrong patient, including 1 ABOi transfusion resulting in patient death. Reports of collection errors have more than doubled over the past 5 years, from 10 in 2018 (Narayan et al. 2019) to 21 in 2022. This trend indicates that learning from these incidents has not been optimal and incident investigations may not be effective. All systemic causal and contributory factors must be addressed to ensure better transfusion safety.

All patients receiving a transfusion must wear a patient ID band (or risk-assessed alternative) (BSH Robinson et al. 2018), but there were 3 instances where the patient was not wearing an ID band, 1 of which resulted in an ABOi red cell transfusion leading to major morbidity.

In 15/44 (34.1%) cases, the primary error occurred at the administration step of the transfusion process. Of these, 3 resulted in wrong component types being transfused, 3 wrong group transfusions and in 9 cases, blood components were transfused to the wrong patient. This step in the transfusion pathway is the final opportunity to avoid an IBCT-WCT, and must be carried out by a trained, competent and authorised healthcare professional.

It is imperative to perform the final administration checks next to the patient. The donation number, blood group and expiry date on the component pack label must match the laboratory-generated label attached to the component and the component blood group must be appropriate for the patient (BSH Robinson et al. 2018). There were 12/44 (27.3%) cases where the blood component was administered without any final pre-administration checks at the patient's side. In 2 cases, the death of the patient was possibly related to the transfusion (imputability 1), and 1 resulted in major morbidity. Short staffing, poor skill-mix and extremely busy clinical areas were noted as additional contributory factors in these incidents.

A safe transfusion checklist was produced by SHOT in response to previous recommendations and the CAS alert: 'Safe Transfusion Practice: Use a bedside checklist' (Department of Health 2017). Despite this recommendation to improve safety, no checklist was used in 19/44 (43.2%) reports of IBCT-WCT.

Learning points

- Collection of blood components remains a critical step in the transfusion process and robust procedures should be in place to ensure that necessary checks are made
- It is **vital** to carry out positive patient identification and complete all the final checks next to the patient immediately prior to administration
- **ALL** recipients of a transfusion must wear an identification band*
- **ALL** recipients must be asked to state (unless unable) their full name and date of birth which must match details on the identification band*
- **ALL** core identifiers on the identification band* must match the details on the blood component label **(or risk-assessed equivalent* (BSH Robinson et al. 2018))

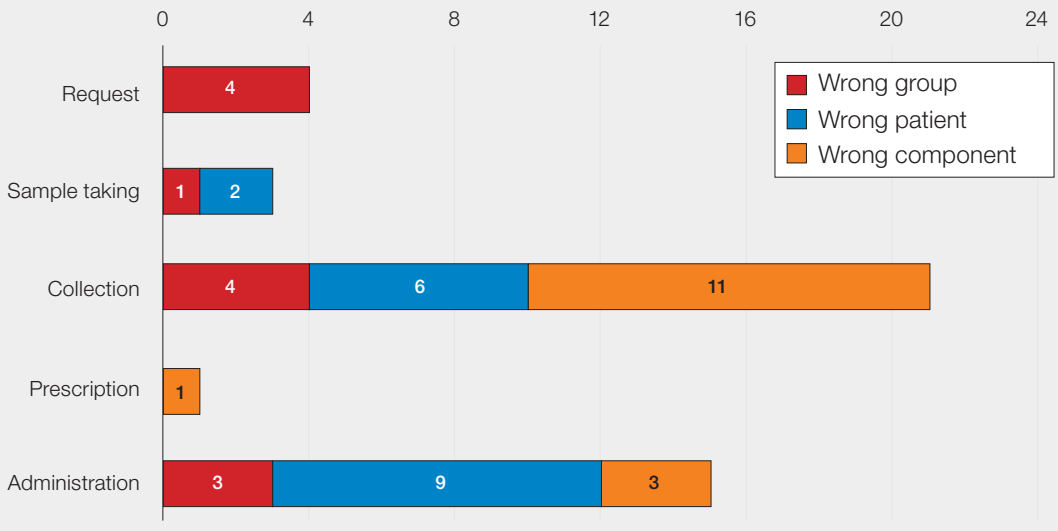


Figure 9.5: Categorisation of clinical IBCT-WCT errors by transfusion step where the primary error occurred (n=44)

Data regarding errors at the request, sample and prescription stage can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Most errors occurred on general wards 20/44 (45.5%) with 19/44 (43.2%) being routine transfusions and 12/44 (27.3%) emergencies. Most transfusions 27/44 (61.4%) had taken place between 08:00-20:00.

IT was involved in 11/44 (25.0%) which included pager failure and problems accessing remote issue storage refrigerators. In some cases, IT systems were available but not used. This was occasionally because the user had not been fully trained to use it.

Two illustrative cases can be found in the supplementary material for this chapter. One describes a case of wrong patient transfusion where units were checked away from the bedside using a pre-printed wristband and the other describes a case of wrong component transfusion due to communication failure.

Clinical IBCT-SRNM events n=100

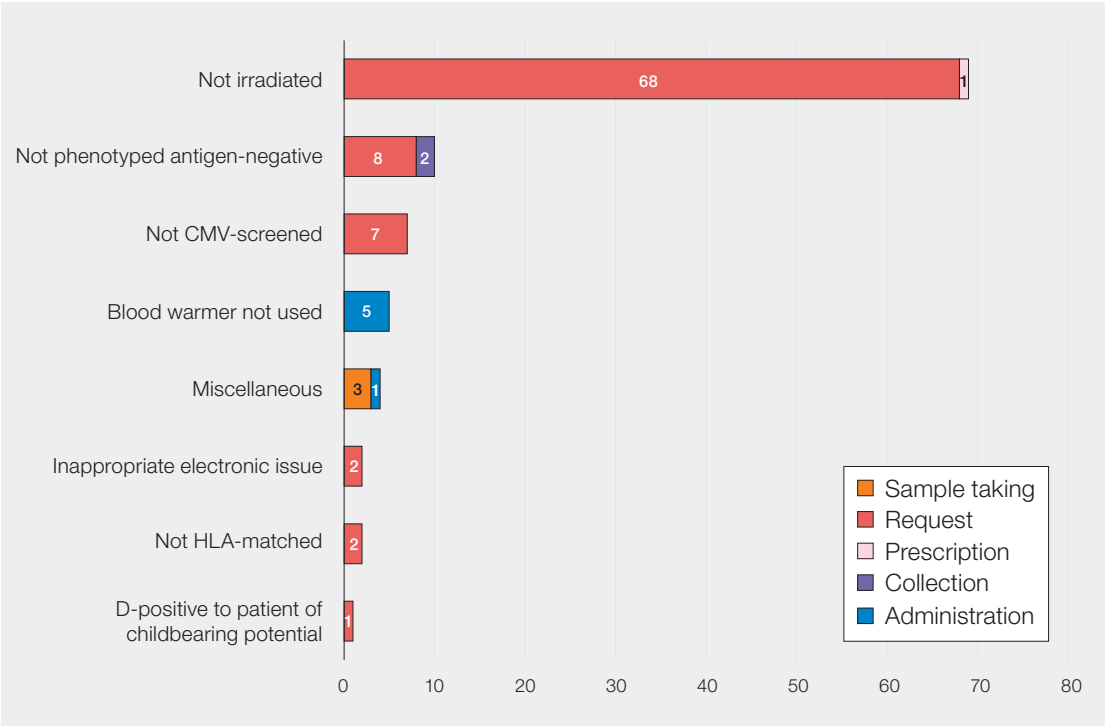
This is an increase from the 79 events in the 2021 Annual SHOT Report.

As has been the case for many years, the most common error in this category was a failure to provide irradiated components 69/100 (69.0%). Many of these recipients, 25/69 (36.2%) had a history of Hodgkin lymphoma but fortunately no patients suffered a clinical reaction. A further 26/69 (37.7%) had received purine analogues again though leading to no reactions. BSH guidelines state that cellular blood components should be irradiated for patients receiving purine analogues and Hodgkin lymphoma (BSH Foukaneli et al. 2020). The requirement for CMV-negative units was missed in 7 cases, this is a slight reduction on recent years. The need for irradiated components is most often missed in patients with current or historical Hodgkin lymphoma (Elliot et al. 2021).

In 88/100 (88.0%) reports the primary error was made at the request step in the transfusion process with 80/88 (90.9%) of prescriptions being incorrect. In 43/88 (48.9%) reports the clinical staff were aware of the requirements but they did not inform the laboratory staff. In many of these cases the requirement was omitted from the request form, with shared cared between hospitals contributing to 4 cases as there was no national database for patients' specific transfusion requirements.

There were 6 errors at administration, 5 of these were due to a blood warmer not being utilised where necessary.

Figure 9.6: Clinical IBCT-SRNM errors and transfusion step where the primary error occurred (n=100)



CMV=cytomegalovirus; HLA=human leucocyte antigen

Two illustrative cases can be found in the supplementary material for this chapter which describe a lack of consideration of pregnancy on other transfusion requirements. This illustrates the importance of accurate training, documentation and communication of transfusion requirements, as when patients have multiple transfusion requirements these can often cause confusion and anchoring bias can occur.

Learning points

- It is vital that all healthcare professionals involved with transfusion have an awareness of specific transfusion requirements, and patient cohorts where these requirements are likely to occur
- Specific requirements for transfusions should be documented in patient records (manual and electronic) and be easily accessible
- Transfusion is a team effort. Robust processes for communication of specific requirements between the clinical area and laboratory increase the likelihood of safe transfusions occurring

Laboratory IBCT errors n=152

In 2022 there has been a slight increase in reports of incorrect blood components transfused from 147 in 2021 to 152 in 2022. There has been a decrease of laboratory errors resulting in IBCT-WCT from last year from 53 to 43, but an increase in IBCT-SRNM errors from 94 in 2021 to 109 in 2022.

Wrong component transfused n=43

Error subcategory	Sample receipt and registration	Testing	Component selection	Component labelling, availability and handling and storage error
				
Number of error reports	**1**	**6**	**33**	**2***

plus 1 miscellaneous error

Table 9.2: Laboratory WCT errors in 2022

There were 43 laboratory errors which led to the wrong component being transfused, most of which were due to component selection errors (33/43).

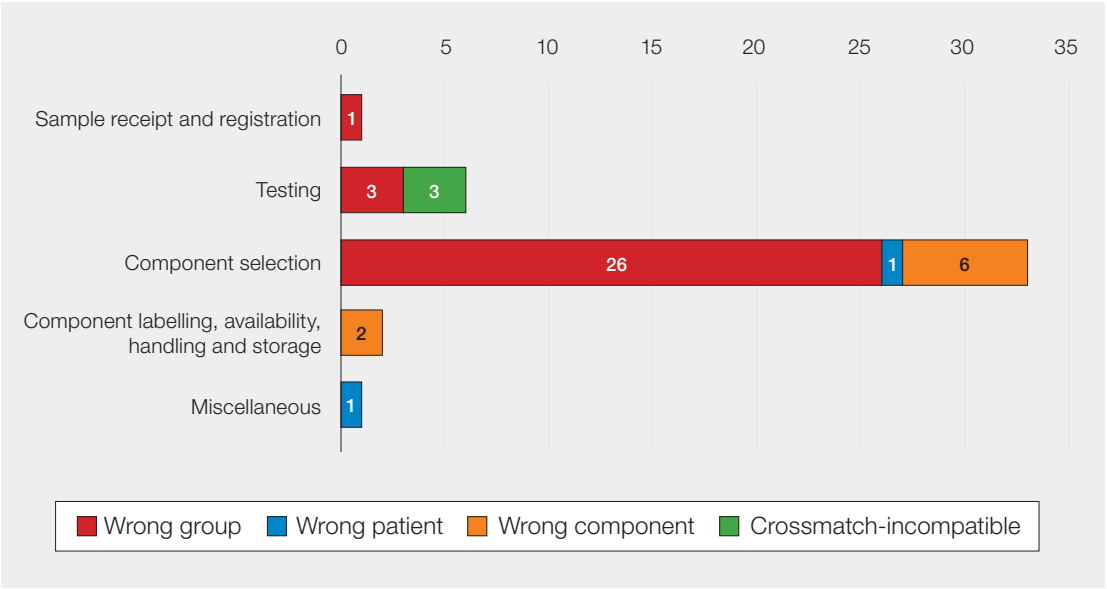
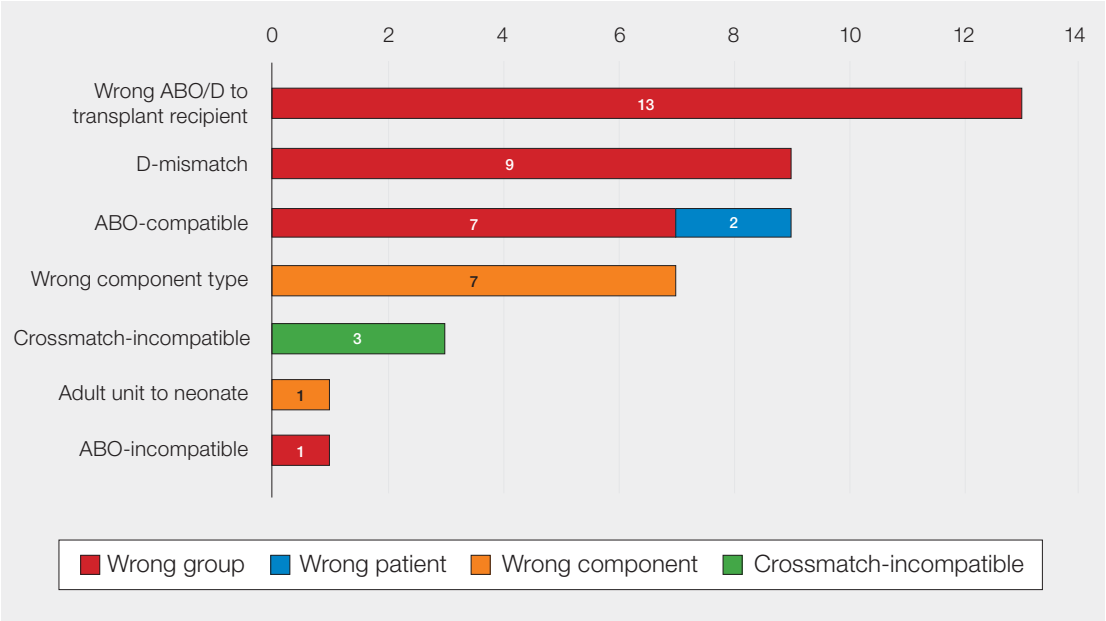


Figure 9.7: Laboratory IBCT-WCT errors by transfusion step (n=43)

Figure 9.8: Laboratory IBCT-WCT error by category (n=43)



There were 28 laboratory errors which led to the wrong ABO group being transfused, of which 13 were to transplant patients (9 HSCT and 4 SOT). All 13 transplant cases stated the errors were IT related with either the LIMS alerts being overridden by the BMS or limitations within the LIMS rules not clearly stating the requirements for this patient group.

Of the 13 transplant cases 10 had received a group O transplant but received a non-group O blood component. There were 4 cases where the transplant group had not engrafted, and 8 cases where the group had transformed into donor ABO group, but original group still given. See Chapter 25, Transfusion Errors in Transplant Patients for more information.

There were 9 laboratory errors which led to D-negative individuals receiving D-positive blood components, of which 3 were either to children or females of childbearing potential.

IT should be used as barrier in preventing IBCT-WCT errors but was stated as an influencing factor in 28/43 errors of which 21/28 led to the issue of components of the wrong ABO/D group. IT errors included LIMS alerts not heeded, lack of functionality within the LIMS, LIMS configured incorrectly, LIMS not updated correctly, and alert fatigue. Illustrative cases can be found in Chapter 15, Errors Related to Information Technology (IT) and the supplementary information for that chapter on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).

Laboratory errors continue to occur where basic knowledge should have prevented the error i.e., K-positive red cells to individuals of childbearing potential, and D-positive units issued to D-negative individuals (BSH Milkins et al. 2013).

Case 9.4: D-positive red cells issued to a D-negative patient due to cognitive bias

A female patient in their 60s was admitted in renal failure, and a request of two units of red cells was made to the transfusion laboratory. The patient had a flag for irradiated components on the LIMS but, due to local policy, this required confirming with the clinical area as several years had passed since their previous admission. The local team completed the required specific requirements form, but two forms were sent to the laboratory with disparity between the requirement for irradiated components. As a precaution the BMS updated the LIMS to state continue to give irradiated until the discrepancy could be resolved. The patient was group AB D-negative, but the BMS issued A D-positive red cells in error. IT alerts were overridden as the BMS assumed these were due to ABO substitution, and as their focus remained on the irradiated requirement, they did not detect the D-incompatibility.

This case highlights the impact that alert fatigue and cognitive bias can have on the ability of staff to perform routine tasks. Staff need to be aware of the potential for such biases, and where possible these must be prevented using simple interventions such as having clear, understandable, and actionable LIMS alerts to prevent component selection errors in the laboratory.

Specific requirements not met n=109

Error subcategory	Sample receipt and registration	Testing	Component selection	Component labelling, availability and handling and storage error
				
Number of error reports	**7**	**56**	**41**	**3***

plus 2 miscellaneous errors

Table 9.3: Laboratory SRNM errors in 2022

There were 109 laboratory errors which led to the patient receiving blood components which did not meet their specific requirements, with the majority due to testing errors (56/109) and component selection errors (41/109).

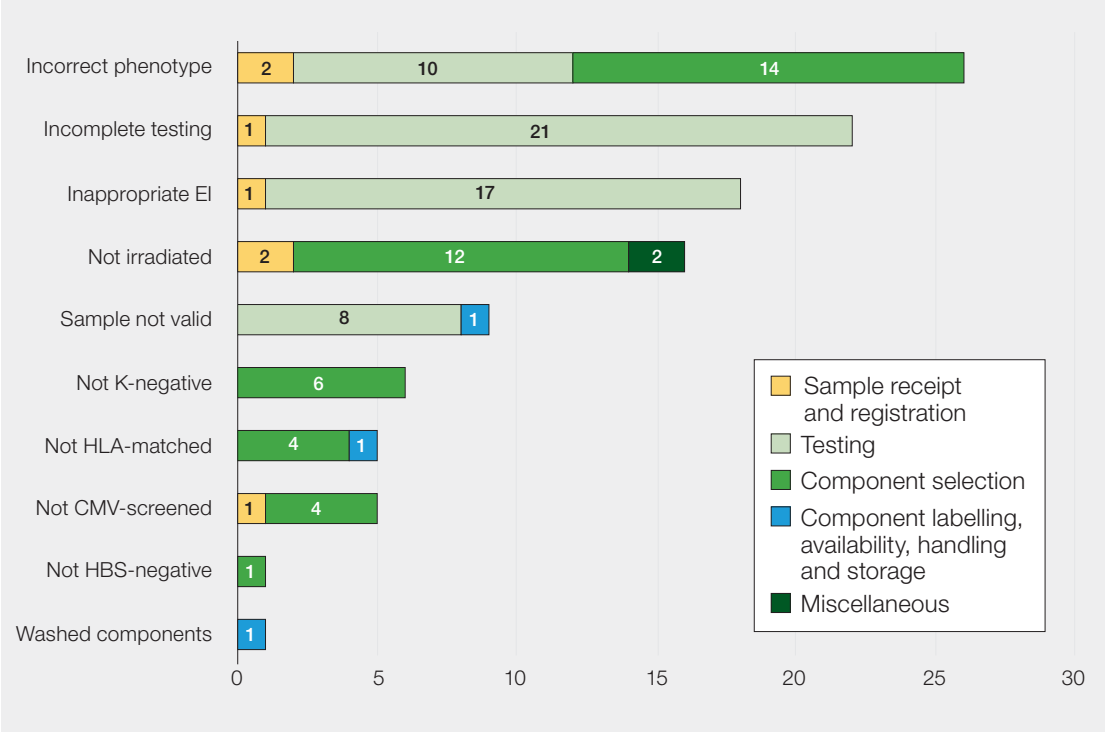


Figure 9.9: Laboratory IBCT-SRNM errors by transfusion step (n=109)

EI=electronic issue; HLA=human leucocyte antigen; CMV=cytomegalovirus

Testing errors n=56

Laboratory testing errors were due to inappropriate issue of components with incomplete testing prior to issue of components, 21/56 (37.5%), inappropriate use of electronic issue, 17/56 (30.4%), issue of red cells which were not phenotype/antigen-matched, 10/56 (17.9%) and testing performed on invalid sample (exceeding validity timing), 8/56 (14.3%). Where testing was incomplete, this was most often a failure to complete antibody identification, 7/21 (33.3%) or internal quality control, 7/21 (33.3%) prior to transfusion.

In 8/21 of the incomplete testing cases, the LIMS was not used correctly. Alerts were overridden and LIMS was set up incorrectly which allowed issue of units prior to completion of tests.

Case 9.5: Crossmatching errors resulted in a patient receiving uncrossmatched red cell units

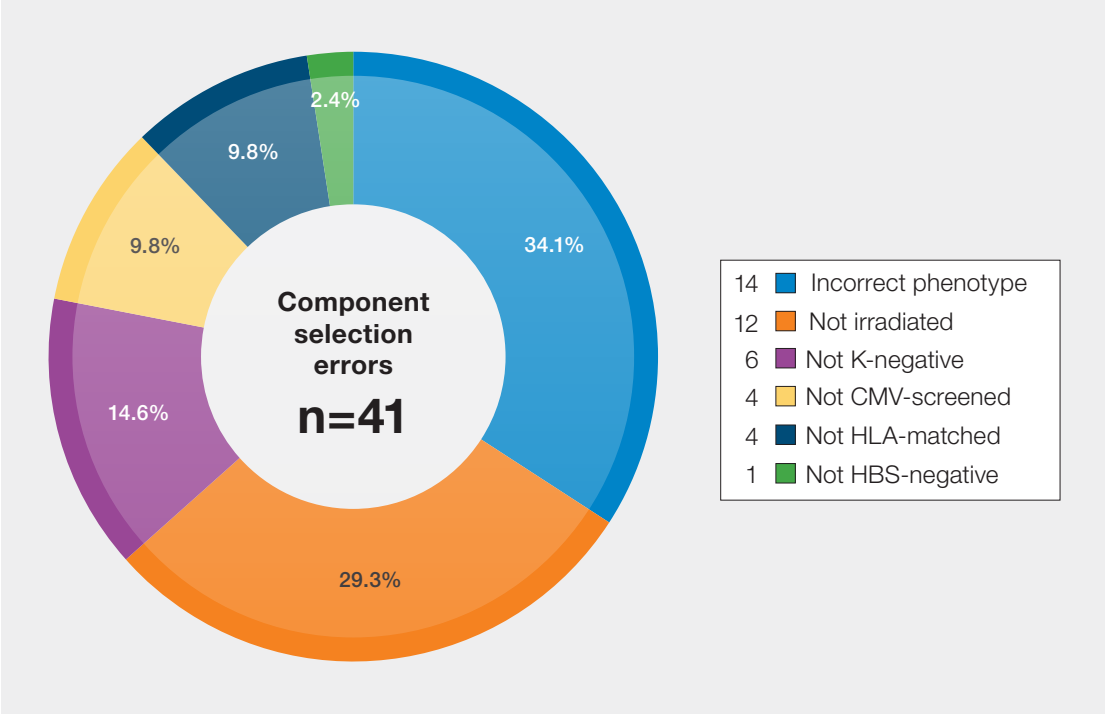
A BMS performed automated crossmatches for Patient 1 and Patient 2 on the blood grouping

analyser. In error they crossmatched the same two units of red cells against both patients. Patient 1 received the two crossmatched units, but Patient 2 received two uncrossmatched units. Later during the day, the BMS detected their error and retrospectively crossmatched Patient 2 with the correct two units, but this was after the transfusions had been completed. The staff member was a bank BMS with known stress-related issues but was working a supported day shift.

IBCT-SRNM testing errors, with illustrative figures are further discussed in Chapter 14, Laboratory Errors, plus a further case in the supplementary material for this chapter.

Component selection errors n=41

Figure 9.10: Laboratory IBCT-SRNM component selection errors 2022 (n=41)



CMV=cytomegalovirus; HLA=human leucocyte antigen

Component selection errors in the laboratory resulted in 14 patients receiving red cell units which were not phenotyped or antigen-negative for their requirements, 12 patients received blood components which were not irradiated, 6 patients of childbearing potential received K-positive red cells, 4 patients did not receive CMV-negative components, 4 patients received non-HLA selected platelets when required, and 1 patient received non HbS-negative red cells.

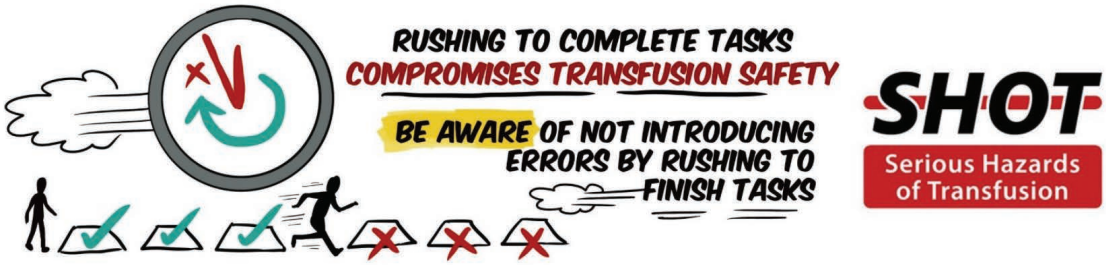
Of the 6 cases of K-positive red cells being issued to a person of childbearing potential, 4 resulted in sensitisation to the K antigen.

IT in laboratory IBCT-SRNM errors

Reporters stated that IT was involved in the error in 28/41 IBCT-SRNM cases including overriding of alerts, overreliance on alerts to 'stop' errors, alerts not updated, and issues around legacy data.

Learning points

- Laboratory staff must have an understanding of 'why' as well as 'how' particular patient groups require specific blood components, and the impact of not meeting these requirements
- LIMS rules and alerts must be used where possible to aid in decision making and prevent units being issued which do not meet a patient's specific requirements



Near miss cases n=167 (95 clinical, 72 laboratory)

Definition: A near miss event refers to any error which if undetected, could result in the determination of a wrong blood group or transfusion.

NM IBCT-WCT

In 2022 there were 115 NM IBCT-WCT, 81 occurred in the clinical area and 34 in the laboratory. A summary of these cases is shown in Figure 9.11.

There was a total of 19 NM ABOi transfusions in 2022 which is a large increase from to 5 NM ABOi in 2021, 6 originated in the laboratory and 13 in the clinical area. These were identified by a combination of patient involvement, staff vigilance and electronic PID.

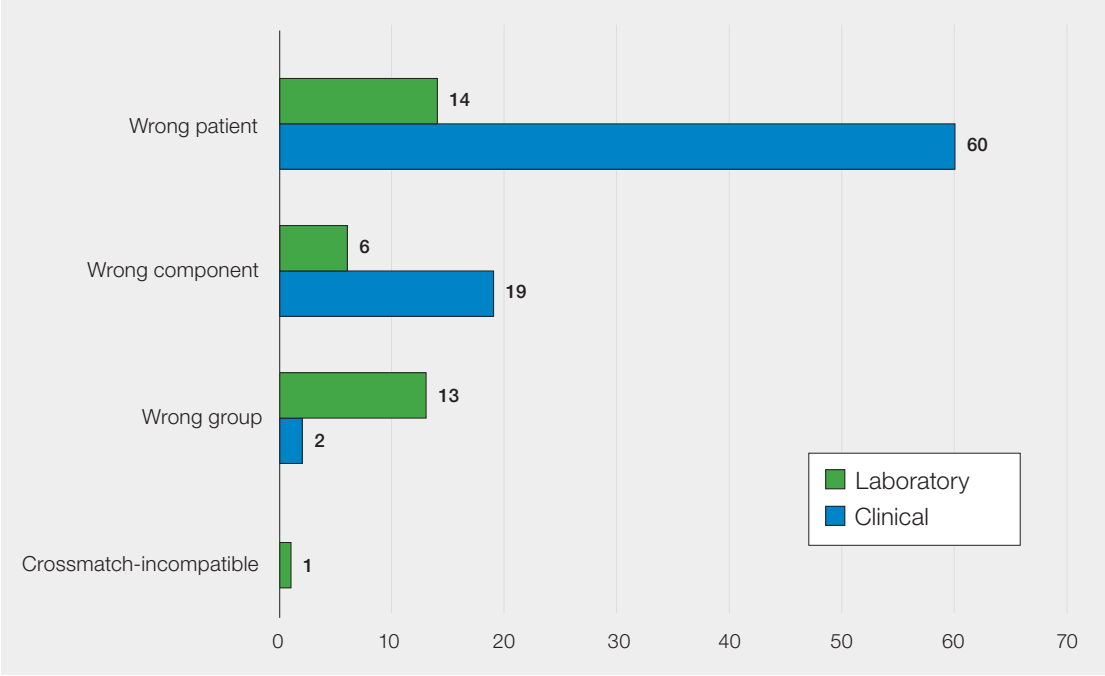


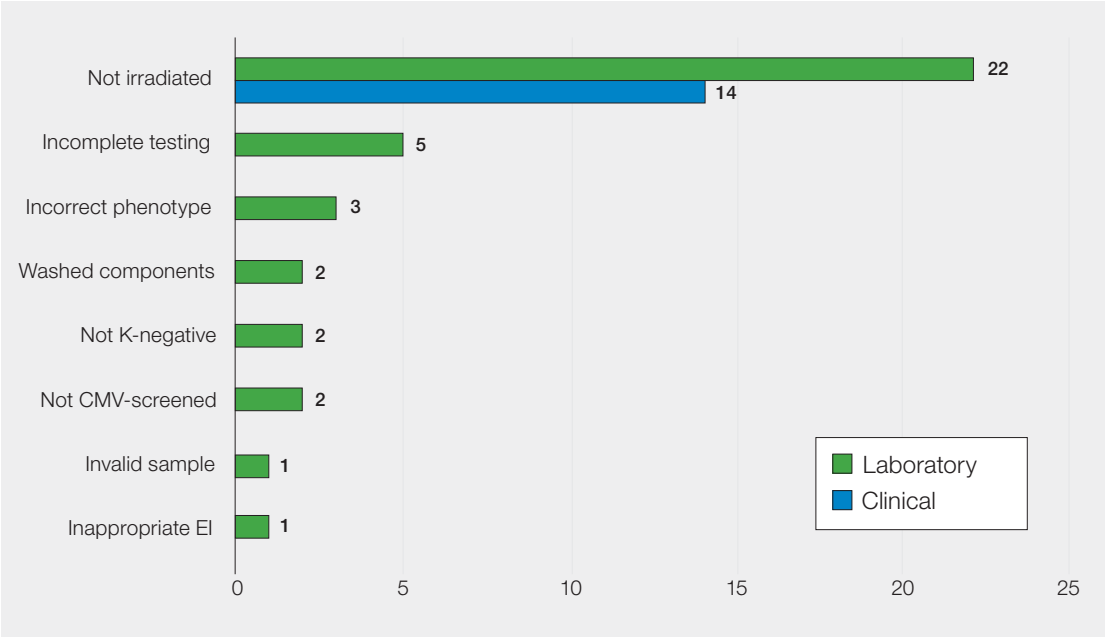
Figure 9.11: NM IBCT-WCT reported to SHOT in 2022 (n=115)

If unidentified most NM IBCT-WCT could have resulted in wrong patient transfusions, 74/115 (64.3%). Most clinical NM IBCT-WCT occurred at the collection stage, 54/81 (66.7%) and most laboratory NM IBCT-WCT occurred at the component selection stage, 12/34 (35.3%).

NM IBCT-SRNM

In 2022 there were 52 NM IBCT-WCT, 14 occurred in the clinical area and 38 in the laboratory. A summary of all NM IBCT-SRNM cases is shown in Figure 9.12.

Figure 9.12: NM IBCT-SRNM events in 2022 (n=52)



If unidentified most NM IBCT-SRNM could have resulted in patients receiving non-irradiated components, 36/52 (69.2%), all clinical NM IBCT-SRNM were in this category and were mostly due to failure to communicate the requirement to the laboratory. In 20/22 (90.1%) laboratory cases the LIMS system was involved, and flags were either not entered in a timely manner or were overridden.

Most clinical NM IBCT-SRNM occurred at the request stage, 13/14 (92.9%) and most laboratory occurred at the component selection stage, 25/38 (65.8%).

Conclusion

As with previous Annual SHOT Reports, one of the main factors leading to IBCT-WCT is the failure to positively identify the patient prior to pre-transfusion sampling or at the point of administration. Most errors occurred during routine transfusions where there is adequate time to carry out the essential safety checks. It is vital to carry out appropriate patient identification checks prior to any transfusion. Transfusion must never commence unless these checks have been completed as it is fundamental to patient safety. Omission of this critical part of the transfusion process can lead to patient harm and death.

Gaps in basic transfusion knowledge continue to contribute to errors and, in some cases, have led to major morbidity in patients. Training, competency, and skills development must be robust and of value, and not a tick box exercise, with sufficient staffing levels needed to maintain these skills. Training should be provided by sufficiently knowledgeable staff. There must be a balance between use of IT and sufficient levels of staff knowledge, reducing the overreliance of IT to 'catch' errors. Limitations within LIMS in relation to complex patient groups such as HSCT can lead to an incorrect blood group being issued or units not meeting specific requirements.

Knowledge gaps and sub-optimal training of clinical and laboratory transfusion staff have been identified to contribute to several instances of poor transfusion decision-making and errors have been seen with trained and competent staff as well (Mistry et al. 2019). It is imperative and timely to review the content, delivery, and assessment of transfusion education to all healthcare professionals. An increasing workload mismatched to staff availability has also been identified as contributory in many incidents. Staff should be supported, and laboratories and clinical areas should be sufficiently staffed to ensure workload is at a safe and acceptable level. Continual recruitment and retention issues, including staff vacancies and sickness, place a training burden on remaining staff and have a negative impact on the ability to train and maintain competency within staff groups.

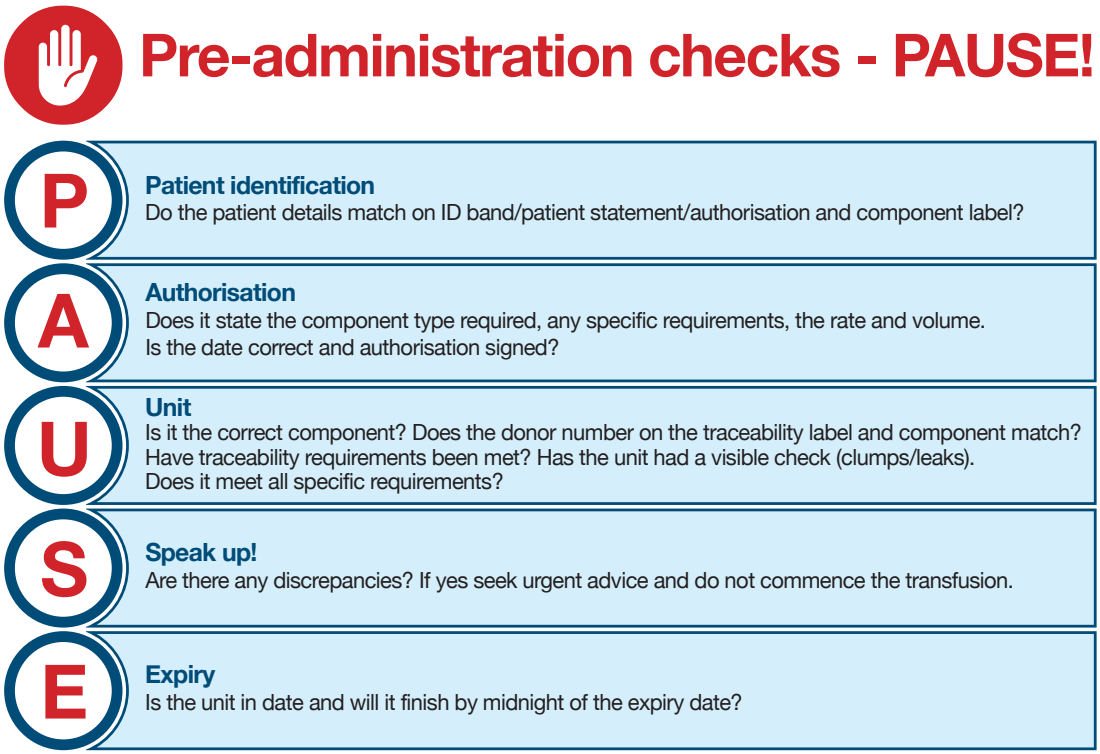
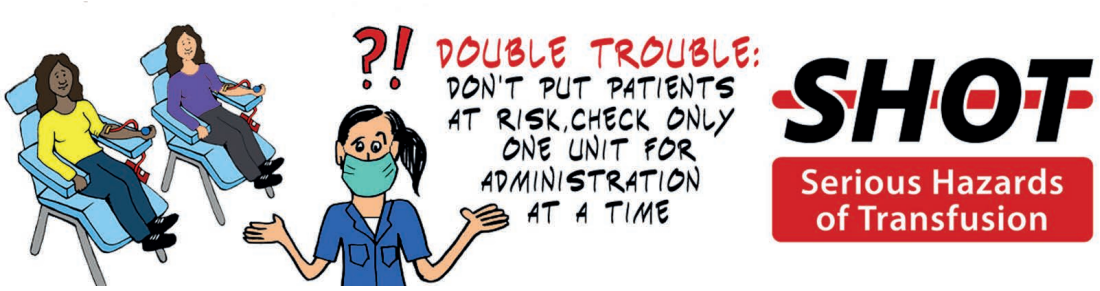


Figure 9.13: Pause and check pre-administration



Recommended resources

A just culture guide:
https://www.england.nhs.uk/wp-content/uploads/2021/02/NHS_0932_JC_Poster_A3.pdf

Use of checklists: Can Checklists Prevent Human Error?
https://www.exida.com/Blog/can-checklists-prevent-human-error

SHOT Video: ABO-incompatible transfusion events: Insights learned from SHOT Reports 2010-2019
SHOT Video: Transfusion errors in haemopoietic stem cell transplant recipients
https://www.shotuk.org/resources/current-resources/videos/

Safe Transfusion Checklist
https://www.shotuk.org/resources/current-resources/

SHOT Safety notice 02: Ensuring patient specific transfusion requirements are met
SHOT Safety notice 02: Gap analysis plan
https://www.shotuk.org/resources/current-resources/safety-notices/

SHOT Bites No. 1a and 1b: Incident investigation
SHOT Bite No. 9: Component Compatibility
SHOT Bite No. 10: Why 2 Samples?
SHOT Bite No. 12: Cognitive Bias
SHOT Bite No. 17: Learning from Near Misses (NM)
SHOT Bite No. 19: Human Factors
SHOT Bite No. 20: IBCT-SRNM
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Webinar: Near Miss and Incident Investigation
SHOT Webinar: Laboratory and IT
SHOT Webinar: Human Factors
https://www.shotuk.org/resources/current-resources/webinars/

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/)

CQC Learning from Never Events
https://www.cqc.org.uk/news/stories/learning-never-events

CAS alert bedside checks
https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102663

HSIB: Never events: analysis of HSIB's national investigations
https://www.hsib.org.uk/investigations-and-reports/never-events-analysis-of-hsibs-national-investigations/

UKTLC Standards 2023
https://www.shotuk.org/resources/current-resources/uktlc/

References

BSH Foukaneli T, Kerr P, Bolton-Maggs PHB, et al. Guidelines on the use of irradiated blood components. *Br J Haematol*. 2020;**191(5)**:704-724. https://doi.org/10.1111/bjh.17015 [accessed 05 May 2022].

BSH Milkins C, Berryman J, Cantwell C, et al. Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. *Transfus Med* 2013;**23(1)**:3-35. http://onlinelibrary.wiley.com/doi/10.1111/j.1365-3148.2012.01199.x/full [accessed 27 April 2023].

BSH Robinson S, Harris A, Atkinson S, et al. The administration of blood components: a British Society for Haematology Guideline. *Transfus Med* 2018;**28(1)**:3-21. http://onlinelibrary.wiley.com/doi/10.1111/tme.12481/full [accessed 28 April 2023].

Department of Health. Safe transfusion practice: use a bedside checklist (CAS) CEM/CMO/2017/005 (2017). https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102663 [accessed 24 April 2023]

Elliot J, Narayan S, Poles D, et al. Missed irradiation of cellular blood components for vulnerable patients: Insights from 10 years of SHOT data. Transfusion. 2021;**61**(2):385-392.

Mistry H, Narayan S, Spinks C, et al. Are competency assessments alone sufficient to reduce transfusion errors? (2019). International Forum on Quality and Safety in Healthcare, Glasgow, Conference Proceedings, Page 252.

Narayan S (Ed), Poles D, et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2018 Annual SHOT Report (2019). https://www.shotuk.org/shot-reports/ [accessed 08 May 2022].

Swarbrick N, Poles D and Narayan S. Learning from ABO-incompatible red cell transfusion never events - Analysis of SHOT data 2010-2021. Oral abstracts book BSH23-OR23. Br J Haematol. 2023;201:4-27. https://onlinelibrary.wiley.com/doi/10.1111/bjh.18718 [accessed 21 June 2023].

Handling and Storage Errors (HSE) n=272

10

Authors: Heather Clarke, Nicola Swarbrick and Victoria Tuckley

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.

Abbreviations used in this chapter

HSE	Handling and storage error	**NHS**	National Health Service
BSQR	Blood Safety and Quality Regulations	**NM**	Near miss
ED	Emergency department	**OPEL**	Operational pressures escalation levels
GP	General practitioner	**SOP**	Standard operating procedure

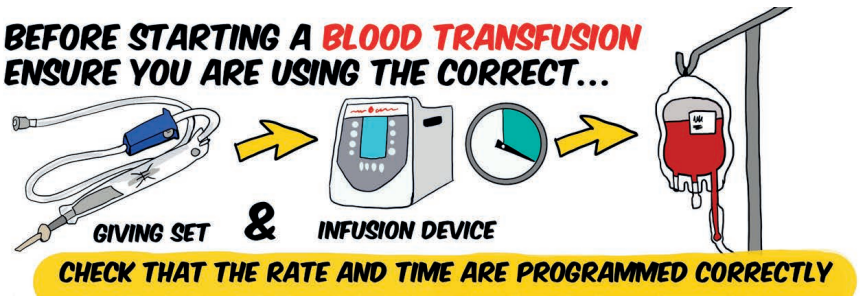
Key SHOT messages

- Clinical errors contribute to more than 80% of HSE errors reported in 2022 with technical administration errors and cold chain errors accounting for most (85.3%) of the clinical HSE errors
- Of the laboratory HSE errors, non-compliance with cold chain and inappropriate return to stock/quarantine were the most common (55.5%) errors reported

Recommendations

- A pre-administration checklist should include checking that the correct giving set is used and that the pump (if used) is set correctly
- To avoid potential patient harm from excessive time to transfuse errors, patients must be monitored during all blood transfusions. Increased education to clinical staff about this must be included in the blood transfusion training and competency-assessments
- Wherever possible cold chain compliance should be controlled by laboratory information management systems and/or electronic blood-tracking systems. Laboratory procedures should be in place for the accurate return of components back into stock and cover quarantine procedures, including information about cold chain compliance

Action: All staff involved in transfusions, laboratory management

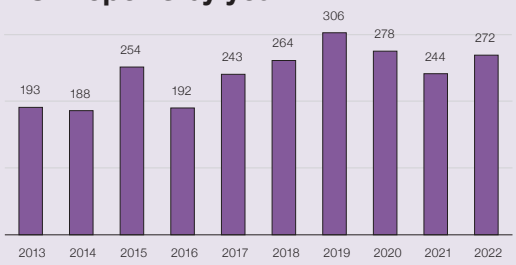


SHOT
Serious Hazards of Transfusion

Headline data 2022

Number of reports n=272
Deaths n=0
Major morbidity n=0

HSE reports by year



Demographic data

Male n=124
Female n=130
Unknown n=18

Adults n=228
Paediatric n=22
Unknown n=22

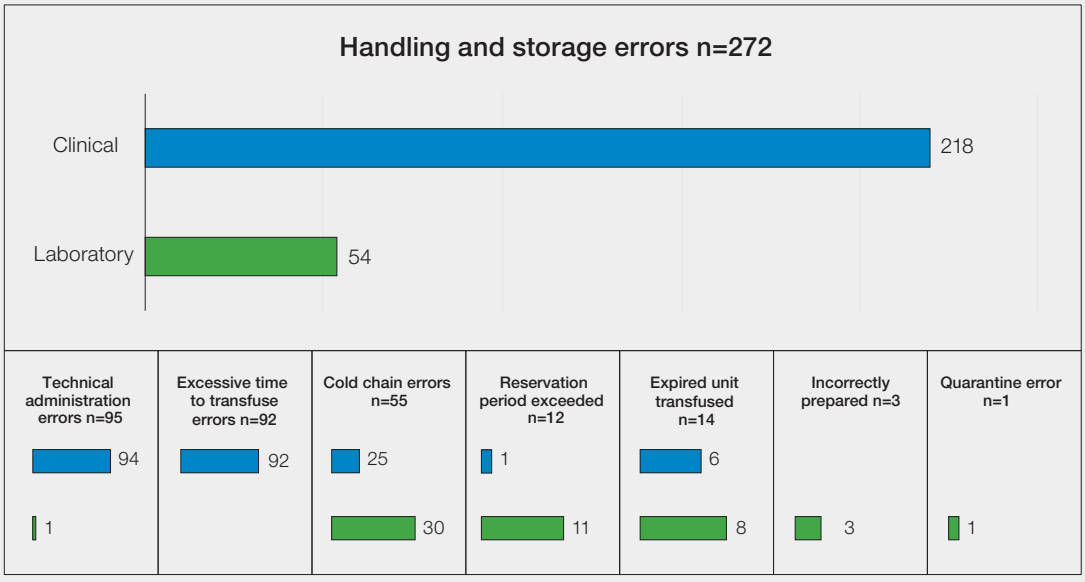
Blood component data

Red cells n=226
Platelets n=25
Plasma n=14
Cryoprecipitate n=1
Multiple components n=6

Introduction

There were 272 cases reported in 2022. HSE errors accounted for 244/3161 (7.7%) reports in 2021 (Narayan et al. 2022) and for 272/3499 (7.8%) in 2022. Clinical errors accounted for 218/272 (80.1%) and laboratory errors for 54/272 (19.9%). The distribution of clinical and laboratory errors are illustrated in Figure 10.1.

Figure 10.1: Breakdown of 2022 handling and storage error (HSE) reports (n=272)



Deaths related to transfusion n=0

There were no deaths reported that were related to errors associated with HSE in 2022.

Major morbidity n=0

There were no HSE cases reported in 2022 that resulted in major morbidity.

Clinical errors

The number of clinical errors has seen a slight rise (from 190 reported in 2021 to 218 in 2022) and

there has been an increase in technical administration errors (94/218 in 2022 and 73/190 in 2021). The percentage of excessive time to transfuse errors is the same as in the last Annual SHOT Report at around 42% (92/218 and 79/190 in 2021). Technical administration errors have been further categorised below in Table 10.1.

Technical administration error	Number of cases
Pump	58
Giving set	28
Same venous access used	2
Staff not trained	1
Miscellaneous	5
Total	**94**

Table 10.1: Clinical technical administration errors (n=94)

Of the 58 administration pump errors, 30 incidents related to the pump being set incorrectly despite a correct prescription. There were 28 errors related to giving sets, of which 26 were wrong giving set used, 1 clamp malfunction and 1 giving set error due to the cannula positioned in the antecubital fossa which resulted in the transfusion being administered over 47 minutes instead of over the 2 hours as prescribed. Those used in these incidents were a combination of fluid and drug giving sets. The trend for these errors continues to be similar to previous years.

Excessive time to transfuse errors mostly occurred during routine hours (08:00-20:00) 57/92 (61.6%) which was consistent with last year's data and the majority (34/57) were routine requests, with 16/57 incidents of urgent/emergency requests.

Case 10.1: Unit of red cells transfused exceeding time allowed after removal from controlled storage

Two units of red cells were removed in a cool box validated for 6 hours at 22:13 for a patient in the ED. The first unit was transfused in the ED over 3 hours and then the patient was moved to a ward. The second unit was transferred with the patient in the cool box to the ward. The second unit was started after being in the cool box for 5.5 hours and transfusion was not completed until 8.5 hours after removal from the blood refrigerator.

On investigation the patient was being transfused in the ED but was not actively bleeding. The blood prescription was for two red cell units each to be transfused over 3 hours. Both units were removed from the refrigerator at the same time by a porter who was used to requests from ED for bleeding patients requiring more than one unit to be transfused quickly and would collect and pack in the 6-hour cool box used for massive haemorrhage activations. There was no documentation to suggest that only one unit was to be collected when two were prescribed.

ED at the time were operating under OPEL 4 conditions (pressure in the local health and social care system continues to escalate leaving organisations unable to deliver comprehensive care). The patient was symptomatic with anaemia caused by severe iron deficiency. There was no facility to transfuse the patient in a more appropriate setting for the next 4 days, so the GP sent the patient to the ED for transfusion.

There was no evidence from the patient's notes of the time when the patient was transferred from the ED to a ward, or that the receiving ward knew how long the blood had been in the 6-hour cool box. The prescription chart should have identified the time the first unit had been commenced and that it was not possible to complete the second unit within the 6 hours from removal from the blood refrigerator, but this was not noticed.

No adverse reaction was reported for the patient.

Case 10.2: Acknowledging continuing excellence case

An NHS organisation has submitted report of an innovation project to address previous red cell transfusions that went over 4 hours, including >5-hour episodes that were reportable to SHOT. Transfusion take-down tags were designed, trialled and produced to increase awareness in the clinical area, to inform all staff in the vicinity and empower the patient, to prompt an appropriately

trained member of staff to take the red cell unit down within 4 hours of removal from the cold chain. The tags increase compliance with the BSQR (BSQR 2005) and reduce the risk of potential bacterial infection. From the feedback received, all patients during the trial period understood the concept and felt this helped them prompt a staff member to complete their transfusion and take the unit down if it is nearing the 'take down time'. The patients reported feeling safer during their transfusion. There were no further incidents of transfusions exceeding 4 hours during the trial usage of the tags.

This is an excellent example of sharing good practice about a process that has been put in place to potentially eradicate excessive time to transfuse errors.

Figure 10.2: Transfusion take-down tag

This registered design is re-produced with permission of Royal Cornwall Hospitals NHS Trust who can be contacted for any further information - Rch-tr.TMGTX@nhs.net

Laboratory errors

The number of laboratory errors were the same in 2022 as the 2021 Annual SHOT Report with 54 errors. Most of the errors were cold chain errors (30/54). Cold chain errors have been further categorised in Table 10.2.

Cold chain error	
Inappropriate return to stock	12
Refrigerator/equipment failure	9
Incomplete cold chain	4
Transport and delivery	3
Inappropriate storage	2
Total	**30**

Table 10.2: Laboratory cold chain errors (n=30)

Of the 9 refrigerator/equipment failure errors, 4 involved the temperature monitoring system and of the 12 inappropriate returns to stock errors, 5 involved the blood-tracking system.

Where units were inappropriately returned to stock these were following temperature excursions due to refrigerator failures, data logger failures, where IT alerts were overridden, or the quarantine process was not followed.

Where units were transfused following a refrigerator failure these were due to IT alarms being ignored, data logger failure or equipment inappropriately returned to use following temperature excursions and/or equipment failure.

Case 10.3: Unit of red cells transfused with no documented cold chain for 36 hours

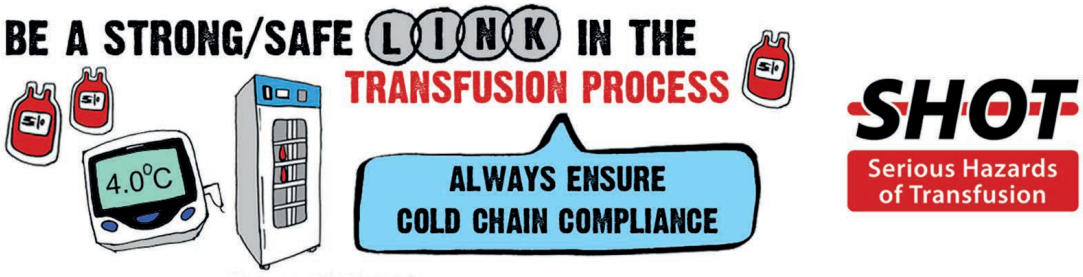
A unit of emergency O D-negative red cells was taken to the ED. It was not used and returned to the laboratory 2 days later. This was returned to stock instead of being put into quarantine as there was no documented cold chain for the 36 hours the red cell unit was out of the laboratory. The unit was then issued to another patient and transfused. The error was only picked up by chance when staff looked for the missing compatibility tag.

On investigation, it was identified that the quarantine SOP and paperwork needed clarification.

No adverse reaction was reported for the patient who received the red cell unit.

Learning points

- Laboratories must have clear SOP for the appropriate and timely return of blood components back into stock and these must include quarantine procedures
- The temperature monitoring systems in use by laboratories should be checked regularly, and should include testing the full functionality of the system to ensure the safe storage of blood components



Near miss HSE cases n=140

There were 140 NM HSE cases reported in 2022, which is the same as reported in 2021. There were 110/140 (78.6%) that originated in the clinical area and 30/140 (21.4%) in the laboratory. The NM HSE cases primarily involved cold chain errors 108/140 (77.1%), followed by 10/140 (7.1%) cases of technical administration errors, 9/140 (6.4%) cases of reservation period exceeded and 7/140 (5.0%) cases where expired units were almost transfused to patients.

Observations from human factors reports

On review of the human factors attached to the administration errors reported this year, there appears to be two common themes. These being a mismatch between workload and staff provision along with issues or gaps with staff skill or knowledge which have worsened post pandemic. Similar themes are also evident in the laboratory workforce from the errors reported. Adequately trained and competent staffing levels are paramount to ensuring patient safety at all points in the transfusion process both clinically and in the laboratory.

Conclusions

By working collaboratively, staff in the laboratory and clinical area can ensure the safety of the blood components that are transfused. Staff need to be aware of the correct rate and duration of transfusions. Other factors, such as staffing levels and appropriate working conditions to ensure safe patient monitoring should be addressed. SHOT reinforces that all staff who participate in the handling and storage of blood components should adhere to correct procedures in accordance with local transfusion policies. Transfusion policies should be easy to access and contain useful information based on the most current published guidance available (BSH Robinson et al. 2018). By embedding these policies in working practice, safer patient care overall can be achieved.

Recommended resource

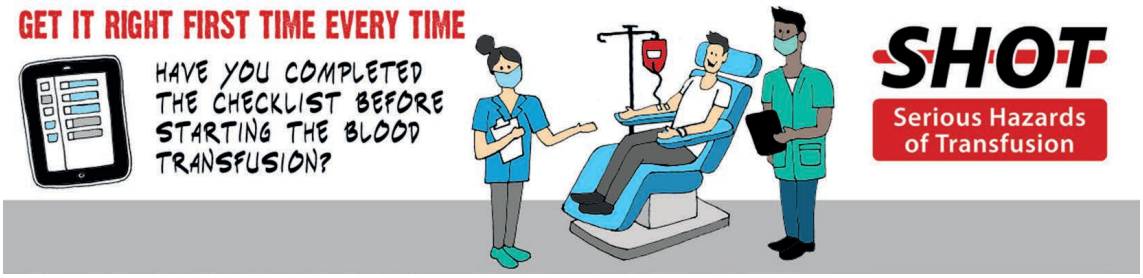
Patient Blood Management - Blood assist app
Apple (https://apps.apple.com/gb/app/blood-assist/id1550911130)
Google play (https://play.google.com/store/apps/details?id=uk.nhsbt.bloodassist)
Web based (https://www.bloodassist.co.uk/)

References

BSH Robinson S, Harris A, Atkinson S, et al. The administration of blood components: a British Society for Haematology Guideline. *Transfus Med* 2018;**28(1)**:3-21. http://onlinelibrary.wiley.com/doi/10.1111/tme.12481/full [accessed 28 April 2023].

BSQR. The Blood Safety and Quality Regulations ISBN 0110990412 (2005). http://www.legislation.gov.uk/uksi/2005/50/contents/made [accessed 28 April 2023].

Narayan S (Ed), Poles D, et al. on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2021 Annual SHOT Report (2022). https://www.shotuk.org/shot-reports/ [accessed 27 April 2023].



Avoidable, Delayed or Under/ Overtransfusion (ADU) and Incidents Related to Prothrombin Complex Concentrate (PCC) n=365

11

Authors: Paula Bolton-Maggs, Simon Carter-Graham, Catherine Booth and Josephine McCullagh

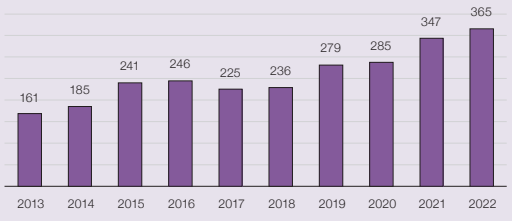
Abbreviations used in this chapter

ADU	Avoidable, delayed or under/overtransfusion
AF	Atrial fibrillation
AML	Acute myeloid leukaemia
BMS	Biomedical scientist
BP	Blood pressure
BSH	British Society for Haematology
CAS	Central alerting system
CPR	Cardio-pulmonary resuscitation
CT	Computed tomography
CML	Chronic myeloid leukaemia
DIC	Disseminated intravascular coagulation
DOAC	Direct acting oral anticoagulant
DOB	Date of birth
ECP	Extracorporeal photopheresis
ED	Emergency department
EWS	Early warning score
FBC	Full blood count
FFP	Fresh frozen plasma
GI	Gastrointestinal
GP	General practitioner
GVHD	Graft-versus-host disease
Hb	Haemoglobin
HSE	Handling and storage errors
ICH	Intracranial haemorrhage
ICU	Intensive care unit
ID	Identification
INR	International normalised ratio
IT	Information technology
ITP	Immune thrombocytopenia
LMWH	Low molecular weight heparin
IV	Intravenous
MAU	Medical admissions unit
MH	Major haemorrhage
MHP	Major haemorrhage protocol
NCA	National comparative audit
NHS	National Health Service
PCC	Prothrombin complex concentrate
SCD	Sickle cell disease
TACO	Transfusion-associated circulatory overload
UK	United Kingdom
VKA	Vitamin K antagonist

Headline data 2022

Number of reports n=365
Deaths n=15
Major morbidity n=10

ADU reports by year



Demographic data

Male n=161
Female n=196
Unknown n=8

Adults n=313
Paediatric n=40
Unknown n=12

Blood component data

Red cells n=263
Platelets n=43
Plasma n=14
Multiple components n=21
PCC n=21
Granulocytes n=1
Unknown n=2

Overview of ADU Cases

- Delayed transfusions n=205
- Avoidable transfusions n=121
- Under or overtransfusion n=18
- Incidents related to PCC n= 21

The number of reports submitted for delayed and avoidable transfusions has increased compared to 2021 (179 and 116 respectively). The under/overtransfusion category has decreased from 34 in 2021 partly due to a change in definition which can be found in that section.

Problems with staffing and workload were identified in many reports. Responses to human factors questions from reporters have highlighted issues relating to a mismatch between staffing and workload, as well as poor communication. These results are discussed further in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/). Relevant to this, the Healthcare Safety Investigation Branch (HSIB) has published an interim report on the effect of staff well-being on patient safety, noting the extreme stress in ED (HSIB 2023) which probably impacts risk of errors. A study from the University of Bath also notes serious problems with staff stress and retention (Weyman et al. 2023).

The key SHOT messages and recommendations are covered in the respective chapters for each category.

Deaths related to transfusion n=15

There were 13 deaths related to delays, and 2 related to PCC administration.

Of the deaths related to delayed transfusion, there was 1 death that was definitely related (imputability 3), 3 probably related (imputability 2), and 9 possibly related (imputability 1). The 2 deaths where patients with ICH did not receive PCC were possibly related (imputability 1).

Major morbidity n=10

Major morbidity was cited in 10 reports.

- Delays n=6
- Undertransfusion n=1
- Overtransfusion n=1
- PCC n=2

Near miss cases n=14

- Delayed transfusion n=6
- Avoidable transfusion n=6
- Under or overtransfusion n=1
- PCC n=1

Problems with MHP activations n=64

In 64 cases in these categories, activation of the MHP was reported (half, 32, of these occurred out-of-hours).

- 41 delays (2 deaths both imputability 1, possible)
- 21 avoidable including 16 instances with use of O D-negative red cells
- 1 overtransfusion
- 1 PCC

Further information about these cases can be found in the respective chapters as well as in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Recommended resources

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

UKTLC: Capacity planning guidance May 2021
https://www.shotuk.org/resources/current-resources/uktlc/

References

HSIB. Interim report explores impact of staff wellbeing on patient safety. (2023) https://www.hsib.org.uk/news-and-events/interim-report-explores-impact-of-staff-wellbeing-on-patient-safety/ [accessed 28 April 2023].

Weyman A, Glendinning R, O'Hara R, et al. Should I stay or should I go? NHS staff retention in the post COVID-19 world: challenges and prospects. (2023) https://www.bath.ac.uk/publications/should-i-stay-or-should-i-go-nhs-staff-retention-in-the-post-covid-19-world/attachments/NHS-staff-retention-IPR-report.pdf [accessed 28 April 2023].

11a Delayed Transfusions n=205

Authors: Paula Bolton-Maggs, Josephine McCullagh and Simon Carter-Graham

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).

Key SHOT messages

- Delays accounted for the largest number of transfusion-related deaths across all SHOT reportable categories in 2022
- Poor communication at multiple points during the patient's care is common and exacerbates delays
- Patients should not die from anaemia or bleeding: irregular antibodies delay provision of compatible components and should be discussed with clinicians as soon as known
- Delayed recognition of bleeding increases morbidity and mortality. Low blood pressure should alert clinicians to consider haemorrhage
- MHP are either not activated when indicated or not followed correctly
- Staffing problems contribute to delayed transfusions

Recommendations

- Hospitals should review their MHP and test them with drills to ensure they are fit for purpose. All steps should be tested by simulation from end-to-end involving the transfusion practitioner and transfusion laboratory manager
- All MHP activations should be followed by a debrief to identify what went well and what did not, and this should include transfusion laboratory staff
- The MHP alert should require a single call to a dedicated telephone line which is then cascaded to all relevant departments
- Hospitals should review their staffing capacity plans for transfusion laboratories. This is an essential service where understaffing can contribute to adverse patient outcomes
- Laboratories must ensure their transfusion staff are contactable at all times for emergencies
- Hospitals should review their use and training of agency staff in areas where blood transfusion may take place
- When there are delays due to antibodies, or difficulty obtaining second samples etc., and the need for transfusion is urgent, laboratory staff should offer a 'Plan B' indicating what can be given immediately (O D-negative or O D-positive red cells) with appropriate monitoring

Action: Hospital transfusion committees

Introduction

Reports of delayed transfusions continue to increase (Figure 11a.1). Patients may die and this prompted publication of a CAS national alert, with actions for hospitals including review of their policies and procedures (SHOT 2022).

In 2022 many problems were related to inadequate staffing in both clinical and laboratory areas. The use of agency staff, inadequate skill mix, and poor transfusion training were contributory. ED were often reported as 'very busy' and the number of overall errors reported from the ED continues to increase (Figure 2.7 in Chapter 2: Participation in UK Haemovigilance).

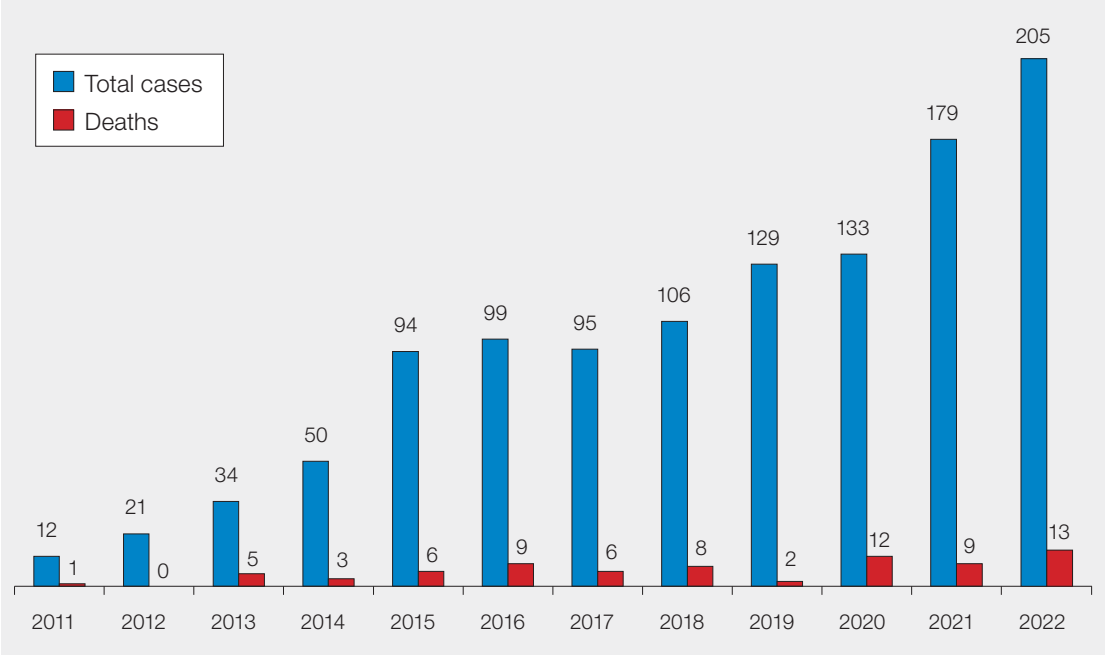


Figure 11a.1: Delayed transfusions by year 2011 to 2022

Key factors in delays

There were 205 delayed transfusions reported in 2022. The primary causes of these delays are detailed in Figure 11a.2. The most common cause of delays were communication, logistical and technical issues, however many cases had multiple errors.

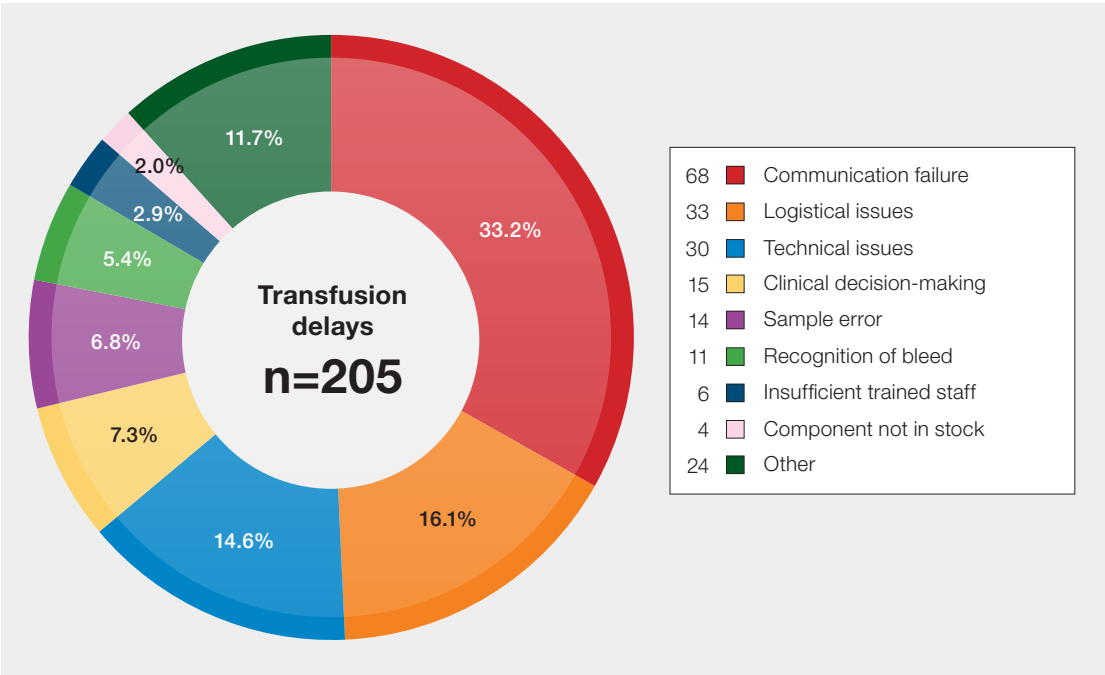


Figure 11a.2: Primary causes of delayed transfusions in 2022 (n=205)

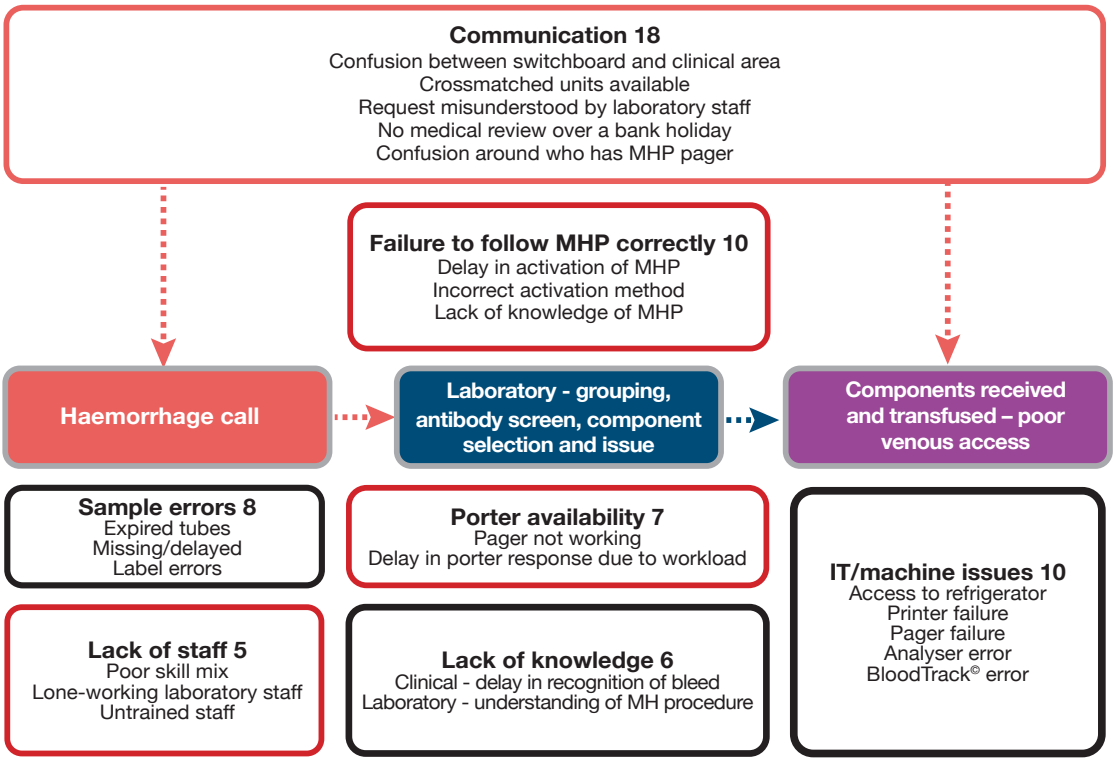
Gastrointestinal bleeding was reported in 27 cases; 5 deaths were related to the delayed transfusion. Recognition of bleeding and timely management is key to prevent delays in these patients.

Irregular antibodies often lead to delayed provision of red cells, noted in 24 cases of delay. Four patients died and of those 1 death was definitely related (imputability 3, see Case 11a.1), 1 death was probably related (imputability 2) and 2 were possibly related (imputability 1, see Case 11a.3).

Eleven cases resulted from delays in laboratory referral to a specialist laboratory.

MHP-related errors continue to cause delays. There were 41 reports of MHP activation including 6 obstetric cases and 14 cases of GI haemorrhage.

Figure 11a.3: Key factors contributing to delayed transfusions in 41 cases of major haemorrhage



MHP=major haemorrhage protocol; IT=information technology

HF contributing to delayed transfusion

- Communication problems were reported in 110 cases and were the most important contributory factor in 24 (21.8%)
- Failures in team function were cited as contributory in 62 (56.4%) cases
- Mismatch between workload and staff provision at the time of the incident was reported in 53 (48.2%)

In addition to answers in the HF section of the questionnaire, a review of cases demonstrated:

- Staff shortages were reported in 5 cases, and poor skill mix in 7 cases
- Busy units and departments were reported in 24 cases, 13 in ED or MAU and 4 in the laboratory
- Lone-working BMS in 6 cases
- Lack of transfusion-trained staff able to administer the transfusion in 12 cases
- Delayed escalation of an increasing EWS was noted in 3 cases

In 30 cases multiple factors were reported.

Learning points

- Urgent transfusions should not be delayed by lack of staff. The need should be escalated to acquire competent staff, or the patient transferred to a location where transfusion can be safely administered
- A pragmatic approach is required to risk-assess and train locum/agency staff to perform transfusion activities to ensure safe delivery of transfusion services

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Deaths related to transfusion n=13

There were 13 deaths reported due to delays. This compares with 9 deaths related to delays in 2021 and 12 in 2020.

- 1 was definitely related (imputability 3)
- 3 were probably related (imputability 2)
- 9 were possibly related (imputability 1)

In 4 cases the patients had irregular antibodies contributing to the delayed transfusion and death.

Case 11a.1: Delayed red cell transfusion and death in a patient with GI haemorrhage

An elderly person (known anaemia due to CML) was seen in the ED at 18:20 with coffee-ground vomit. Blood samples ('routine') were received in the laboratory 3 hours later (21:24), Hb 58g/L. Red cell units were requested (not identified as urgent) but irregular antibodies were detected, delaying provision of compatible units until 23:00. The MHP was activated at 23:40 and due to communication failures, the patient received emergency group O D-negative units (possibly incompatible); the patient was hypovolaemic, arrested and died.

Review noted that the ED was very busy. Transfusion and MHP training had been suspended due to COVID-19 pressures. Similar cessation of training was noted in another death due to delayed transfusion.

In 2 cases delayed provision of platelets contributed to death.

Case 11a.2: Delayed platelet transfusion in a patient with severe thrombocytopenia due to AML

An elderly man with AML had a Hb of 65g/L and platelets $2x10^9$/L at an outpatient visit. He was contacted to return for transfusion. Platelets were ready at 15:30. He attended the ED at 17:00, and fell at 19:30 sustaining a head injury. He was transfused platelets at about 22:30. He died of a subdural haematoma with brain herniation as a result of traumatic head injury following the fall. The 5-hour delay in platelet transfusion was considered contributory.

The ED was very busy and there were gaps in communication. The local review concluded that the haematology day unit was a more appropriate location for patients to wait for review of their blood counts to avoid such delays.

The second case is included in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Learning points

- Failure to communicate the urgency of requests leads to delays in blood component provision. Ensure that the request for samples and blood components is clear and that the urgency is stated
- Transfusion laboratory managers could consider education of clinical staff with a traffic light system detailing the meaning and time to red cell availability for 'emergency', 'urgent' and 'routine' requests
- Access to emergency components (red cells and platelets) should be clearly communicated to staff and form part of their MHP training

Case 11a.3: Delayed transfusion and death - sample errors and failure to recognise GI bleeding

A woman in her 60s, recently in hospital with myocardial infarction, was readmitted 3 weeks later at 04:10 with recurrent chest pain, vomiting and acute anaemia. Her Hb had fallen from 113g/L to 68g/L over 3 weeks. She was thought to have further myocardial infarction secondary to anaemia.

The first sample at 04:30 was rejected; transposed first and last names. The same error was repeated with a second sample at 08:26. The BMS made several unsuccessful attempts to contact the ED, unanswered telephone calls. Eventually new samples were received at 11:39; two red cell units were available at 13:36. However, the MHP was activated at 13:04 (Hb 34g/L) and four units of emergency O D-negative red cells were used. Despite this she died. Her anticoagulants had not been reversed and the GI bleeding was not identified until the very low Hb was recorded. A serious incident investigation was undertaken to establish what caused the delay in identification of GI bleeding; noted that the patient's first language was not English, and this may have been a contributory factor.

Another death in an elderly man with major GI bleeding occurred as a direct consequence of delayed transfusion. The pre-transfusion Hb was 38g/L, there was poor communication, confusion and a failure to escalate by the junior doctor.

Learning points

- Recognition of bleeding is crucial for timely and appropriate treatment
- GI bleeding is associated with a high risk of death in elderly patients. Low blood pressure is an important sign. Bleeding should be excluded before assuming the low BP is caused by something else
- Good handover information is essential especially when serious bleeding occurs out-of-hours
- It is essential to correctly identify patients and their samples; this can be a particular problem where the patient's first language is not English, and where there is also an alternative alphabet (such as Arabic) so that the spelling used in English may not be consistent on different occasions

Case 11a.4: Delayed transfusion due to haemolysis contributes to death

An elderly woman was admitted to the ED at 20:06 following collapse at home (chemotherapy 10 days earlier). Hypotension improved with IV fluids. Venous blood gas Hb was 54g/L. Blood tests were uninterpretable due to haemolysis (including blood group, antibody screen and crossmatch). The haematology consultant advised immediate transfusion of emergency group O red cells with steroid cover. At 03:13 prednisolone was given but no red cells. She suffered cardiac arrest at 05:10 with successful resuscitation but resuscitation was not attempted after another cardiac arrest. Death was considered 'possibly related' to this delay.

A further case is included in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/). In total there were 24 cases of delays related to irregular antibodies in the patient.

Learning points

- When patients have irregular antibodies and require urgent transfusion clinicians should liaise with the transfusion laboratory staff and haematologist
- A 'Plan B' should be in place, i.e., use group O D-negative or positive (with close monitoring and steroids) rather than risk patient death from severe anaemia. Transfusion laboratories should have an SOP for concessionary release

Additional case reports of deaths possibly related (imputability 1) to transfusion can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Major morbidity n=6

Of these, 2 cases involved young adults with SCD who deteriorated as a result of delayed transfusion.

A further case involved a patient with irregular antibodies which is discussed in the supplementary chapter; a child with a brain tumour whose platelet transfusion was delayed and developed ICH; delayed recognition and management of haemorrhage which resulted in a cardiac arrest call (the patient recovered with transfusion and surgery) and in the other case postoperative bleeding was associated with poor communication and multiple errors in the MHP.

Case 11a.5: Delayed transfusion in a patient with SCD associated with clinical deterioration

A patient with SCD, and a Hb of 64g/L, had two units of red cells authorised to be given as soon as available, but was not transfused until the following day. Nursing staff were unclear when the blood was meant to be given despite verbal handover the day before. The patient deteriorated with worsening chest pain and new oxygen requirement and subsequently required exchange transfusion.

Timely transfusion would likely have prevented deterioration.

The second case with SCD was similar, a delay of more than 12 hours receiving transfusion when he presented with acute chest syndrome. The patient needed exchange transfusion.

Learning points

- People with SCD benefit from specialist referral at an early stage of admission
- Junior medical staff should not hesitate to escalate for advice and discuss transfusion requirements with the transfusion laboratory

Case 11a.6: Delayed transfusion due to communication failures and lack of clarity in the MHP

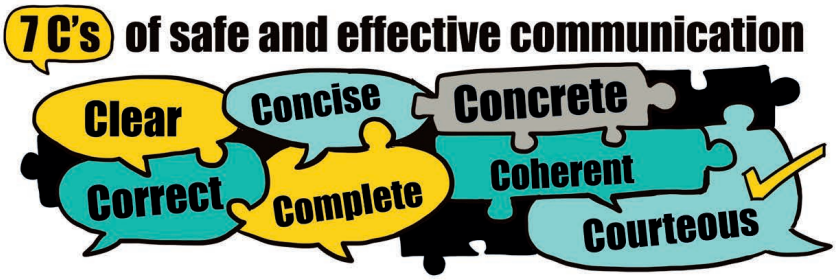
A woman experienced unexpected major bleeding the day after routine cholecystectomy (accidental damage to the portal vein) resulting in MHP activation. She was haemodynamically unstable with a pre-transfusion Hb of 36g/L. There was a 15-minute delay in the issue of red cells because the BMS was unclear about the patient location (transferred from ICU to theatre) and whether formal patient ID was needed. She received 15 units of red cells, six of plasma, one of platelets and fibrinogen.

There were several communication failures during the MHP. There was a lack of clarity and unfamiliarity with the MHP, and miscommunication across all three departments involved in the care of this patient.

In total poor communication was identified as contributory in 110 cases of delayed transfusions.

Learning points

- Poor communication frequently contributes to delayed transfusions. Be clear and concise
- MHP need drills covering each step of the process, including how to step down. Drills should also include obtaining blood packs



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Delays associated with the laboratory n=62

In 21/62 reports issues were noted with laboratory staff skills or knowledge and 9 cases reported a mismatch between workload and staff provision at the time of the incident. There were 15/62 delays that involved IT (16 clinical delays also involved IT). In 10 cases, delays were related to the presence of irregular antibodies or autoimmune haemolysis leading to delays in testing. Three of these were at the Blood Centre.

Learning points

- Laboratory staff working in transfusion must be adequately trained and competency-assessed
- Lone working out-of-hours is a risk factor for delayed transfusion
- Changes to routine practice, such as bank holiday working hours, should be clearly communicated to all staff

Information about responses related to HF questions can be accessed in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Near miss n=6

These included issues with storage in emergency and satellite refrigerators, and problems in the laboratory with sample validity (3 cases).

In 1 case staff in the ED made emergency units unavailable for 12 hours by trying to place a unit of patient-specific red cells in the refrigerator (this is not allowed). In another case the laboratory had failed to include details about irregular antibodies on serial reports in pregnancy so that when a MH was called at delivery the red cell units were incompatible but fortunately were not required. This was identified as an issue with the LIMS which made it difficult to add these results.

Conclusion

Delayed transfusion puts patients at risk and can contribute to death. Poor communication exacerbated transfusion delay in more than half the reported cases. Staffing shortages are a widespread problem in NHS hospitals and have been identified in many cases of delayed transfusion. Staff should escalate these issues to their managers and review their capacity plans. The recommended actions as per the SHOT CAS alert will help address preventable transfusion delays and improve patient safety. Patients should not die or suffer harm from avoidable delays in transfusion.

Recommended resources

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

SHOT Video: Delayed Transfusion in Major Haemorrhage
https://www.shotuk.org/resources/current-resources/videos/

SHOT Webinar: Every Minute Counts
https://www.shotuk.org/resources/current-resources/webinars/

2018 National Comparative Audit of Major Haemorrhage https://hospital.blood.co.uk/audits/national-comparative-audit/reports-grouped-by-year/2018-audit-of-the-management-of-major-haemorrhage/

Can you PACE yourself? The power of language to flatten hierarchy and empower multi-disciplinary healthcare teams in simulated critical scenarios
https://www.gloshospitals.nhs.uk/work-for-us/training-staff/gsqia/quality-improvements/Can-you-PACE-yourself/

15s30m stands for 15 seconds, 30 minutes – taking a few extra seconds at the start of a process can save someone a lot of time further along, reducing frustration and increasing joy at work.
https://fabnhsstuff.net/fab-stuff/15-seconds-30-minutes

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SHOT. Preventing transfusion delays in bleeding and critically anaemic patients SHOT/2022/001 (2022) https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103190 [accessed 28 April 2023].

11b Avoidable Transfusions n=121

Authors: Paula Bolton-Maggs, Catherine Booth and Simon Carter-Graham

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.

Reporting should include:

- **Components that are not required or are inappropriate because of erroneous laboratory results, transcription errors, miscommunication or faulty clinical judgement**
- **Components that are for an inappropriate indication**
- **Transfusion of an asymptomatic patient with haematinic deficiency**
- **Avoidable use of emergency group O blood (D-negative or D-positive) where group-specific or crossmatched blood was readily available for the patient or the laboratory could have supplied a more suitable component, including use of group O when time would allow a more appropriate group to be remotely allocated from a remote release refrigerator system**

Key SHOT messages

- Group O D-negative units, a precious resource, continue to be used inappropriately
- Poor communication and flawed decision-making contribute to avoidable transfusions, including use of O D-negative units when crossmatched or group specific units were available
- Haematinic deficiencies are poorly recognised and managed inappropriately. Transfusion in patients with haematinic deficiency carries increased risk of TACO
- Transfusion decisions based on inaccurate blood results continue to be reported

Recommendations

- Unless the transfusion is an emergency, the pre-administration bedside checklist should include a review of the patient's Hb or platelet count and confirmation with the patient that they have given consent
- Centres using electronic authorising should consider pulling through laboratory results to the request form, to alert the prescriber to any discrepancies
- Blood authorisation charts should be designed to capture the indication for transfusion and any specific instructions, such as the circumstances under which transfusion should be given
- By authorising a blood component, the prescriber affirms they are requesting the correct component for the correct patient and have confirmed this is clinically necessary. Systems should be designed to make as many opportunities as possible to check that this is the case

Action: Hospital transfusion teams, UK medical schools, transfusion laboratory managers, clinical haematology teams

Introduction

There were 121 reports of avoidable transfusion compared to 116 in 2021 and 110 in 2020.

Deaths related to transfusion n=0

There were no deaths related to avoidable transfusions.

Major morbidity n=0

There were no cases of major morbidity related to avoidable transfusions.

Group	Red cells	Platelets	Plasma components	Multiple components	Total reports
Flawed decision	16	4	2	0	**22**
Decision based on inaccurate results	32	8	1	2	**43**
Failure to respond to change in circumstances	11	4	0	1	**16**
Transfusion without decision	5	1	0	1	**7**
Appropriate decision, inappropriate component	33	0	0	0	**33**
Total	**101**	**17**	**3**	**4**	**121**

Table 11b.1: Classification of avoidable transfusions

This year, the incidents reported have been mapped to the stage of the transfusion process and the staff members likely to be involved in the errors (Figure 11b.1).

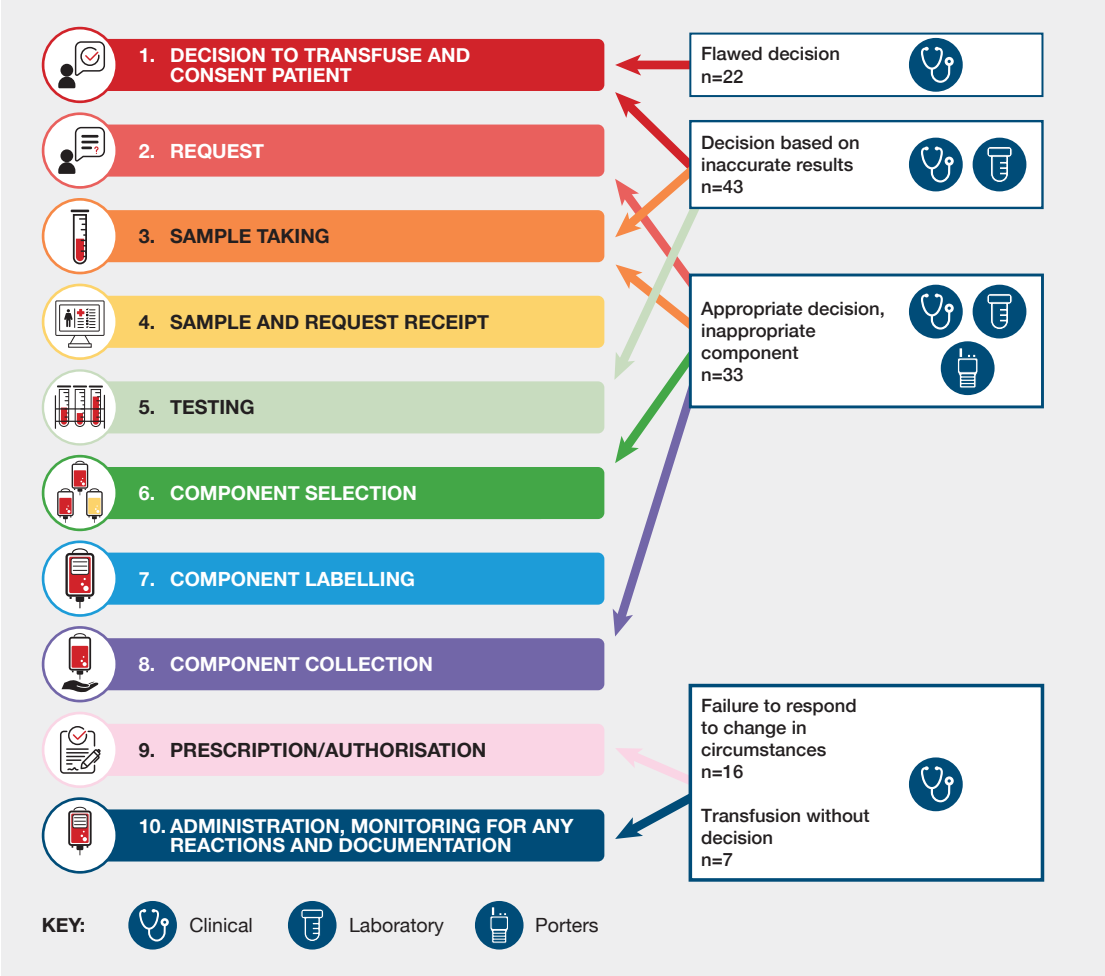


Figure 11b.1: Step in transfusion process with associated errors

Flawed decision n=22

Cases of flawed decision included: excessive transfusion for haematinic deficiency (n=6), transfusion of multiple units without review (n=7), transfusion above recommended thresholds (n=2), transfusion of platelets/plasma components to 'treat a number' in the absence of bleeding (n=3), misidentification of major haemorrhage (n=1), transfusion of a patient who had withheld their consent (n=3), all Jehovah's Witnesses.

Case 11b.1: Excessive transfusion for iron deficiency

A woman with menorrhagia, a Hb of 69g/L and moderate symptoms of anaemia received four units of red cells authorised by a junior doctor. One was warranted, but she should have been reviewed and Hb checked after each unit (or at the very least after two units). Her Hb was not measured until after the third unit and the result (Hb 105g/L) was not checked until after the fourth unit had been given. Her ferritin of 8micrograms/L was not acted on. There was a lack of understanding about the appropriate treatment of anaemia without transfusion. An anaemia clinic had been suggested but there was no funding.

Learning points

- Anaemia due to haematinic (vitamin) deficiencies is treated by replacing the missing vitamin. Transfusion should only be given where there is risk of haemodynamic instability, which is very unlikely in a young fit patient. If transfusion is essential, a single unit should be given followed by clinical review
- Clinicians authorising blood components for patients who cannot consent for themselves should check for any cautions or contraindications, just as they would check for allergies when prescribing a drug

Decision based on inaccurate results n=43

Cases where decisions were based on inaccurate results included: acting on old results (n=7), WBIT for FBC sample (n=4), use of another patient's results (n=2), misreading results (n=2), sample from drip arm (n=5), verbal handover of incorrect results (n=5), inaccurate results from a point-of-care device (n=4), spurious thrombocytopenia due to platelet clumping (n=3), other anomalous FBC results (n=11).

In 15 cases, these errors might have been prevented had there been a second check of the patient's laboratory parameters before proceeding with transfusion.

Case 11b.2: Results transcription error leads to unnecessary transfusion

An oncology patient received a transfusion of three units of red cells in a community hospital after a transcription error on the blood results recording page led to the platelet count of '80' being misread as the Hb. At the outpatient follow up appointment after transfusion, the Hb was over 200g/L.

Even if the Hb had been 80g/L, it is unlikely that three units would have been required.

Learning point

- There are multiple opportunities for an additional check of results prior to transfusion: at the time of the decision to transfuse, authorisation, release of units from the laboratory or immediately before administration. Systems making use of these checkpoints may be more likely to pick up erroneous decisions based on old or spurious results

Failure to respond to change in circumstances n=16

Cases where there was a failure to respond to change in circumstances included: components authorised for 'just in case' but transfused routinely (n=4), platelets given prophylactically for a procedure which

was cancelled (n=1), authorisation done in advance and recent results not checked (n=5), change in plan not communicated (n=3), transfusion already given but not documented (n=3).

Case 11b.3: Recent results not reviewed before commencing a transfusion prescribed in advance

A patient in their 80s with pure red cell aplasia was referred to the day ward for regular transfusion, two units of red cells every 2 weeks. She had recently been started on steroids. FBC was taken on arrival to the ward but transfusion of the first unit of red cells was started before the Hb result came back. The Hb was 140g/L and transfusion was stopped. Her Hb check 1 day before was also normal.

Learning points

- Where components are authorised 'just in case', e.g., for surgery, the authorisation should be accompanied by notes to explain under what circumstances these should be given
- Where authorisations are written in advance for patients attending for elective outpatient transfusions, there should be a routine step to check latest results and any change in patient circumstances before proceeding

Transfusion without decision n=7

Cases where patients were transfused without a formal written authorisation included: verbal handover of the plan to transfuse (n=3), transfusion prescribed for wrong patient (n=3), additional units given without prescription (n=1).

Case 11b.4: Miscommunication at verbal handover leads to a patient receiving an unnecessary red cell transfusion with an invalid prescription

A female (Patient 1) in her 50s was admitted to a haematology ward with AML and GvHD. Her Hb result on admission was 120g/L. She was due to receive ECP the following day, and there was a unit of red cells on standby in case they were required for this procedure. During a verbal handover Nurse 1 asked Nurse 2 to carry out two separate tasks; to obtain blood samples from Patient 1, and administer a red cell transfusion to Patient 2. Nurse 2 thought that they had been asked to transfuse Patient 1 and as there was a unit of blood in the refrigerator for Patient 1 (on standby for ECP), they collected this.

Pre-administration checks, including positive patient identification, checking the details of the patient with the ID band and prescription chart, and the final check of the compatibility tag with the ID band were carried out by two nurses. They did not notice the blood transfusion prescription dated 2 days previous to this and had not reviewed the patient's Hb result at any point. The red cells were administered. The patient suffered no ill effects from this avoidable transfusion.

This incident occurred on a very busy haematology ward which was full to capacity at the time. Nurse 2 thought they had understood what Nurse 1 had said when they took over the care of the two patients. They felt under pressure when asked to complete the requested tasks, as they were already caring for several other patients. The two nurses involved in the administration were already tired from previous long, busy shifts and there was a lack of staff at this particular time due to lunch breaks.

Learning points

- An authoriser should not authorise a blood component based on a verbal request without checking the indication and patient's results themselves
- Those administering transfusions should not rely on verbal handover but check there is a documented plan and completed authorisation before proceeding

Appropriate decision, inappropriate component n=33

Cases where an appropriate decision to transfuse was made but an inappropriate component was administered included avoidable transfusion of group O D-negative (n=28) and O D-positive (n=5) red cell units to patients with bleeding.

Thirty were due to clinical errors and 3 to laboratory error. Poor communication issues between the laboratory and clinical areas were implicated in 13 cases, while communication between different staff within the clinical area played a role in 7 cases.

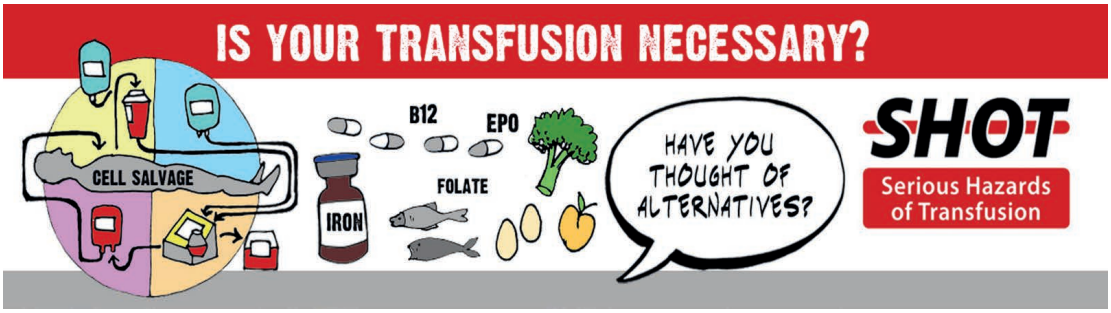
Crossmatched or group-specific units were available for 19 patients. In 7 cases, delays in taking a group and screen sample or mislabelled samples meant emergency units had to be selected. In 6 cases, a sample had been sent but the laboratory was not informed that the red cell units were required urgently. Three reports related to problems accessing group-specific units in remote refrigerators, 2 due to lack of trained staff and 1 due to an IT malfunction.

Case 11b.5: Multiple mislabelled samples result in prolonged use of group O D-negative units

A woman in her 20s was admitted to the ED following major trauma and issued an emergency trauma identity. The sample and request form did not match on the first set of two crossmatch blood samples received - Unknown Unknown on the sample, but a patient's name on request form. The second set of two samples both had unknown spelt incorrectly - Uknown on the sample. A third set of two blood samples was received 2 hours later. One did not have a DOB and was rejected. Group-specific blood components could only be made available after the seventh sample was received, resulting in prolonged use of emergency O D-negative blood.

Learning points

- Rules on correct sample labelling still apply in a major haemorrhage setting, including spelling of trauma ID names
- Taking samples promptly, delivering them to the laboratory and communicating their urgency are all central to provision of appropriate group-specific units



Near miss cases n=6

All of these were due to clinical errors, and 4/6 were discovered at the pre-administration checks.

The MHP was activated for an elderly woman with a GI bleed whose blood gas Hb was 43g/L but a repeat was 127g/L, so the MHP was cancelled (with wastage of a unit of O D-negative blood). The prescription was cancelled for two patients and detected at the pre-administration checks. A man in his 90s queried the need for a second unit which was then not given.

Conclusion

In a year where there have been shortages of blood components, particularly group O red cells, it is more important than ever that any transfusion given is clinically indicated and that group-specific components are given where possible. Including patients (where possible) in the decision to transfuse

is an important additional safety barrier, as a patient's questions might prompt greater scrutiny of the rationale for transfusion.

The largest number of reports related to patients receiving inappropriate transfusions based on incorrect laboratory results. These might have been prevented by an additional check of blood results prior to transfusion, which could be done at the stage of decision-making (e.g., a sense-check with a colleague, particularly if results are unexpected), authorisation (e.g., making use of IT systems to integrate laboratory results), issue from the laboratory (if BMS are empowered to question decisions) or administration (making review of results part of the pre-transfusion check).

Appropriate laboratory tests should be performed in patients with suspected iron deficiency to help direct onward investigation and management based on national gastrointestinal and gynaecology guidelines and local pathways within individual healthcare settings (BSH Fletcher et al. 2022). The 2019 national comparative re-audit of the medical use of red cells showed significant numbers of asymptomatic or only mildly symptomatic patients being transfused when their Hb levels are above the recommended thresholds. In this audit, one in five patients were transfused because of iron-deficiency anaemia and nearly 5% of transfusions were documented as given because of B12 or folate deficiency or both (NCA 2019). The 2021 national comparative audit of NICE Quality Standard QS138 helped identify areas where there were gaps in implementing patient blood management measures and recommended that hospitals explore barriers to the implementation of the NICE Quality Statements for Blood Transfusion (NCA 2021) (NICE 2016).

Clear lines of communication are central to an effective MHP, but this generally focuses on clinicians being able to rapidly contact the laboratory. To facilitate an effective switch to group-specific red cells, a defined communication channel from laboratory to clinical staff managing the haemorrhage is equally important. Local policies and processes must be in place and aligned with national guidelines for appropriate haematological management of major haemorrhage (BSH Stanworth et al. 2022).

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Recommended resources

E-learning modules:

Anaemia
Includes modules 'Anaemia - the only introduction you need', 'Anaemia in primary care patients', 'Anaemia in hospital patients' and 'Anaemia of inflammation and chronic disease'. Accessible via: https://hospital.blood.co.uk/training/clinical-courses/

Blood component use in major haemorrhage
https://www.e-lfh.org.uk/programmes/blood-component-use-in-major-haemorrhage/

The NHSBT O D-negative toolkit
https://hospital.blood.co.uk/patient-services/patient-blood-management/o-d-negative-red-cell-toolkit/

The A-E Decision Tree to facilitate decision making in transfusion
https://www.shotuk.org/resources/current-resources/

JPAC – Guidance for UK health professionals on consent for blood transfusion
https://www.transfusionguidelines.org/transfusion-practice/consent-for-blood-transfusion/guidance-for-healthcare-practitioners-involved-in-this-role

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National Institute for Health and Care Excellence Quality Standard (QS138) for Blood Transfusion published December 2016 https://www.nice.org.uk/guidance/qs138 [accessed 01 May 2023].

Under or Overtransfusion n=18

11c

Authors: Paula Bolton-Maggs, Catherine Booth and Simon Carter-Graham

Definition:

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

Key SHOT messages

- More than 50% (10/18) cases in this category in paediatric patients. Volume calculation for transfusions in paediatric patients continues to be a concern
- Instances of overtransfusion continue to be reported where staff failed to check Hb increment following transfusions. This would help guide further transfusions

Recommendations

- Paediatric transfusion protocols should be readily available for reference by all clinical staff
- Staff who authorise paediatric transfusion should be trained so that they know how to calculate the correct dose of all components
- Major haemorrhage drills should include taking samples for intermittent Hb checks, using a blood gas analyser if appropriate (and quality-assured for that purpose)
- Mandatory transfusion training should include information about special patient groups where standard guidelines may not apply, such as haemoglobinopathy patients
- Specialist haematology advice should be sought for management of patients with haemoglobin disorders

Action: Hospital transfusion teams

Introduction

This year, recognising that there has been some confusion between cases of 'avoidable' transfusion and 'overtransfusion', the definition has been revised. Some cases reported in 2022 have been reclassified as avoidable, e.g., where a second unit was transfused that was not necessary. This has resulted in a smaller number classified this year as overtransfusion. As a result, 14 cases were recategorised from overtransfusion to avoidable transfusion.

There were 10 cases reported in children and these are discussed further in Chapter 23, Paediatric Cases. Errors in prescribing and administering blood components in children are common and hospitals should review their paediatric transfusion policy which must be aligned with national guidelines (BSH New et al. 2016).

Deaths related to transfusion n=0

There were no deaths reported related to under or overtransfusion.

Major morbidity n=2

Case 11c.1: Overtransfusion during major haemorrhage

An elderly woman had an estimated GI blood loss of about 500mL and was peri-arrest. A major haemorrhage call was made; she received six units of red cells and two of FFP. Her Hb post transfusion was 179g/L. There was no pre-transfusion Hb, and it was not assessed during the treatment.

Case 11c.2: Undertransfusion caused by a bleed back into red cell bag associated with peri-arrest in a man with GI bleeding

A man in his 60s was admitted with haematemesis and melaena and a Hb of 54g/L. The first unit of red cells was transfused but the bag was disconnected from the pump and put on the bed while he had an urgent CT scan at night and then needed to use the urine bottle. While the nurse was fetching the second unit, about 500mL bled back into the first bag; the patient complained of chest pain and a feeling of doom. An arrest call was put out; he received further transfusion and recovered.

A clamp on the line could have prevented the bleed back into the bag. The ward had a very poor skill mix. There were only two qualified nurses on duty overnight with a full ward and four patients who were actively bleeding. The nurse was exhausted and had to take time off work. She was a very experienced nurse but following a period of sick leave and counselling, she has resigned from her post.

Haematinic deficiency

Case 11c.3: Excessive transfusion for folate deficiency

A woman in her 70s and a low body weight of 29kg was admitted with symptoms of anaemia and a Hb of 61g/L. She received two units of red cells. On the following day she was reviewed by another consultant and was transfused a further two units. The post-transfusion Hb was 155g/L. Her anaemia was due to severe folate deficiency.

Every year SHOT receives reports of over or avoidable transfusion for haematinic deficiencies. Patients are put at unnecessary risk as severe anaemia is associated with an increased risk of transfusion-associated circulatory overload and death (see Case 17a.1 in Chapter 17a, Transfusion-Associated Circulatory Overload (TACO)). A single unit transfusion followed by reassessment is safer where symptoms indicate a limited transfusion to be appropriate.

Haemoglobin disorders n=2

Two patients with SCD were transfused excess red cells due to poor communication, staff misread the prescription in both cases.

One was an adult who was admitted with a sickle crisis and chest infection to a hospital unfamiliar with SCD (he was known to another tertiary centre). The laboratory was not informed of this diagnosis, so he did not receive appropriate phenotyped red cells; in addition, he received excessive transfusion requiring venesection. The other case involved a child with SCD who was overtransfused.

Near miss cases n=1

An incorrect volume was prescribed for a child without taking into consideration the child's body weight. The consultant identified the error on a ward round and prevented the transfusion of the second unit of red cells.

Conclusion

Transfusion in paediatric patients continues to be the main source of error reported in this section. Measures are needed to improve patient safety. This is a role for paediatricians and paediatric nurses as well as transfusion staff.

Blood loss in major haemorrhage in adults can be difficult to assess. Regular monitoring of blood parameters is recommended. Blood gas analysers may be used for this as long as they are quality assured for this purpose and the sample is handled correctly.

Unnecessary or excessive transfusion continues to be reported in patients with haematinic deficiencies, suggesting a reactive response in transfusing to correct anaemia rather than investigating and treating the cause (BSH Fletcher et al. 2022).

Recommended resources

SHOT Bite No. 4: Paediatrics
https://www.shotuk.org/resources/current-resources/shot-bites/

Key information from the BSH paediatric guidelines
https://www.shotuk.org/resources/current-resources/paediatric/

Reference

BSH New HV, Berryman J, Bolton-Maggs PHB, et al. Guidelines on transfusion for fetuses, neonates and older children. *Br J Haematol.* 2016;**175(5)**:784-828.

BSH Fletcher A, Forbes A, Svenson N, et al. Guideline for the laboratory diagnosis of iron deficiency in adults (excluding pregnancy) and children. *Br J Haematol.* 2022;**196(3)**:523-529. https://doi.org/10.1111/bjh.17900 [accessed 28 April 2023].

11d Incidents Related to Prothrombin Complex Concentrate (PCC) n=21

Authors: Paula Bolton-Maggs, Josephine McCullagh and Simon Carter-Graham

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 MHRA through the yellow card scheme, https://yellowcard.mhra.gov.uk/).

Key SHOT messages

- Failure to administer PCC in a timely manner contributes to patient deaths
- Lack of clear understanding of the processes involved in ordering, procuring, and administering PCC has been identified as a common factor in the delays reported
- PCC dosing errors continue to be reported

Recommendations

- PCC are used mainly for oral anticoagulant reversal in an elderly vulnerable population. The ED should ensure they have a protocol for their use with clear instructions for dose and administration, and ensure that staff are appropriately trained in their use
- Use of PCC should be regularly audited for timeliness and appropriateness

Action: Medical directors of acute NHS Trusts/Health Boards

Introduction

PCC administration is an emergency treatment used for reversal of oral anticoagulants (warfarin and DOAC) which should be started within an hour of the decision being made and before the patient is transferred to other wards or departments. Patients with ICH are at high risk of death or serious sequelae and require urgent anticoagulant reversal.

PCC incidents were reported mainly in an elderly population, median age 71 years. There were 4 patients under 60 years of age. There were 12/21 reports of delayed PCC infusion. Other errors included administration of either under or over recommended doses.

All patients were taking anticoagulants, either warfarin or apixaban/edoxaban. Ten patients had ICH (8 delayed infusions and 2 received less than the recommended dosage).

Deaths related to transfusion n=2

There were 2 deaths possibly related (imputability 1) to failure to administer PCC in patients with ICH, both aged >80 years.

Case 11d.1: Failure to administer PCC to an elderly man with ICH

A request was made from the ED to the transfusion laboratory to issue PCC 1000IU to reverse warfarin for a patient with an acute subdural haematoma resulting from a fall. PCC was issued at

00:58 but never collected. At 12:25 the PCC was returned to stock by the transfusion laboratory. A verbal handover in the ED stated that the patient had received the PCC and was also documented wrongly in the patient notes. Failure to give PCC was considered contributory to his death.

Case 11d.2: Failure to give PCC for ICH due to misunderstanding of a new IT system

An elderly man on edoxaban for AF presented to the ED with a history of a fall at home. He sustained another fall in a cubicle in the ED hitting his head. A CT scan of his brain demonstrated ICH. PCC was prescribed on the new electronic patient record system (which had only been in use for a month) at 17:56 however the request was not automatically received in the laboratory. PCC was not issued until nearly 4 hours later at 21:39 when the laboratory was contacted by telephone. This delay was considered contributory to the patient's death.

The staff considered that training for the new system had been rolled out too rapidly and was inadequate.

Major morbidity n=2

Case 11d.3: Life-threatening delay in administration of PCC for GI haemorrhage

A woman in her 50s on warfarin (metallic heart valves) presented to the ED with melaena and a Hb of 48g/L. PCC was authorised by the on-call haematologist at 06:30 but not requested until much later, at 17:55. The patient was topped up with red cells but failed to receive PCC as the INR result was delayed (coagulation analyser recorded INR as >10 but was recorded on LIMS as 'unable to analyse' in error). She developed haemodynamic instability requiring transfer to ICU for inotropic support. Endoscopy was eventually done at 02:00.

A review identified the following concerns:

- Lack of understanding by both admitting and ward teams of the importance of immediate reversal of warfarin in the context of life-threatening bleeding
- Failure to appreciate that the risk of bleeding far outweighs the risk of thrombosis so the advice from cardiology consultant to the ward team that the INR should not be less than 2 was poor
- Delayed reporting of INR result
- Poor communication between the haematology consultant and the night team about administration of PCC and vitamin K

Case 11d.4: Incomplete dose of PCC given without prescription for a patient with ICH

A dose of 3000IU PCC was advised by the consultant haematologist for a patient with ICH; this correct dose was issued from the transfusion laboratory. At 21:58 the nursing notes documented that 3000IU had been given, but only 2000IU was given and not correctly recorded by an agency nurse working in a busy ED. The patient was admitted to ICU and made a full recovery. A vial of 1000IU PCC was returned to laboratory from ED 12 days after issue.

Delays n=12

Delays were caused by poor communication, transfer of patients between departments or setting inappropriately long infusion times. Patients with ICH experienced delays up to 12 hours.

Case 11d.5: Delayed PCC administration for ICH

A man in his 70s on anticoagulants for AF and with left sided weakness arrived in the ED at 02:01. At 07:15 it was noted that the patient had a long wait in ED. A CT scan showed ICH. At 10:40 the haematology registrar advised PCC which was issued, but not administered until 2 hours later, 11 hours after admission. There were delays in the prescribing, ordering, collection, and administration of the drug due to lack of knowledge (new nurse and agency nurse looking after the patient).

Case 11d.6: Delay in adequate reversal of anticoagulation following pelvic fracture

An elderly lady fell sustaining a fracture of her pelvis. She was on warfarin for AF and was admitted at 05:55. Scanning suggested active bleeding and at 08:21 the MHP was activated; a haematology registrar advised an inappropriately low dose of PCC (15IU/kg). A corrected dose of 50IU/kg was given 3 hours later. Death was not thought related to the suboptimal first PCC dose.

Additional factors included unfamiliarity of staff with PCC prescription and administration.

Additional cases can be found in the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).

Learning points

- Medical and nursing staff working in the ED and medical/surgical admissions units should be trained in the use of PCC so that it can be administered without delay for anticoagulant reversal in the face of major haemorrhage
- PCC should be rapidly accessible, and consideration given to keeping a stock in the ED (note that this blood product must be fully traceable)
- Immediate reversal of anticoagulant should take place (and certainly within an hour) especially in cases of suspected ICH

Commentary

Fixed dose PCC?

The two PCC are currently only licensed for reversal of vitamin K antagonists. There is published evidence for benefit in haemorrhage in patients on DOAC (see references in Annual Report for 2021). There are specific reversal agents for DOAC demonstrated to be of benefit in ICH (Vestal et al. 2022).

Continued confusion about dose and rate of infusion suggest that a fixed dose regimen might be safer. The literature was reviewed in the Annual SHOT Report for 2021. It is not clear what the optimal fixed dose should be. Whether a fixed dose or weight-based regimen is used, follow up of the INR for patients on warfarin (who should also receive vitamin K) is essential to ensure the dose was adequate and to determine if further PCC is required.

Use of PCC for DOAC reversal

PCC may also be used for DOAC. A meta-analysis of reversal agents (PCC, idarucizumab and andexanet) for bleeding related to DOAC evaluated 60 studies with 4735 patients. Mortality of those with ICH was 20%; effective haemostasis was achieved in 75-81% and was similar for all agents and a particularly high thromboembolism rate was noted for andexanet (Gomez-Outes et al. 2021).

Ciraparantag is a new reversal agent in trial, a small synthetic molecule. In two randomised placebo-controlled, dose-ranging trials in normal adults, treated with either apixaban or rivaroxaban, haemostasis was assessed by whole blood clotting time. This agent resulted in dose-dependent reversal of both agents with minimal side effects. (Ansell et al. 2022).

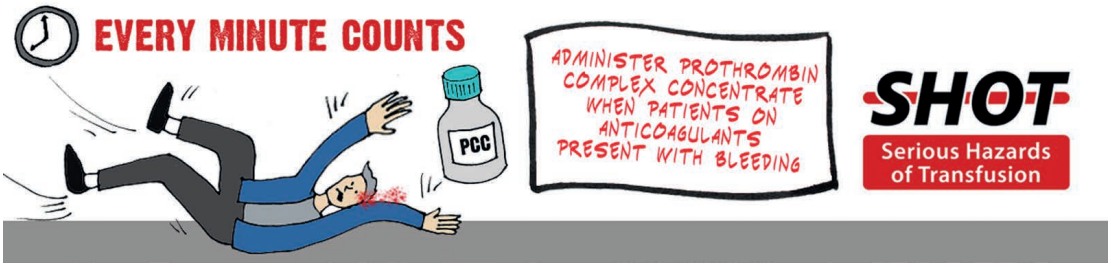
Near miss cases n=1

Two vials of PCC had transposed compatibility labels after a printer had been jammed; the labels were re-printed and applied to the wrong vials. The error was discovered at the pre-administration checks and the vials returned to the laboratory for re-labelling.

Conclusion

PCC are an important treatment for immediate reversal of vitamin K antagonists and other oral anticoagulants and should be given immediately a decision is made. All clinical staff involved in the acute care of patients with suspected serious haemorrhage, particularly ICH, who are eligible for reversal should ensure that they know how to obtain and how to administer PCC. Delay can contribute to death.

The SHOT CAS alert released in 2022 also addresses preventable PCC delays. One of the recommended actions was for all healthcare organisations to ensure their transfusion policies and procedures include agreed criteria where rapid release of PCC is acceptable without the initial approval of a haematologist.



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Ansell J, Bakhru S, Laulicht BE, et al. Ciraparantag reverses the anticoagulant activity of apixaban and rivaroxaban in healthy elderly subjects. *Eur. Heart J.* 2022;**43**:985-992 doi: 10.1093/eurheartj/ehab637

Gomez-Outes A, Alcubilla P, Calvo-Rojas G, et al. Meta-Analysis of Reversal Agents for Severe Bleeding Associated With Direct Oral Anticoagulants. *J. Am. Coll. Cardiol*. 2021;**77**(24): 2987-3001.

SHOT. Preventing transfusion delays in bleeding and critically anaemic patients SHOT/2022/001 (2022) https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103190 [accessed 28 April 2023].

Vestal ML, Hodulik KJ, Mando-Vandrick ML, et al. Andexanet alfa and four-factor prothrombin complex concentrate for reversal of apixaban and rivaroxaban in patients diagnosed with intracranial hemorrhage. *J. Thromb. Thrombolysis.* 2022;**53**(1):167-175.

12 Near Miss (NM) Reporting n=1366

Authors: Caryn Hughes, Debbi Poles and Shruthi Narayan

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.

Abbreviations used in this chapter

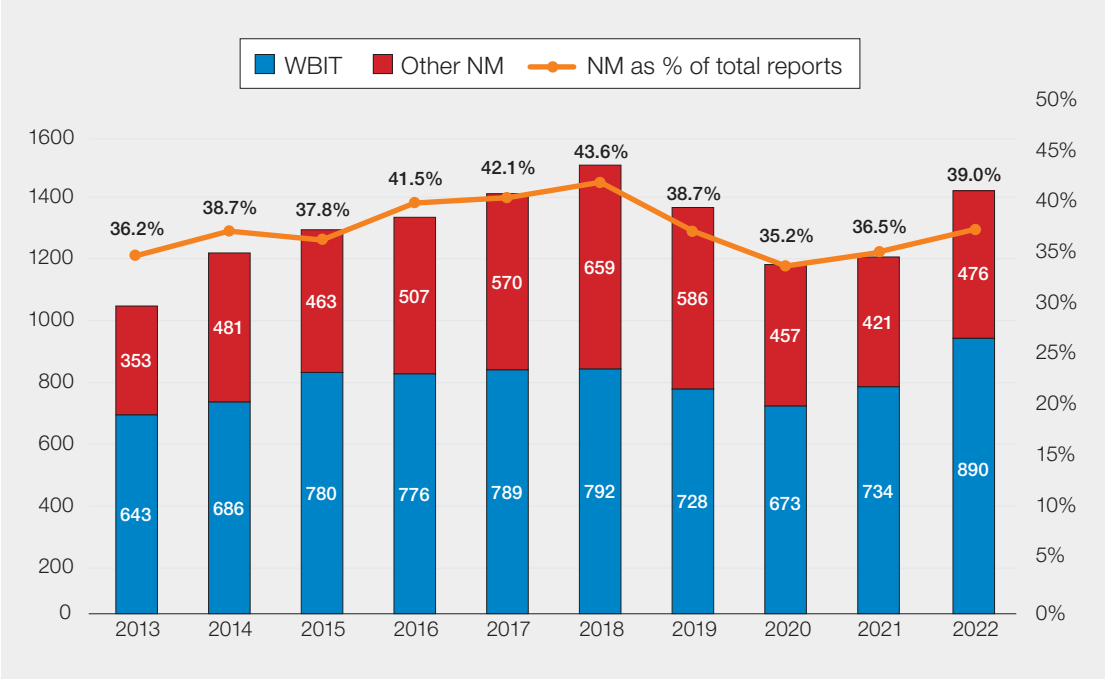
cffDNA	Cell-free fetal deoxyribonucleic acid	**NM**	Near miss
ED	Emergency department	**RBRP**	Right blood right patient
IBCT	Incorrect blood component transfused	**WBIT**	Wrong blood in tube
G&S	Group and screen	**WCT**	Wrong component transfused

Introduction

Near miss events account for the largest proportion of the events/reactions reported to SHOT, 1366/3499, (39.0%). The number of NM reports submitted continues to increase with 2022 seeing 211 more reports than in 2021 (n=1155). The largest number of NM in a single category continues to be WBIT incidents 890/1366 (65.2%). Increases in the near misses in the following categories have also been noted; IBCT-WCT 115/1366 (8.4%), RBRP 118/1366 (8.6%) and adverse events related to anti-D Ig 37/1366 (2.7%).

Figure 12.1 shows the trend in near miss and WBIT reports included in the Annual SHOT Reports between 2013-2022.

Figure 12.1: A decade of near miss and WBIT reports 2013-2022



WBIT=wrong blood in tube; NM=near miss

Near misses are often overlooked as they do result in actual patient harm. Recognising, reporting, and investigating near miss errors are vital in identifying processes and factors which increase the risk of resulting in actual transfusion errors.

Understanding how near miss errors occur requires an acknowledgement of the complexity of the transfusion process as demonstrated by the 'Ten Steps in Transfusion' (see 'Recommended resources'). While these ten steps provide an overview of the stages at which a potential error can occur, they also highlight the stages at which errors can be detected. This requires a co-ordinated, collaborative approach by all clinical and laboratory staff involved in the transfusion process.

Discussion of near miss errors in other categories

Near miss cases have been appraised in each relevant chapter for this Annual SHOT Report and Table 12.1 shows the chapters that include near miss events according to SHOT definitions.

		Discussed in chapter	Number of cases	Percentage of cases
Incorrect blood component transfused (IBCT)	Wrong component transfused (WCT)	Chapter 9	115	8.4%
	Wrong blood in tube (WBIT)	Chapter 12a	890	65.2%
	Specific requirements not met (SRNM)	Chapter 9	52	3.8%
Handling and storage errors (HSE)		Chapter 10	140	10.3%
Right blood right patient (RBRP)		Chapter 13	118	8.6%
Adverse events related to Anti-D Ig (Anti-D Ig)		Chapter 8	37	2.7%
Avoidable, delayed or under/overtransfusion (ADU)		Chapter 11	14	1.0%
Total			**1366**	**100%**

Table 12.1: Categorisation of all near misses according to SHOT definitions (n=1366)

The promotion of reporting NM events helps to identify and control risks before actual harm results, providing valuable opportunities to improve transfusion safety. Systems and processes involved in the transfusion pathway should have control measures in place to ensure quality outcomes for patients and where variations occur opportunities for improvement should be identified (Barnard 2020). Additionally, in organisations where NM are seen as vulnerabilities i.e., events which 'nearly happened' rather than a sign of resilience in which events 'could have happened' there is stronger willingness amongst healthcare professionals to report (Jung et al. 2021).

Reporting, investigating, and analysing the factors associated with near miss events provides additional vital information to determine corrective actions and areas for improvement to improve transfusion safety. While a NM event provides valuable opportunities to learn and improve systems, it is important to have clear definitions and clear pathways to investigate NM, address causal factors and implement corrective actions. Without these, in depth investigations are futile.

A scoping review about the value of learning from near misses to improve patient safety concluded that interventions following investigations of near misses are commonly aimed at the human and there is a need for more system-level actions (Woodier et al. 2023).

Recommended resources

Ten steps in transfusion
https://www.shotuk.org/resources/current-resources/

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

References

Barnard S. 'This is the wrong patient's blood!': Evaluating a Near-Miss Wrong Transfusion Event. Patient Safety Network. (2020) https://psnet.ahrq.gov/web-mm/wrong-patients-blood-evaluating-near-miss-wrong-transfusion-event. [accessed 28 April 2023].

Jung OS, Kundu P, Edmondson AC, et al. Resilience vs. vulnerability: psychological safety and reporting of near misses with varying proximity to harm in radiation oncology. *Jt Comm J Qual Patient Saf. 2021;***47(1)**:15-22. https://www.jointcommissionjournal.com/action/showPdf?pii=S1553-7250%2820%2930241-5 [accessed 28 April 2023].

Woodier N, Burnett C, Moppett I. The Value of Learning From Near Misses to Improve Patient Safety: A Scoping Review. *J Patient Saf*. 2023;**19**(1):42-47. https://pubmed.ncbi.nlm.nih.gov/36538339/ [accessed 28 April 2023].

SHOT
Serious Hazards of Transfusion

Near Miss – Wrong Blood in Tube (WBIT) n=890

12a

Authors: Paula Bolton-Maggs, April Molloy and Simon Carter-Graham

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

Key SHOT messages

- Failure to adhere to basic safe procedures remains the major cause of WBIT
- In almost a fifth of cases, 159/890 (17.9%) the patient was neither correctly identified nor was the sample labelled at the patient's side

Recommendations

- Correct patient identification is fundamental for patient safety whether related to blood sampling or any other interaction with health services. This must be reinforced with all staff and by mandatory transfusion training and be audited regularly
- Blood sample tubes must be labelled next to the patient and systems adjusted to facilitate this

Action: Hospital chief executives and medical directors

Introduction

WBIT samples continue to be a problem with a large increase in reports in 2022 (n=890) compared to 2021 (n=734) (Figure 12.1). Cases from maternity departments make up 40% of the reports.

What errors lead to WBIT?

WBIT errors result from two main causes: failure to identify the patient correctly at phlebotomy (n=353) and labelling the blood samples away from the patient (n=286). In 50 reports, the cause of error was left blank. In 159/890 (17.9%) cases where the cause was recorded both errors occurred together.

Mistakes can occur at the first contact with the hospital. In 5 cases, patients were wrongly identified at initial registration. In 1 case this was associated with the patient being non-English speaking. In another instance a woman was misidentified by clerical staff on admission to the ED because a patient with a similar name was picked from the patient information system. This mistake was detected when the blood group was found to be discrepant with the previous records of the wrong patient. These cases are another reminder that correct patient identification is vital at all times.

Overall, 639/890 (71.8%) were attributed to failure to identify the patient at the time of sampling or the sample was not labelled at the bedside.

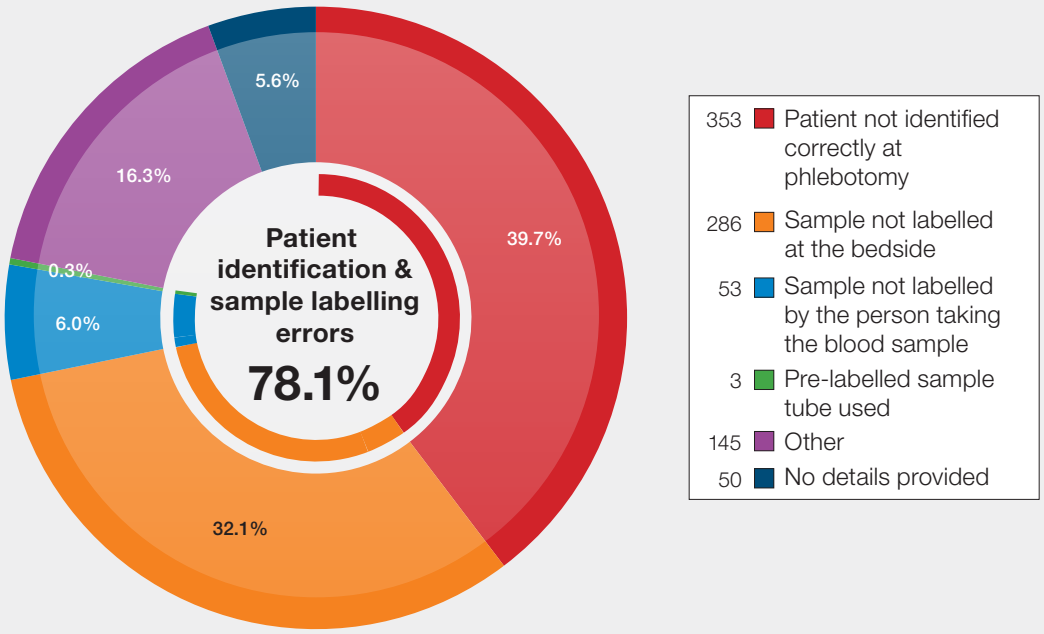
Case 12a.1: Multiple errors resulted in a WBIT

A nurse asked the phlebotomist to take a group and screen sample from the 'patient in bed 2'. The intended patient had been moved to another bed and no positive patient identification was carried out before or after taking the sample. The phlebotomist then handed the blood sample to the nurse to label. This was done away from the patient's bedside using the request form.

Learning points

- Failure to adhere to safe procedures remains the major cause of WBIT. Staff involved in taking pre-transfusion samples from patients should be aware of the potential consequences of patient misidentification
- Positive patient identification, sample taking, and labelling are part of a single, continuous process (see 'Sample circle', Narayan et al. 2022)

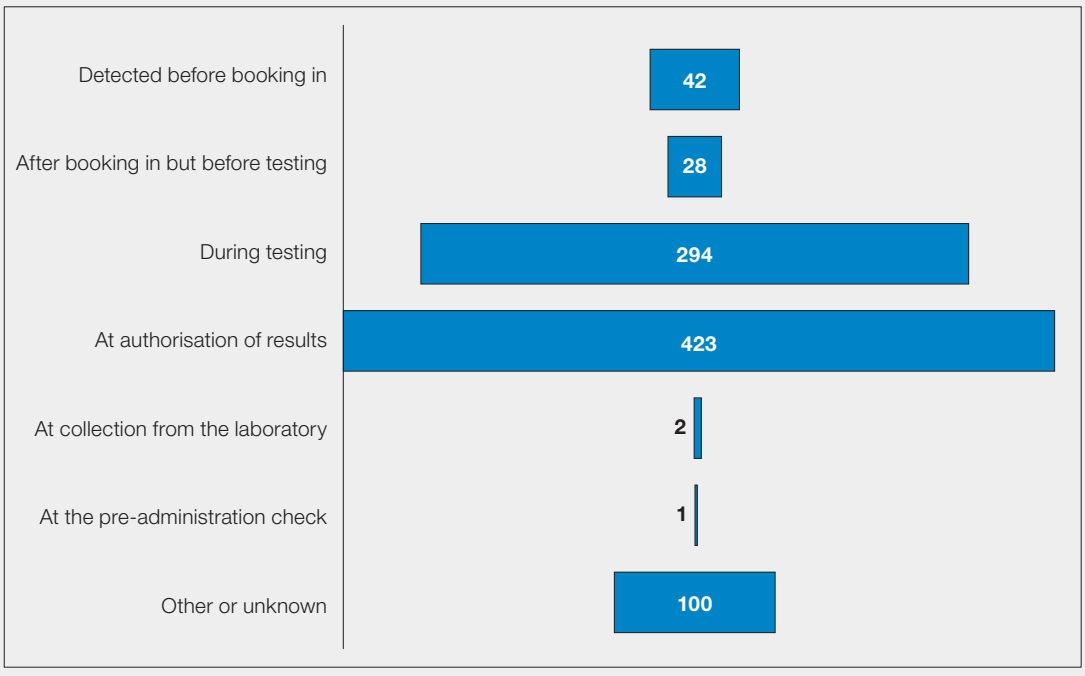
Figure 12a.1: Primary errors leading to WBIT (n=890)



There were 7 cases of mix-ups between maternal and cord blood samples, and 2 cases where an agency staff nurse (who had not received transfusion training) took samples from multiple patients and labelled them later away from the bedside 'to save time'.

Most errors were detected by laboratory staff, 717/890 (80.6%) during testing or at authorisation of results.

Figure 12a.2: Point in the process where the error was detected (n=890)



ABO-incompatibility

In 689 cases blood group data were provided. If these WBIT had not been detected, 320/689 (46.4%) could have received ABO-incompatible components with a risk of serious harm or death.

Patient blood group	Group of the blood component that might have been transfused					
	A	B	AB	O	Compatible	Incompatible
A	45	40	11	141	186	51
B	35	7	4	52	59	39
AB	16	4	2	17	39	0
O	146	64	20	85	85	230
Totals	**242**	**115**	**37**	**295**	**369**	**320**

Table 12a.1: Potential for ABO-incompatible transfusion

Who takes the samples?

Information about the healthcare professional involved in taking the pre-transfusion sample was available in 767/890 (86.2%). In these cases, as in previous years many errors are noted for midwives (Figure 12a.3).

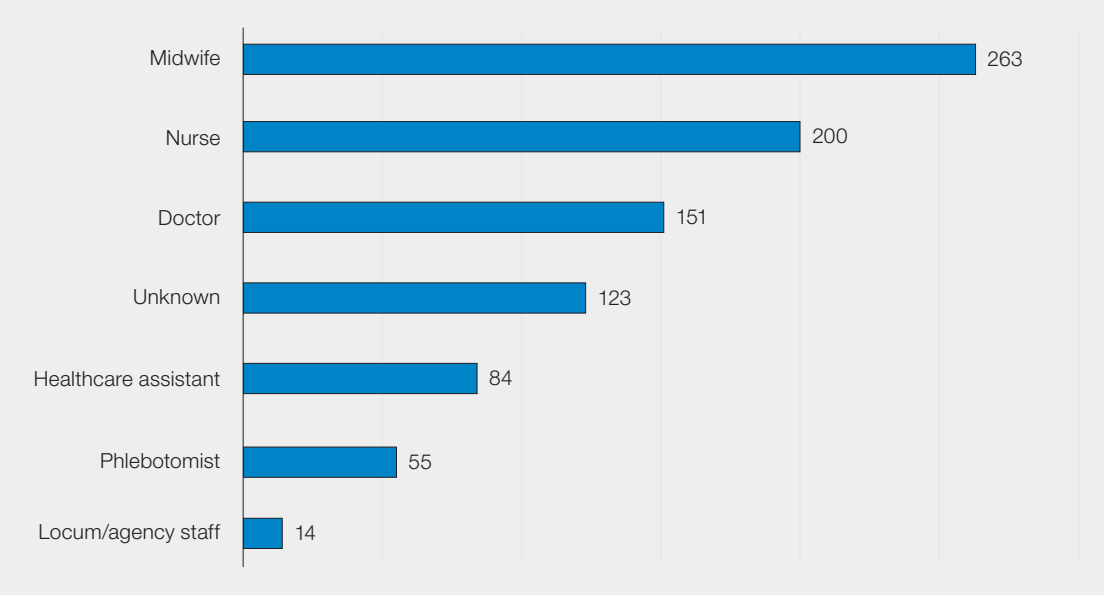


Figure 12a.3: Numbers of different healthcare professionals who took blood samples (n=890)

The pattern of error varies in the different professional groups (Table 12a.2). WBIT attributable to phlebotomists are mostly caused by failure to identify the patient correctly. Reasons noted in this group included distraction, patients not being where they were expected to be on the ward, patients having similar names, assumptions that they had found the correct patient, staff shortages and busy wards.

Midwives were over-represented in the errors where the sample was not labelled at the patient's side. In all groups of healthcare professionals, there were cases reported with both errors (Table 12a.2) with the highest percentage (15.6%) from doctors.

	Patient not identified correctly	Sample not labelled at patient's side	Total	Number with both errors
Phlebotomists	39 (70.9%)	10 (18.2%)	**55**	8 (14.5%)
Nurses/HCA	122 (43.7%)	82 (29.48%)	**279**	31 (11.1%)
Midwives	90 (34.5%)	108 (38.7%)	**261**	23 (8.8%)
Doctors	58 (41.1%)	51 (36.2%)	**141**	22 (15.6%)

HCA=Healthcare assistants

Table 12a.2: Errors associated with WBIT in different professional groups

Hospitals were asked whether they had a two-sample policy for patients receiving their first transfusion: 826/890 (92.8%) did, and 33 (3.7%) did not (31 did not answer). In 317/826 (38.4%), the error was

detected as a result of the two-sample policy. In 110 cases it was the second sample that was the WBIT. Most of these errors were detected by laboratory staff during testing or at authorisation of results usually because the results did not match with a previous sample.

A recent survey of doctors in the ED demonstrated deliberate deviation from safe practice – 65.1% (136/209) of the respondents reported having taken two G&S at once and labelling them with different times; 52 (24.9%) did this routinely and were from 17 different hospital sites. Non-compliant behaviour was not associated with training or seniority. Sample urgency 100/134 (74.6%) and difficult venepuncture 98/134 (73.1%) were the most frequent reasons for non-compliance. A high number of respondents commented on time and resource pressures in ED (Cain et al. 2023). It is essential to address these unsafe practices with an enhanced transfusion education so that clinical staff can understand the rationale behind the two-sample rule and avoid workarounds or deviations from correct practice.

Maternity and neonatal cases

Maternity cases were reported for 369/890 (41.5%), an increase compared to 2021 (n=257, 35.0%). These included 34 errors involving neonates:

- Mother and cord mix ups n=12/34
- Confusion in sampling from twins n=8/34

Sampling the infant's umbilical cord after the placenta had been removed to the ward sluice area and labelling this sample away from mother and baby was identified as a risk as noted last year.

In 45 cases women who were D-negative were incorrectly identified as D-positive, and in 9 of these, the baby was D-positive so that administration of anti-D immunoglobulin could have been missed, putting future pregnancies at risk.

Case 12a.2: Incorrect group detected by cffDNA prediction

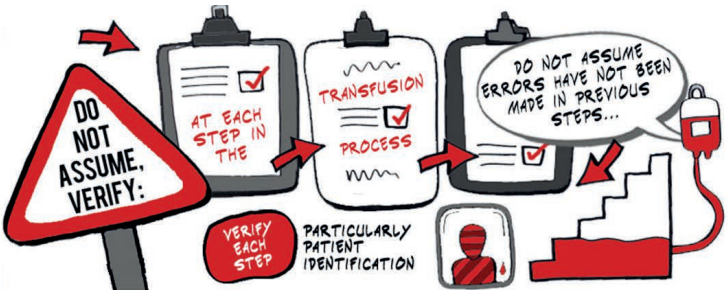
Baby group and Kleihauer samples were received in the transfusion laboratory. The baby sample grouped as O D-negative, same group recorded as maternal blood. The cffDNA test predicted baby as D-positive. Further testing confirmed the baby group was O D-positive.

Case 12a.3: Neonate not adequately identified by two doctors

During an induction week, Doctor 1 was paired with Doctor 2, who took a blood sample from a one-day old baby. Doctor 1 filled out the request form to help and did not do this at the bedside and incorrectly wrote the details out from the wrong patient's notes. Doctor 1 did not check with Doctor 2 before sending the request.

Case 12a.4: Two samples are safer than one

A neonate was transferred from another hospital for cardiac surgery. A sample grouped as O D-positive, and one unit of red cells was issued. The local agreement for neonatal cardiac surgery allows issue of red cell units with one sample. A second sample received in the afternoon grouped as O D-negative. Then staff checked with the referring hospital (which should have ideally happened when first sample was received). The patient's group recorded there was O D-negative.



SHOT
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Cases from other departments

Case 12a.5: Patient wrongly identified in an emergency at home

Paramedics were called to a patient in cardiac arrest at home. A paramedic registered the patient as somebody with a similar name and these details were used by hospital staff to print the patient identity band and label blood samples. The patient deteriorated and died in the intensive care unit, and a death certificate was completed for an incorrect patient. The general practitioner was informed of his patient's death and realised the patient was still alive and there had been an incorrect identification of the patient. He requested the episode of care be removed from his patient's records. Transfusion group and screen result was removed as part of this process.

Learning points

- The labelling of neonatal samples taken from the umbilical cord is prone to error when the sample is taken from the placenta away from the mother. Correct patient identification is essential; neonates are at particular risk
- Good handovers with documentation and without assumptions will reduce risks

An international prospective study identified the same non-compliance errors or protocol violations in 260 WBIT errors reported from 36 centres in 11 countries (Dunbar et al. 2022). It was notable that in 43 cases the electronic positive patient identification was either not used when available or was used incorrectly. In this study 78% of samples were taken by nursing staff. Most WBIT errors had more than one contributing factor, mean 2.3 range 1 to 6.

Additional case studies, and a review of the human factors questions related to WBIT reports showing that the most common factor identified was a mismatch between workload and staff provision can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Conclusion

The number of reported NM-WBIT has increased again in 2022 with several that could have resulted in potentially fatal ABO-incompatible transfusions. They are caused by the same two errors identified regularly in SHOT reporting for the past 25 years, namely failure to identify the patient correctly at the time of phlebotomy and failure to label the blood samples while next to the patient. Both these errors occurred together in a fifth of all cases. Maternity departments and clinics are high-risk areas.

It is disappointing that poor practice continues. Near miss events should be monitored and investigated using human factors principles. In 2012, the BCSH guidelines recommended that any patient who has never been transfused should have a second group-check sample taken to reduce the risk of wrong blood transfusions (BCSH Milkins et al. 2012). A recent survey of junior doctors and physician associates in ED demonstrated an alarming rate of non-compliance including 136/209 (65.1%) who reported having taken two group and antibody screen samples together and labelled them at different times (Cain et al. 2023). Clearly better understanding of the risk is needed.

Recommended resources

SHOT Bite No. 17: Learning from Near Misses (NM)
SHOT Bite No. 19: Human Factors
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Safe Transfusion Checklist
https://www.shotuk.org/resources/current-resources/

Can you PACE yourself? The power of language to flatten hierarchy and empower multi-disciplinary healthcare teams in simulated critical scenarios
https://www.gloshospitals.nhs.uk/work-for-us/training-staff/gsqia/quality-improvements/Can-you-PACE-yourself/

15s30m stands for 15 seconds, 30 minutes – taking a few extra seconds at the start of a process can save someone a lot of time further along, reducing frustration and increasing joy at work.
https://fabnhsstuff.net/fab-stuff/15-seconds-30-minutes

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Cain L. and the HaemSTAR collaborators. The 'Two Sample Rule' in Emergency Departments: a UK-wide survey of junior doctors/physician associates. Oral abstracts book BSH23-OR26. Br J Haematol. 2023;**201**:4-27. https://doi.org/10.1111/bjh.18718 [accessed 21 June 2023].

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Right Blood Right Patient (RBRP) n=264 13

Authors: Terrie Perry, Nicola Swarbrick and Victoria Tuckley

Definition:

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

Abbreviations used in this chapter

BSH	British Society for Haematology	**IT**	Information technology
CAS	Central alerting system	**LIMS**	Laboratory information management systems
DOB	Date of birth	**NHS**	National Health Service
HSE	Handling and storage error	**RBRP**	Right blood right patient
IBCT	Incorrect blood component transfused	**PID**	Patient identification

Key SHOT messages

- Most RBRP transfused errors originated in the clinical area, 193/264 (73.1%)
- Conversely, most near miss RBRP errors were laboratory errors, 94/118 (79.7%)
- More than half the RBRP errors involved incorrect patient demographic details being used, 143/264 (54.2%)
- Data suggests that pre-administration checks are not always being carried out effectively, as 172/264 (65.2%) of transfused RBRP cases stated that a checklist had been used but the error was not identified
- Of the 118 near miss cases, 98/118 (83.1%) were detected during collection of the blood component, or at the pre-administration checks
- Almost all the laboratory errors could have been prevented by using a laboratory exit check, 70/71 (98.6%), highlighting the importance of safety checks at critical steps in the transfusion pathway

Recommendation

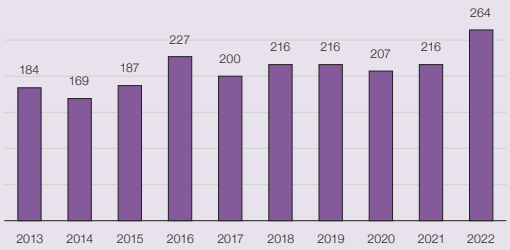
- The key SHOT recommendations from 2021 remain pertinent: importance of PID, laboratory exit checks, collection checks and pre-administration checklist (Narayan et al. 2022)

Action: All staff in transfusion

Headline data 2022

Number of reports n=264
Deaths n=0
Major morbidity n=0

RBRP reports by year



Demographic data

Male n=131
Female n=123
Unknown n=10

Adults n=228
Paediatric n=20
Unknown n=16

Blood component data

Red cells n=203
Platelets n=20
Plasma n=15
Multiple components n=25
Other n=1

Introduction

There were 264 cases reported in 2022, an increase of 48 cases from 2021 (n=216). Clinical errors accounted for 193/264 (73.1%), laboratory errors for 71/264 (26.9%). Clinical errors decreased from 76.3% in 2021 and laboratory errors increased from 23.7%.

Deaths related to transfusion n=0

There were no deaths related to the transfusion as a result of RBRP errors.

Major morbidity n=0

No patient suffered major morbidity as a result of RBRP errors.

Overview of RBRP errors

The majority of laboratory reports were due to component labelling (37/71) and errors with patient demographic details (30/71). Of these labelling errors 25/37 were due to transposed labels between units. Sample receipt and registration errors accounted for 25/71 laboratory reports, with 11 demographic data entry errors and 10 cases where available information was not heeded. Review of all laboratory errors found that most, 70/71 (98.6%), could have been detected by using a laboratory exit check such as PAUSE, which was introduced in the 2021 Annual SHOT Report (Narayan et al. 2022).

The majority of clinical RBRP reports were due to PID errors at sample taking, 69/193 (35.8%), with 40/193 errors at administration including 14 patients who were transfused without a wristband. In 41/193 cases the primary error was in the prescription.

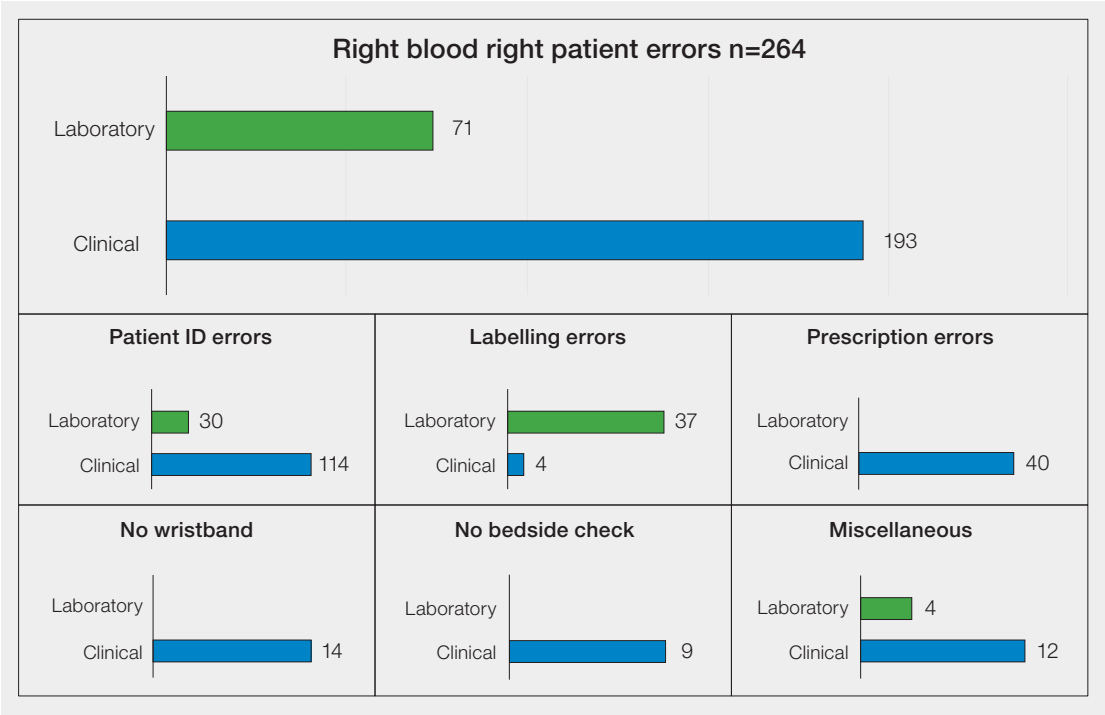


Figure 13.1: Breakdown of 2022 RBRP reports (n=264)

Most errors occurred at sampling 69/264 (26.1%) followed by component labelling, availability and HSE 43/264 (16.3%) with administration errors accounting for 40/264 (15.2%) (Figure 13.2).

Errors where the primary error was related to prescription, have increased from 20/216 (9.3%) in 2021 to 41/264 (15.5%) in 2022. Of the 40 cases with administration errors, 3 involved cases where blood components were not administered in the order in which they were prescribed for the patient.

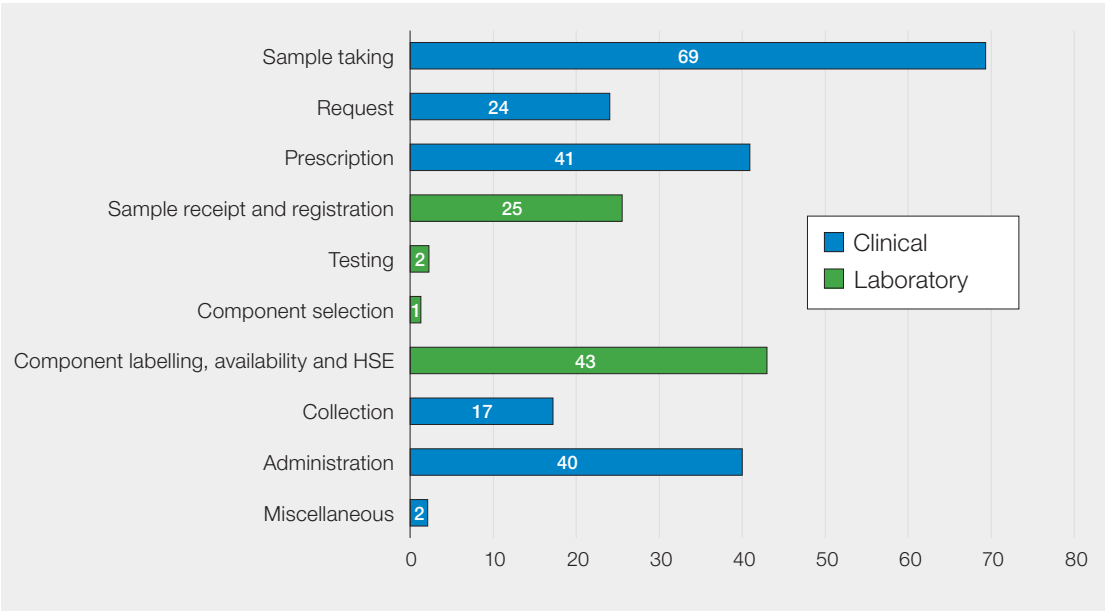


Figure 13.2: RBRP classified by the stage when the primary error occurred in 2022 (n=264)

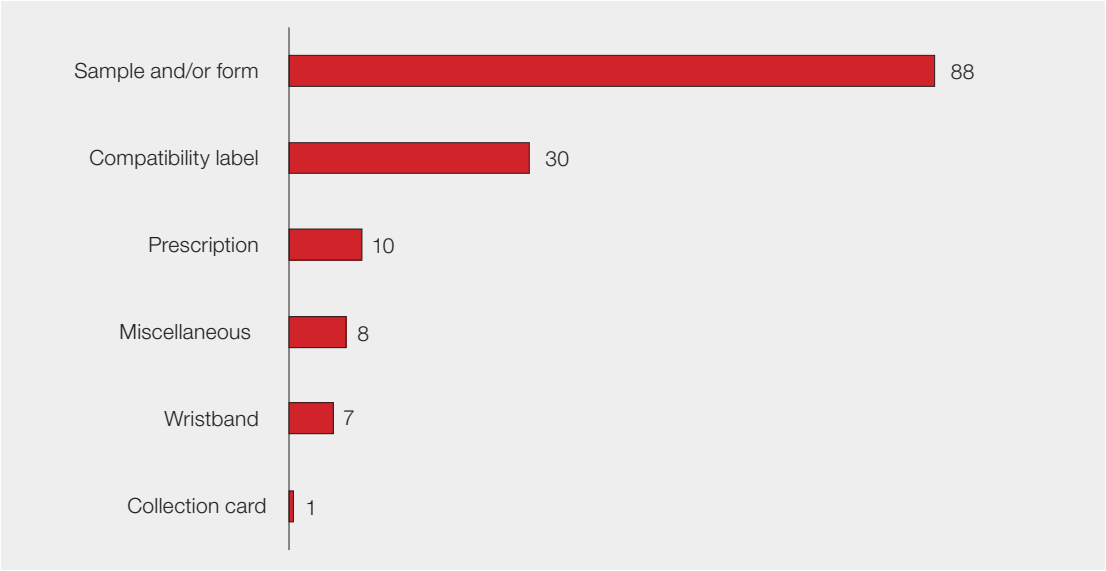
HSE=handling and storage errors

PID errors n=144

PID errors accounted for 144/264 (54.5%) of all RBRP errors, these are errors with patient demographic details either at the clinical or laboratory end. PID errors occurred throughout all stages of the transfusion process, with 88/144 (61.1%) due to errors with sample tubes and request forms. These included both clinical errors where patient details were wrongly transcribed onto samples and request forms, and laboratory errors where laboratory staff entered data incorrectly into LIMS. Most of these were due to

transposed numbers, misspelt names and DOB being inaccurately recorded. In PID errors sample tube and request form errors show similar trends to previous years (from 86/134 (64.2%) in 2021 to 88/144 (61.1%)).

Figure 13.3: Details of patient identification errors (n=144)



Data demonstrates RBRP errors most frequently occur at the sample taking step or at request 93/264 (35.2%).

Case 13.1: No patient identifiers on the blood prescription form

A female in her 70s was receiving a unit of red cells prior to revision of her hip. Red cells were administered with staff checking the patient details on the drug chart rather than the blood prescription. The right component was transfused, and the error was only identified when the transfusion practitioners were carrying out a periodic spot check audit. The staff reflected on the incident and noted that the shift was a busy stressful shift and substantive staff were having to take on extra tasks that agency staff were unable to do.

During a routine audit of transfusion practices, this incident was picked up and the blood prescription form was found to contain no patient identifiers. There was no addressograph or handwritten patient details. This was against the hospital transfusion policy as the prescription had to be fully completed, and the patient identifiers were to be checked against the blood component and patient ID band prior to the transfusion.

Case 13.2: Blood components administered in the wrong order

A female in her 80s was prescribed platelets and red cells (in that order) following treatment for myeloma. The HCA was asked by the medical staff to collect the blood component/s without the right authorisation sheet. The prescription chart had also not been completed and the red cells were transfused first after checking patient identification details. When the paperwork was completed, the nurse noted that the doctor had prescribed platelets to be administered first followed by red cells. All the necessary blood components were transfused with no adverse impact.

This is an example where correct procedures were not followed, and staff felt 'pressurised' to action without the correct paperwork in place. All steps should comply with the BSH guidelines on administration of blood components (BSH Robinson et al. 2018).

Learning point

- All staff working in transfusion should always follow their correct local procedure/policy including during emergencies and demanding periods as this is when errors are more likely to occur

Prescription errors

Of the 193 clinical errors, 41 (21.2%) were related to prescription errors, 5 errors had incorrect patient details on the prescription. A pre-administration checklist had been used in 18/41 errors. A pre-administration checklist should include checking the patient's identity against the prescription and that the blood component about to be given is the prescribed component. The pre-administration checklist from SHOT (see 'Recommended resources') covers all the key checks that need to be carried out to ensure safe transfusions.

Pre-administration checklists

In 2017 the CAS alert: 'Safe Transfusion Practice: Use a bedside checklist' (Department of Health 2017) was issued in response to SHOT recommendations. A pre-administration checklist was used in 172/264 (65.2%) RBRP cases and stated as 'not used' or 'not available' in 54/264 (20.5%). In 38 cases no information was provided.

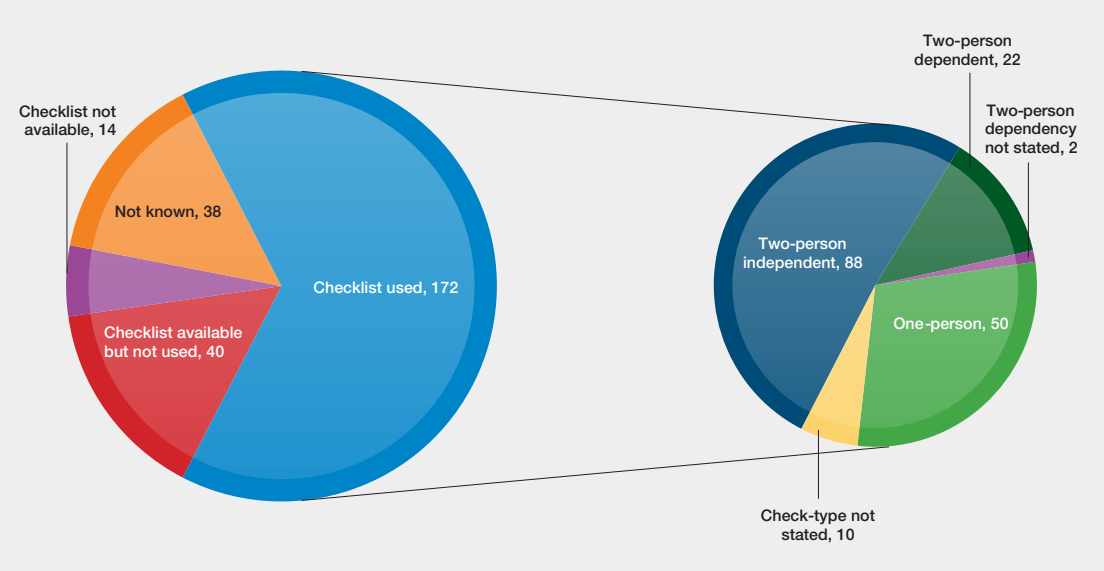


Figure 13.4: The presence and types of pre-administration check in RBRP errors (n=264)

In the 172 reports which stated a pre-administration checklist was used, most 112/172 (65.1%) had a two-person check, and the majority of these, 88/112 (78.6%) used a two-person independent check. Data regarding dependency of checks was not consistently reported. SHOT recommends that local blood transfusion policies are aligned with national guidelines and if local policy requires a two-person checking procedure, each person should complete all the checks independently (double independent checking) (BSH Robinson et al. 2018). See 'Recommended resources' at the end of this chapter for an educational video produced by SHOT and NHS Blood and Transplant patient blood management team.

Near miss RBRP cases n=118

There were 118 near miss RBRP incidents, 24/118 (20.3%) originated in the clinical area and 94/118 (79.7%) originated in the laboratory.

Most cases, 98/118 (83.1%), were detected when collecting the blood component or at the pre-administration checks, with 72/118 (61.0%) using a formal pre-administration checklist.

Conclusion

Pre-administration patient side safety checks can pick up RBRP errors, but these have to be carried out correctly to be effective. Transfusion errors can potentially result in patient harm; these incidents were where a patient was transfused correctly despite one or more serious errors that in other circumstances might have led to an incorrect blood component transfused. As in previous years, some of the incident investigations and questionnaires do not find or state the main causal and contributory factors. There

are still reports mentioning clerking errors due to misinformation provided by patients themselves or from ambulance teams or completely new entries on Trust/Health Board systems. Sampling and labelling errors continue to be reported. Lack of appropriate checks at collection of blood components meant that there were missed opportunities to pick up some of the RBRP errors. While the collection process may differ between establishments, there are essential checks that must made at this point which could reduce the number of RBRP (and IBCT) incidents. This has been discussed in previous Annual SHOT Reports and collection checks should follow BSH guidelines (BSH Robinson et al. 2018).

Many RBRP errors could be avoided by careful checking of the documentation on the prescription during the pre-administration checking process.

Recommended resources

SHOT Video: The Pre-administration Blood Component Transfusion Bedside Check 2020
https://www.shotuk.org/resources/current-resources/videos/

SHOT Safe Transfusion Practice: Transfusion Checklist
https://www.shotuk.org/resources/current-resources/

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Laboratory Errors n=651 (431 transfused errors and 220 near miss)

14

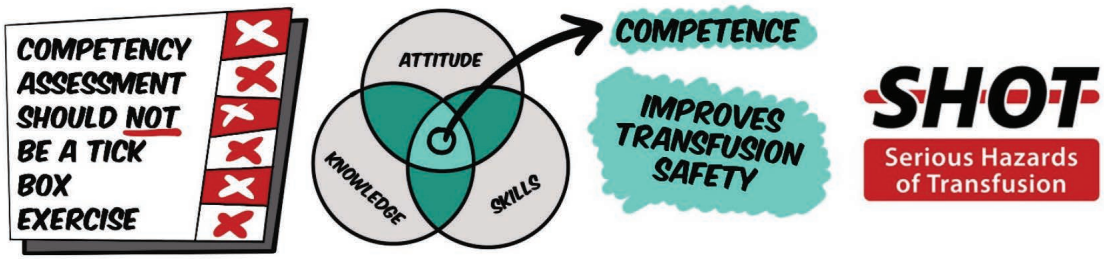
Authors: Victoria Tuckley, Nicola Swarbrick, Heather Clarke and Peter Baker

Abbreviations used in this chapter

ABOi	ABO-incompatible
BMS	Biomedical scientist
CAS	Central alerting system
cffDNA	Cell-free fetal deoxyribonucleic acid
CLAHSE	Component labelling, availability and handling and storage
DHTR	Delayed haemolytic transfusion reaction
EQA	External quality assessment
FFP	Fresh frozen plasma
HSCT	Haemopoietic stem cell transplant
IBCT	Incorrect blood component transfused
ICU	Intensive care unit
Ig	Immunoglobulin
IT	Information technology
LIMS	Laboratory information management systems
MHP	Major haemorrhage protocol
NHSBT	National Health Service Blood and Transplant
NM	Near miss
PID	Patient identification
RBRP	Right blood right patient
SOP	Standard operating procedure
SRNM	Specific requirements not met
SRR	Sample receipt and registration
UK	United Kingdom
UKNEQAS	UK National External Quality Assessment Scheme
UKTLC	UK Transfusion Laboratory Collaborative
WBIT	Wrong blood in tube
WCT	Wrong component transfused

Key SHOT messages

- Sensitisation to the K antigen in patients of childbearing potential is preventable in most circumstances
- A mismatch in workload and staffing levels had some impact upon over half of all laboratory incidents. When staffing levels are unsafe this must be escalated
- Electronic systems should act as an additional barrier. Having transfusion IT systems in place does not negate the need for staff knowledge and skills. Staff should not rely on IT as the only fail-safe mechanism
- Final checking of the unit prior to issue is essential. The use of label verification in LIMS or electronic blood-tracking systems helps to optimise safety. Use of the PAUSE checklist would detect many laboratory errors prior to release of the unit



Recommendations

- Many errors occur due to established procedures not being followed. It is important that laboratory staff understand the 'why' of an action before they move onto the 'how'. The UPTAKE model of competency-assessment (Narayan et al. 2020) remains a useful model to base competency-assessments upon
- Inadvertent sensitisation to the K antigen is classed by SHOT as causing major morbidity and can have devastating consequences in future pregnancies. Standard operating procedures surrounding provision of K-negative components when appropriate should be reviewed to identify any gaps

Action: Transfusion laboratory managers, training leads

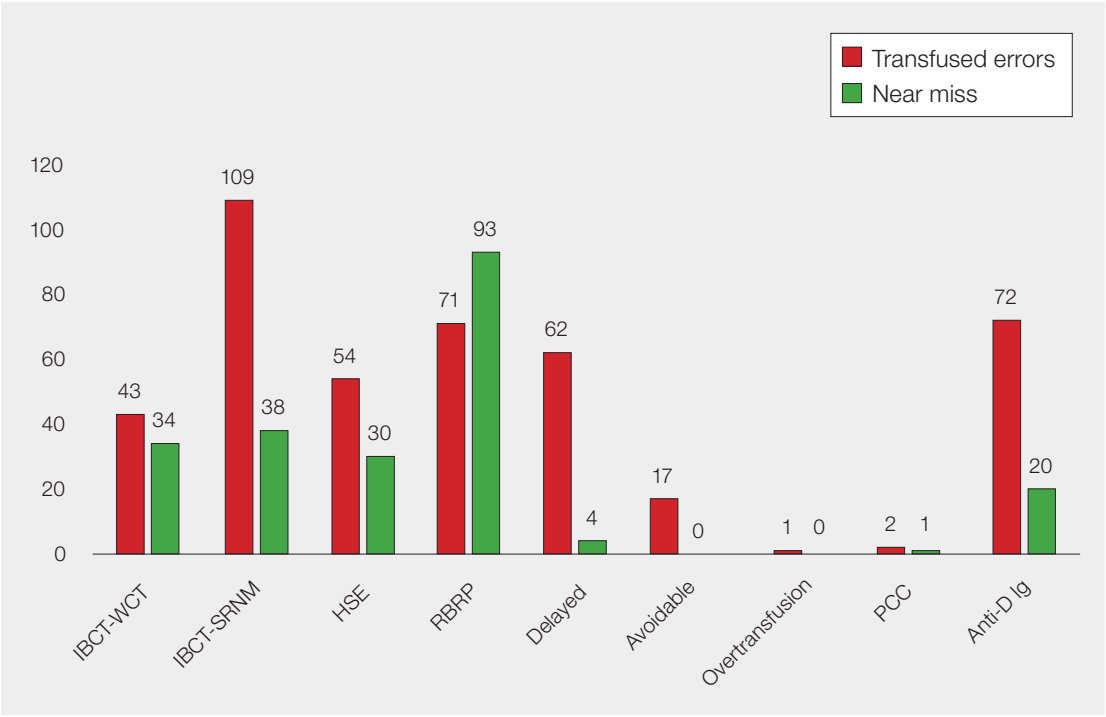
- Staff who are providing training within the laboratory should have the requisite knowledge before delivering this training, in line with UKTLC standards (see 'Recommended resources') to ensure knowledge gaps are not perpetuated

Action: Transfusion laboratory managers, pathology management, training leads

Introduction

In 2022 there were 651 laboratory errors in total, comprising 431 transfused errors, and 220 near miss errors, which is a slight increase from 2021 (573 errors).

Figure 14.1: Laboratory incidents and near misses by category of outcome (n=651)



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 concentrate; Ig=immunoglobulin

The highest proportion of errors occurred within the testing step, 157/431 (36.4%), followed by component labelling, availability, handling, and storage, 146/431 (33.9%), and component selection, 81/431 (18.8%). This highlights the safety critical steps to ensure safe transfusions. Laboratory managers should regularly review their SOP and competency-assessments for staff in these areas to identify any deficiencies. Figure 14.2 illustrates at which stage in the laboratory the error occurred.

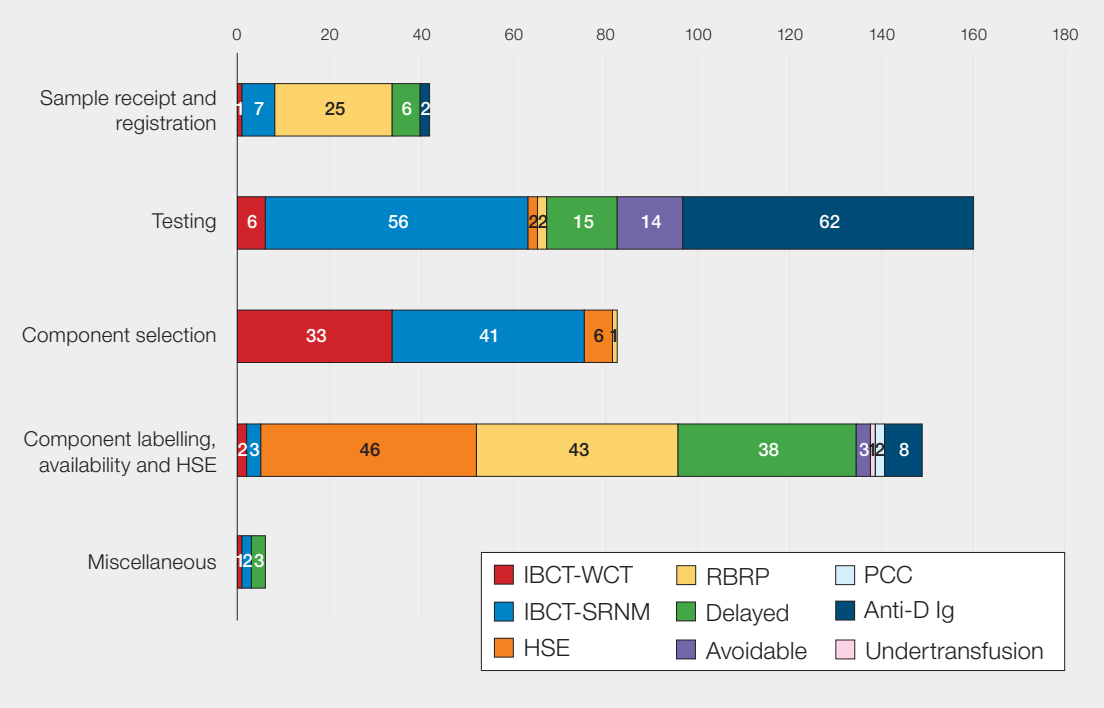


Figure 14.2: SHOT laboratory data across all categories showing the stage in the transfusion process where the primary error occurred (n=431)

Of the 7 incidents classed as 'miscellaneous', 3 resulted in IBCT-SRNM errors, 3 delayed transfusions and 1 IBCT-WCT

Once again, most errors occurred within the IBCT-SRNM category, 109/431 (25.3%) and suggests gaps in staff knowledge related to specific transfusion requirements.

Most NM laboratory errors (Figure 14.3) occurred at the CLAHSE stage, 114/220 (51.8%). Collection errors assigned to the laboratory were instances where the laboratory staff handed over the component to clinical staff themselves. The 1 case identified as 'miscellaneous' was due to a component being received from the Blood Service which contained multiple clots that were identified in the clinical area.

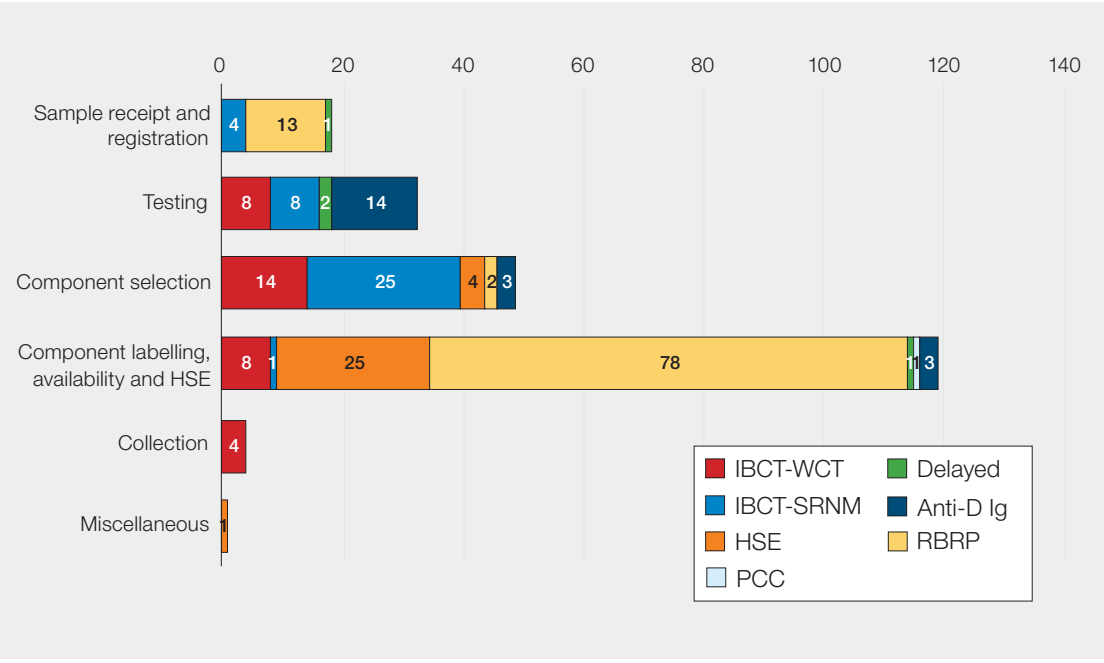


Figure 14.3: SHOT near miss laboratory errors showing at which stage in the transfusion process the primary error occurred with outcome (n=220)

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 concentrate; Ig=immunoglobulin

If unidentified, most NM laboratory errors could have resulted in RBRP events, 93/220 (42.3%). These errors are often identified by vigilant clinical staff and show how teamwork is essential for patient safety.

The use of electronic label verification systems could help reduce both NM-RBRP errors and so many errors that occur at the CLAHSE step. SHOT recommends the use of the PAUSE tool and component exit check as found in the Annual SHOT Reports 2021 and 2020 respectively to ensure components are suitable before release to the clinical area.

Deaths related to transfusion n=0

No deaths occurred due to laboratory transfusion errors.

Major morbidity n=4

There were 4 cases which resulted in major morbidity, all involved sensitisation to the K antigen in patients of childbearing potential and were component selection errors. All patients were females under the age of 34, and in 3/4 cases the transfusion was required for acute bleeding directly related to pregnancy. See Case 14.2.

A further patient required admission to the ICU following a DHTR. This occurred in a patient with sickle cell anaemia who received a non-phenotype matched transfusion. The patient subsequently formed an anti-C. This case is included in the figures and commentary for Chapter 18, Haemolytic Transfusion Reactions (HTR).

ABO-incompatible transfusions n=1

One laboratory error resulted in the ABOi transfusion of group O FFP to a group A patient. The error was detected by laboratory staff prior to transfusion however due to the emergency situation, the transfusion was approved by the clinician and no adverse impact was reported in the patient. This case can be found within the supplementary material for Chapter 9, Incorrect Blood Component Transfused (IBCT) (https://www.shotuk.org/report-summary-and-supplement-2022/).

Errors by step in the transfusion process in the laboratory

Sample receipt and registration (SRR) n=59 (41 transfused errors and 18 NM)

Transfused errors were mostly RBRP PID errors 25/41 (61.0%) and were due to demographic data entry errors. Where IBCT-WCT or IBCT-SRNM errors occurred, this was mainly due to staff not noticing details on the request form which therefore meant that appropriate actions were not taken.

'Many RBRP investigations only address laboratory errors at sample receipt and registration, but this may not be the primary cause. Reporters should look back to the original error (the oversight at sample taking, and why this occurred) to help identify the primary cause and prevent these errors recurring.' (Narayan et al. 2021).

Learning point

- Checking to ensure that all details on the transfusion request, sample and LIMS are aligned helps to identify errors and enhance safety of transfusions

Testing errors n=189 (157 transfused errors and 32 NM)

Testing errors have increased by over 25% from 2021, and are the largest group of laboratory errors, which was last seen in 2020. The majority of these adverse events were in the categories anti-D Ig, 62/157 (39.5%) and IBCT-SRNM, 56/157 (35.7%) (Figure 14.4). IBCT-SRNM errors are discussed further in Chapter 9, Incorrect Blood Component Transfused (IBCT), but in summary were mainly incomplete testing prior to issue of units (21/56) or inappropriate electronic issue (17/56). Antibody identification errors (7/21) and internal quality control issues (7/21) accounted for the largest proportion of incomplete testing (Figure 14.4).

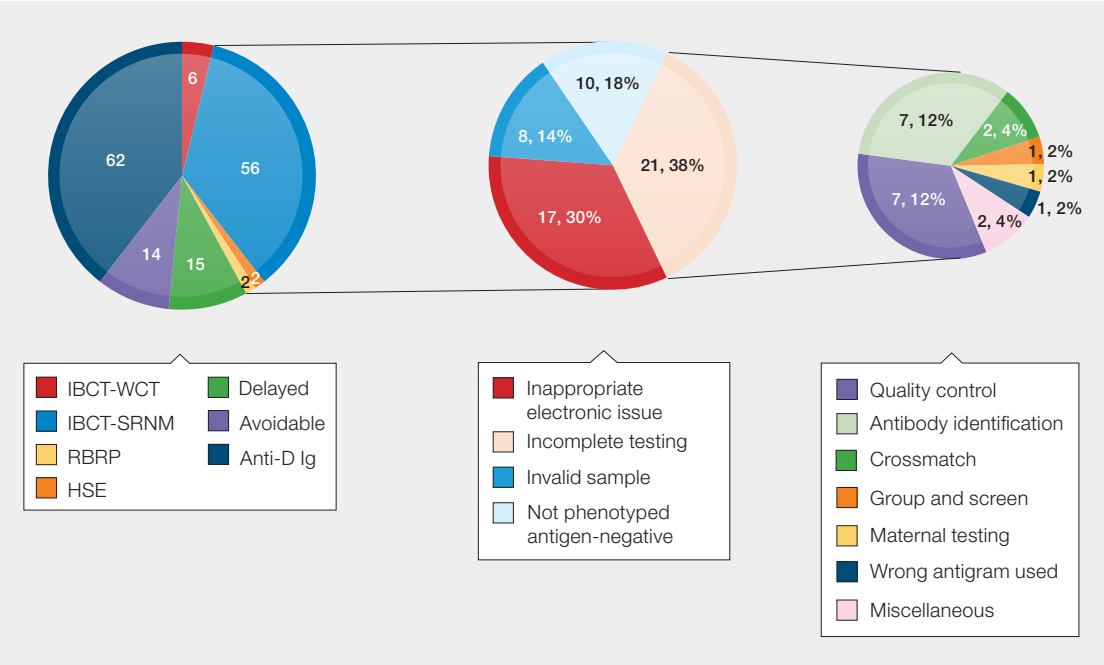


Figure 14.4: Laboratory testing errors by reporting category (n=157) and SRNM testing errors by subcategory (n=56)

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; Ig=immunoglobulin

Most anti-D testing errors were procedural errors, 18/62 (29.0%), where laboratory staff did not follow the processes set out within the SOP. Additionally, 10/62 (16.1%) were due to communication issues surrounding test results, and errors in result input from referral services.

A total of 19/62 of anti-D testing errors were due to discrepancies in cffDNA results. There were 11/19 that gave a false positive result and 8/19 gave a false negative. This is not aligned with published rates; which state false negatives are up to 200 times less likely than false positives (0.1% false negative compared to <2% false positive) (NHSBT 2022). NHSBT, which is one of multiple providers of cffDNA testing in the UK, have confirmed 13 false negative cffDNA results were reported in 2022. No information about reports are available from other providers of cffDNA testing. It is important to report inaccurate results to both cffDNA testing providers and to SHOT, to ensure accurate data can be published and accurate risk assessments formed. Figure 14.5 shows the number of cffDNA prediction errors reported to SHOT since 2019.

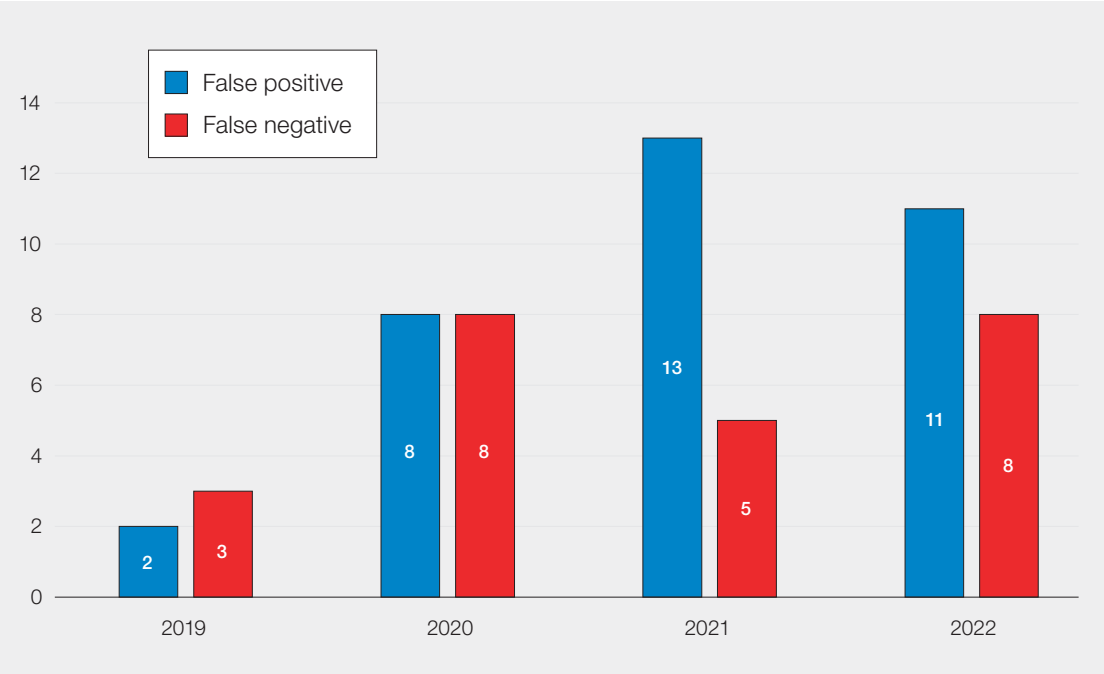


Figure 14.5: Cell-free fetal DNA prediction errors reported to SHOT 2019-2022

Case 14.1: Missed anti-D Ig administration following delivery due to multiple errors with inconclusive cffDNA result

A D-negative woman in her 30s had an emergency caesarean section. The cffDNA result was inconclusive, so cord and maternal samples were sent for testing. The cord sample was found to be positive but no anti-D Ig was issued. The BMS assumed this had been done immediately following delivery as with pregnancies that are predicted D-positive. The ward was not contacted to inform them that anti-D Ig was needed and a Kleihauer test was also not performed. The clinical staff did not check whether anti-D Ig was required, the woman was discharged without having anti-D Ig administration and had to return for this >72 hours after giving birth. The reporter noted that staffing levels directly impacted the correct procedures being followed. The laboratory had implemented contingency plans for staffing and non-registered staff were the only staff present for 4 and a half hours earlier in the day, causing a large backlog of work. This sample was also processed whilst two other major haemorrhages required support by a single member of BMS staff.

Errors in both clinical and laboratory areas can be identified in this incident and multiple factors appeared to be contributory including staff issues, mismatched workload, cognitive bias (assumption) and lack of appropriate checks in the process. Hospital management has a responsibility to ensure that adequate staff are available in clinical and laboratory areas to support safe transfusions. Clear communication between the laboratory and clinical areas is essential to prevent patient harm.

Learning points

- Anti-D testing and results can be complex. Standard operating procedures and competency-assessments must ensure that laboratory scientists have the required fundamental knowledge to issue advice and support patient care
- Failure to administer prophylactic anti-D Ig within 72 hours can cause maternal sensitisation to the D antigen. Ensure postnatal testing and prophylactic anti-D Ig administration are completed before discharge

Component selection errors n=129 (81 transfused errors and 48 NM)

Component selection errors accounted for 81/431 (18.8%) of laboratory errors, with the majority due to specific requirements not being met, 41/81 (50.6%) and wrong component selected for transfusion, 33/81 (40.7%).

Where the components did not meet the patient's specific requirements this included units not phenotyped/antigen-negative when required (14/41), not irradiated (12/41), and K-positive units given to patients of childbearing potential (6/41).

Where wrong components were issued by the laboratory the majority were cases of wrong ABO group selected (28/33), of which 13/28 were related to wrong ABO components issued to HSCT and SOT patients. All these 13 cases stated the error was related to IT, with either the LIMS alerts being overridden by the BMS or limitations within the LIMS rules not clearly stating the requirements for this patient group.

SHOT issued a Safety Notice (see 'Recommended resources') regarding the importance of identifying and providing components with specific requirements in 2022. This was in response to the increasing trend in IBCT-SRNM errors. A gap analysis tool was also made available to assist laboratories in evaluating their current policies and procedures.

Case 14.2: Major morbidity due to a component selection error for a female of childbearing potential

A female in her 30s was found to have an anti-K as part of antenatal screening. She had required two units of red cells post-delivery in a previous pregnancy due to active bleeding. One of these units issued by the BMS was K-positive. The LIMS had an alert for all females less than 50 years to state 'Females of childbearing potential should receive K-negative red blood cells unless they are unavailable in an emergency', but this did not prevent the issue of K-positive red cells to this patient

despite the availability of K-negative units. The investigation stated there was a lack of knowledge in recently qualified BMS staff about K-negative requirements, and that continued recruitment and retention issues had placed a training burden on the remaining staff. Additionally, there were leadership issues due to changes to restructuring.

The preventative actions included a better learning environment for trainees and improved competency-assessments, recruitment of a new band 7 post to assist with training and additional out-of-hours band 3 staff, with the aim of moving to a new LIMS where this issue would be addressed. There were 3 other cases which involved K-positive units issued to K-negative patients of childbearing potential which resulted in sensitisation.

Learning points

- Understanding the reasons for specific transfusion requirements will help reduce errors
- Appropriate LIMS rules and algorithms for patients with specific requirements improves safety

Component labelling, availability and handling and storage errors n=263 (146 transfused errors and 117 NM)

There has been an increase in CLAHSE errors, which accounted for 146/431 (33.9%) of laboratory errors, and included 46 handling and storage errors, 43 right blood right patient errors and 38 delays. Factors leading to these delays involved laboratory staff not having a clear understanding of the request including urgency, communication gaps between laboratory and clinical areas following rejected crossmatch samples and blood availability in MHP/urgent cases. Lack of awareness of concessionary release processes also led to delays in provision of blood components.

There were 30/46 handling and storage errors related to cold chain errors, of which 12/30 were units inappropriately returned to stock and 9/30 refrigerator/equipment failures. There were also 9 cases where the reservation period of the crossmatch sample had been exceeded.

The majority of RBRP errors were due to labelling errors (37/43) of which 25/37 were due to transposed labels between units intended for the same patient.

Learning points

- Incorporating the PAUSE checklist or IT as an additional safety check can help reduce the risk of transposed label errors
- A clearly defined quarantine process will prevent units being inappropriately returned to stock following cold chain issues
- Clear communication between laboratory and clinical areas is essential in understanding transfusion urgency, requirements, and availability of units
- Not informing the clinical area of rejected crossmatch samples can lead to delays in provision of blood
- Errors can be prevented when transfusion laboratory staff check that the date of the required transfusion does not extend beyond the date of the sample expiry

Collection errors n=4 (0 transfused errors and 4 NM)

All these near miss collection errors were due to the transfusion laboratory staff handing over incorrect units to clinical or portering staff at the point of collection, with 3 for the wrong patient, and 1 of the wrong component type.

Miscellaneous errors n=7 (6 transfused errors and 1 NM)

These miscellaneous errors included misunderstanding of requests, data entry errors, misreading of results, LIMS configuration issues, poor communication regarding a transferred patient and 1 case of a red cell unit containing clots.

Laboratories under pressure

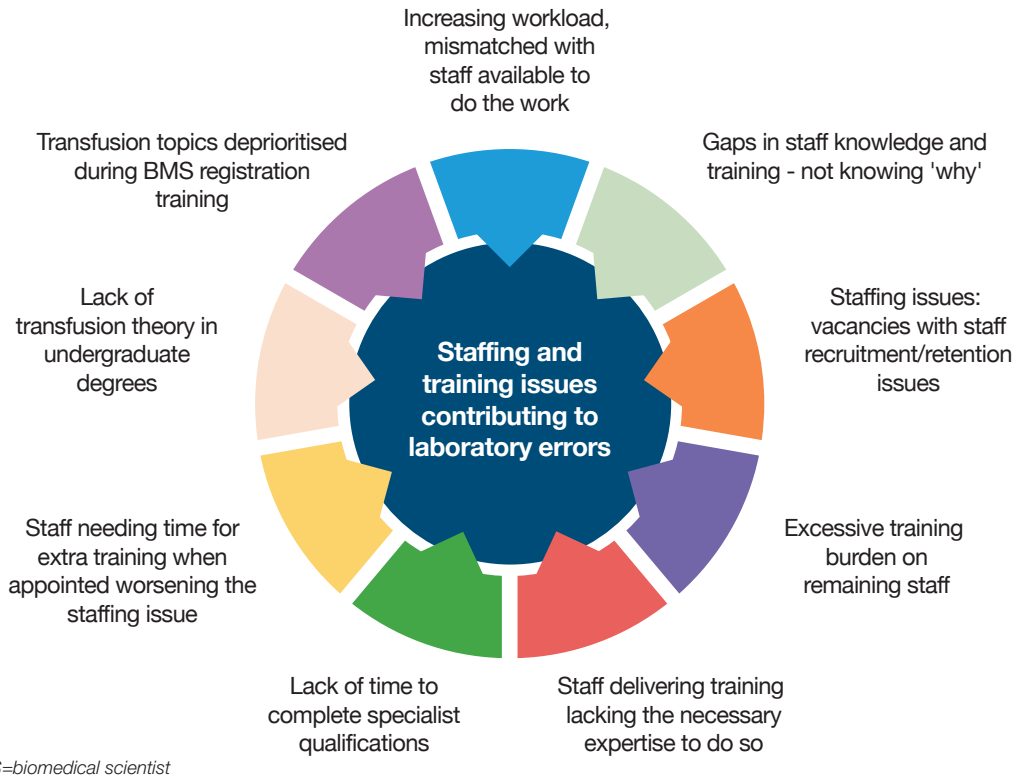
Basic errors in the laboratory continue to occur and, in some cases, have led to major morbidity in patients. Gaps in staff knowledge contribute to transfusion errors. The correct use and configuration of IT systems, underpinned by sufficient levels of knowledge within laboratory staff can prevent these errors. Training, competency, and skills development must be of value, and not a tick box exercise.

There are discrepancies between staff who have completed their competency-assessment and those who have sufficient knowledge to complete the task, with many reporters stating that gaps in knowledge was an influential factor in the laboratory error despite being up to date with competency-assessments. In total 70/431 (16.2%) of reporters stated there was 'some', 'a lot' or 'fully' a mismatch between workload and staffing provision at the time of the incident. Staff should be supported, and transfusion laboratories should be adequately staffed to match workload.

See the supplementary information on the SHOT website for further analysis of the human factors for laboratory incidents (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Staffing and workload issues compounded by suboptimal training contribute to errors and are illustrated in the figure below.

Figure 14.6: Summary of issues contributing to laboratory errors



BMS=biomedical scientist

Acknowledging laboratory excellence

Whilst there are many challenges identified in the transfusion laboratory, data submitted to SHOT also identifies areas where laboratory staff are excelling. In 2021 a question was added to the SHOT questionnaire 'Was any specific good practice identified as a result of this incident? If so, please provide details. Within laboratory reports 81/431 (18.8%) identified areas of good practice. Analysis of this data has identified key themes of excellence within the laboratory:

- Swift action - staff were able to identify errors and quickly rectify them to prevent further harm
- Communication and collaboration with clinical areas to improve patient outcomes
- Improved processes following an adverse incident - several processes were reviewed post incidents to identify areas for improvement
- Initiative - in many case the laboratory staff acted upon their knowledge to investigate unusual occurrences, which identified errors and allowed for further follow up
- Candour, escalation and follow up - staff were honest and escalated matters to senior staff where appropriate. Laboratory staff realise the importance of their actions and the impact upon patients

Laboratory processes detected 717 of the 890 reported WBIT samples in 2022, highlighting the important role that the laboratory plays in preventing patient harm.

Instances of excellent practice continue to be under-recognised. Studying excellence in healthcare, including in transfusion laboratories, can create new opportunities for learning, help improve resilience and staff morale. Transfusion laboratory staff have a pivotal role to ensure transfusion safety with decisions having an impact on patient care and outcomes. One such case reported under the acknowledging continuing excellence category this year illustrates how laboratory staff knowledge can be critical in saving lives.

Case 14.3: Good practice by laboratory staff triggers lifesaving treatment of baby

A BMS identified a mixed field result within a group and screen sample for a pregnant patient. This prompted the BMS to contact the clinical area to request an additional sample and highlight the risk of large fetomaternal haemorrhage. The patient was brought back into hospital for cardiotocography, the results of which were suspicious and resulted in early delivery of the baby. The baby was very anaemic and required red cell transfusion. If this had not been noted by the BMS and escalated, the mother may not have been reassessed and the baby not successfully delivered. A 'Greatix' report was raised within the organisation to acknowledge the prompt action of the BMS who has also received acknowledgment throughout the pathology network.

Conclusion

Transfusion laboratories are critical for providing safe and timely blood components. To deliver this life saving service the laboratory must be sufficiently staffed, with trained and competency-assessed staff for the tasks undertaken. There must be the right skill mix to ensure a safe service provision, and those providing training to others must have adequate knowledge to provide this. Embedding a learning culture in all organisations will support the individuals, the organisation as a whole, and the service provided by laboratories.

There needs to be a clear understanding of not only how staff perform steps but why they are required, and how the patient may be impacted should these steps not be followed. This is particularly important to ensure the right components with the correct specifications are provided for patients.

Use of IT supports safe transfusions, but its effectiveness is reliant on correct setup, sufficient staff training, and ongoing system development. Overreliance of IT to 'catch errors' must be avoided, with staff knowledge and understanding being sufficient to prevent the primary error. Alert fatigue must be avoided as this can lead to errors.

Before development of a new process, or the introduction of new equipment, a thorough systems design which incorporates the consideration of human factors must be undertaken. This will aim to reduce the occurrence of future errors, thus improving transfusion safety. Human factors principles must also be incorporated into incident investigation procedures to ensure all influencing factors have been considered, and appropriate corrective and preventative actions can be introduced. Learning from errors, and sharing that learning, is an essential step of these preventative actions.

Laboratories have faced many difficulties over recent years which seem to have been exacerbated following the COVID-19 pandemic. These have included staff shortages, difficulties in recruitment and retention of staff, staff sickness, poor system designs, and insufficient or inadequate resources. These concerns must be addressed to ensure that transfusion laboratories have a stable future, where staff feel supported, and care of patients is not negatively impacted.

UK Transfusion Laboratory Collaborative update

Author: Kerry Dowling, Chair of the UKTLC

The UKTLC continues to support laboratories with an aim to increase the safety of transfusion. This year has seen the release of the 2023 updated version of the UKTLC minimum standards for staff qualifications, training, competency and the use of information technology. The 2022 survey results were also released with the main themes covering ongoing staffing shortages and poor transfusion knowledge for newly registered BMS staff. The survey highlighted negative impacts on laboratory functions related to the COVID-19 pandemic and the formation of networks. Also, despite SHOT and UKTLC recommendations for implementation of EBMS for patient safety, approximately a third of respondents had no electronic blood management system in place and less than a quarter had full vein-to-vein systems.

Following the 2022 CAS alert (preventing transfusion delays in bleeding and critically anaemic patients (SHOT 2022)), the 2022 survey asked about delays associated with staffing and education. Approximately a third of respondents noted an incident or near miss delay in provision of blood due to inadequate staffing levels and/or staff education and knowledge.

On a positive note, the survey data shows that laboratories are embracing learning from excellence and incidents, have introduced business continuity plans and have staff capacity plans.

This year the UKTLC will be reviewing where we can take action with our partner organisations to help laboratories achieve compliance with the standards and to consider tools to help education of BMS staff in the workplace.

UK NEQAS update

Authors: Richard Haggas, Katy Veale and Claire Whitham, UK NEQAS BTLP

Participation in 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.

As in other years, 'procedural' errors (errors caused by sample or result transposition, and/or data transcription into the UK NEQAS website) continue to be a significant cause of penalty during 2022. There were no ABO grouping errors, but three laboratories made a D-typing error as a result of transposition of samples or data entry errors. Understandably, more of these procedural errors occur during 'R' coded exercises, due to the additional tests required over an 'E' coded exercise. Since ABO/D grouping and antibody screening tests are largely automated, with automatic transmission of results to the LIMS, the errors seen in EQA for these tests may not be fully representative of a similar error in a clinical situation, where the automated processes are functioning as intended. However, during analyser and/or LIMS downtime, these procedural errors acquire a greater significance in terms of risk to the patient. Where tests are still performed manually, with no automated transmission of results to the LIMS, the risks of procedural errors are a constant that should be mitigated as far as possible. When testing samples, or entering data for EQA samples, it is important to check that the data is being recorded and transcribed against the correct patient or donor; this also applies to the positive identification of the sample being tested, data entry of results of manual testing of clinical samples into a LIMS, or in the event of LIMS downtime. Care should be taken to confirm the identity of all samples before testing. For clinical samples, this requires a full check of the patient demographic details to ensure that results are assigned to the correct patient. EQA samples should be subject to the same process with a check of the patient number and exercise code on each sample.

Like ABO and D grouping, antibody screening sees very low error rates. Although few in number, false negative antibody screens can have a significant impact, particularly in laboratories employing electronic issue as a means of establishing compatibility. In exercise 22E9, one participant did not notice that the analyser had flagged an 'incorrect volume flag' and this was not acted upon; the participant missed the anti-c+K in the patient plasma sample as a result. Flags against reactions or results on an analyser are intended to draw attention to a problem with testing and laboratories should have a policy in place for handling all flags to ensure invalid results are not accepted.

Antibody identification continues to see the highest proportion of errors, particularly when two antibodies are present in a sample. In exercise 22E1, two laboratories made errors for Patient 1 (anti-E+M), reporting a single antibody (anti-M) without noting the presence of the second specificity. In exercise 22E3, two laboratories recorded a total of three antibody identification errors. The first switched results for Patients 3 and 4 during data entry. The second, recording anti-Fy^{a} only for Patient 3, made a transcription error when recording screening cell results and antigen profiles onto an antibody identification sheet, and also did not take account of reactions obtained in an enzyme panel when reporting. In exercise 22E7 the Patient 2 sample contained anti-D+Jk^{a}; all laboratories were able to identify the anti-D, but seven laboratories misidentified the second specificity (six recording anti-M and one anti-Fy^{b}). In many cases of antibody identification errors there is either a failure to take account of all positive reactions with available panel cells, or a misunderstanding of the BSH guidelines (BSH Milkins et al. 2013) regarding the inclusion and exclusion criteria for antibody identification. To avoid misidentification, every antibody investigation should include a systematic process for exclusion and positive identification of antibody specificities, and all positive reactions should be accounted for before a conclusion is reached. BSH guidance (BSH Milkins et al. 2013) for inclusion of antibody specificities requires that 'the plasma is

reactive with at least two examples of reagent red cells expressing the antigen and non-reactive with at least two examples of reagent red cells lacking the antigen.

In exercise 22R2, one laboratory missed an ABO-incompatibility, selecting a group A donor as theoretically compatible with a group B patient, as they failed to notice the group of the donor on the sample bottle. In exercise 22R5, one laboratory obtained negative serological crossmatching results for Patient 1 (anti-K) vs. Donor Z (K+). In exercise 22R8 four laboratories missed seven incompatibilities for Patient 3 (anti-Fy^{a}) vs. Donors W and Y (Fy(a+b-) and Fy(a+b+) respectively; three recorded false negative reactions in a serological crossmatch and one selected Donor Z as theoretically compatible. The rate of crossmatching errors was six times higher than antibody screening errors in 2022, which likely reflects a number of factors. Antibody screening cells are of a known antigen profile, are prepared at the correct cell suspension and are stored in the optimal medium. Donor cells used for crossmatching, however, are of unknown zygosity, variable condition and require manipulation before testing. Serological crossmatching also involves manual steps even if automation is used.

Recommended resources

SHOT Safety notice 02: Ensuring patient specific transfusion requirements are met
SHOT Safety notice 02: Gap analysis plan
https://www.shotuk.org/resources/current-resources/safety-notices/

PAUSE Checklist
https://www.shotuk.org/resources/current-resources/

UKTLC Standards 2023
https://www.shotuk.org/resources/current-resources/uktlc/

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Errors Related to Information Technology (IT) n=376

15

Authors: Jennifer Davies and Megan Rowley

Definition:

This chapter includes transfusion adverse events that relate to LIMS as well as other IT systems and related equipment used in the delivery of hospital transfusion services.

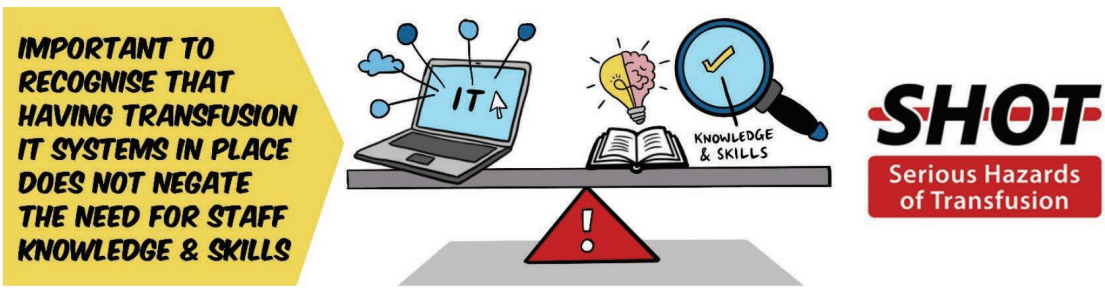
Cases selected include events where IT systems may have caused or contributed to the errors reported, where IT systems have been used incorrectly and includes cases where IT systems could have prevented errors but were not used.

Abbreviations used in this chapter

ADU	Avoidable, delayed and under or overtransfusion	**Ig**	Immunoglobulin
BMS	Biomedical scientist	**IT**	Information technology
BSH	British Society for Haematology	**LIMS**	Laboratory information management system
CMV	Cytomegalovirus	**NHS**	National Health Service
EBMS	Electronic blood management system	**RBRP**	Right blood right patient
ED	Emergency department	**SCRIPT**	SHOT Collaborative Reviewing and reforming IT Processes in Transfusion
EI	Electronic issue		
IBCT	Incorrect blood component transfused	**SRNM**	Specific requirements not met
ICU	Intensive care unit	**UK**	United Kingdom
ID	Identification	**WCT**	Wrong component transfused

Key SHOT messages

- Electronic systems and technology make transfusions safer, but they must be designed with consideration of human factors and ergonomics. Staff must be trained for their correct use. If systems are used as designed and as intended, without workarounds or short cuts, the safety features and benefits of use will be realised
- Staff responsible for implementing or upgrading systems must understand the functionality and interoperability of the system to ensure adequate validation is completed and avoid unexpected consequences. This process should be supported by the supplier, as the subject matter experts, and local IT departments



Recommendations

- Staff must use LIMS and EBMS as intended and avoid workarounds
- Staff must fully understand the nature and scope of the electronic system or technology being used and the purpose of the manual system it supports or replaces
- Healthcare leaders should ensure there are sufficient numbers of staff trained to use electronic systems and technology when they are introduced to provide confidence in benefits for workflow and for patient safety
- Only trained and competent staff should have access to IT systems that support transfusion. Sharing of access cards or computer logins must not be permitted under any circumstance
- Equipment, including communication devices, should be regularly tested, maintained and on a replacement program to ensure that it is available and functions correctly when required

Actions: Healthcare leaders and all staff involved in transfusions

Background

SHOT Collaborative Reviewing and reforming IT Processes in Transfusion (SCRIPT)

The SHOT SCRIPT group was formed in 2019. The main driver was to improve transfusion safety through improved IT systems and practices. SCRIPT aimed to identify gaps in practices, barriers for IT, recognise areas for improvement and begin a constructive dialogue between transfusion stakeholders and IT providers. Further goals included identifying training needs, promoting subject matter experts, and supporting and maintaining a community of practice within transfusion IT. Since 2019 SCRIPT have completed two surveys: an understanding of the status of IT in transfusion with users and an insight into LIMS functionality with LIMS suppliers. The survey results are available via the SCRIPT page on the SHOT website. The user survey results have been shared with NHS England Pathology Transformation Team to highlight the challenges facing hospitals transfusion laboratories with a view to inform decision making around funding bids for IT upgrades within Pathology networks in England.

SCRIPT have added other resources to the web page including how IT can be used to support safe practice with anti-D Ig management in pregnancy, and a variety of IT specification and validation documents shared by reporters. New resources will be added to the website when they become available. SCRIPT would welcome ideas for future resources and invite contributions from all. If you are interested in contributing your own documents or templates, or if you are interested in sharing your experience for the benefit of others in our transfusion community, please email shot@nhsbt.nhs.uk.

The BSH IT guidelines have been updated and should be published in 2023. This will provide a valuable resource for those looking to implement, upgrade or change IT systems.

Digital healthcare is a core strategy for all governments across the devolved nations in the UK. Following the merger of NHS Digital and NHS England on 1 February 2023, NHS England is responsible for designing and operating national data infrastructure and digital systems (NHS England, 2023). Scotland have refreshed their digital health and care strategy (Scottish Government, 2021). Northern Ireland's

digital strategy describes how the country will rise to the challenge of delivering the digital transformation needed to improve health and care outcomes (HSC Northern Ireland, 2022). Health Technology Wales (2023) have published evidence supporting the adoption of electronic blood management systems with associated safety and cost saving benefits.

As the UK moves forward with digital healthcare transformation, transfusion services should strive to ensure that appropriate and effective IT systems are implemented. This should include reliable interoperability with other clinical systems to support transfusion safety.

Implementing new and upgrading existing IT systems

The implementation and upgrade of IT systems are complex multidisciplinary projects involving subject matter experts and IT specialists as well as staff with operational and project management skills. Involvement of quality managers as well as staff with expertise in testing, validation and training is key to successful implementation.

IT systems that support blood transfusions may be single system or networked across several sites and sometimes regional or national. Alternatively, the whole-hospital system covering all aspects of patient care including electronic patient record, patient administration, diagnostics and reporting could be managed by a single system.

The errors reported to SHOT that have an IT or technology element are those where there has been an unexpected or unpredicted consequence *after* implementation. Problems and potential for errors are usually identified during the planning, testing and validation stages – before the systems are used in clinical or laboratory practice. These are not SHOT-reportable, but the SCRIPT group would be very interested to hear of your experience with LIMS or EBMS implementation to help share learning from experiences.

- **What did you learn from this project that would help others?**
- **And if you knew then, what you know now, what would you do differently?**

Below are some examples of cases reported to SHOT in 2022 and, in Table 15.1, the categories where IT errors are derived. Additional case studies can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

Primary reporting category	Number of cases 2022
Incorrect blood component transfused-wrong component transfused (IBCT-WCT)	32
IBCT-specific requirements not met laboratory (IBCT-SRNM)	118
Right blood right patient (RBRP)	71
Avoidable, delayed and under or overtransfusion (ADU)	54
Handling and storage errors (HSE)	101
Total	**376**
Anti-D Ig administration errors	54
Total including anti-D Ig errors	**430**

Table 15.1: Source of cases containing errors related to information technology

Electronic blood management systems

These vein-to-vein IT systems include blood-tracking systems in the clinical areas linked to the LIMS. Most commonly these include tracked blood refrigerators and remote electronic issue refrigerators and increasingly bedside electronic ID systems for sampling and administration of blood components. There are some examples to be aware of where these systems can contribute to adverse events.

Case 15.1: Remote electronic issue on samples with an edited group (IBCT-SRNM)

During correspondence with the LIMS provider, it was mentioned that another site had found a problem with the LIMS/blood-tracking interface which meant samples where the group had been manually edited were still available for remote electronic issue. The IT search identified three samples which had a 'result manually edited' flag but remote electronic issue was still enabled, and blood had been collected for transfusion.

Case 15.2: Multiple errors and misuse of the EBMS (RBRP)

Emergency group O red cells assigned to a specific patient were collected from the laboratory by emergency department staff without a pick-up slip as it was an emergency. The laboratory received an alert to say that there was an incompatibility between the patient ID band and the blood component. The transfusion was stopped immediately, and the component was returned part-transfused. The staff member who administered the transfusion came to the laboratory with two patients' ID bands in their hand stating they had scanned the wrong one and that it was not attached to the patient at the time. Furthermore, the person who started the transfusion was not the same person whose ID badge was used in that process. The ID band printers were not working in the ED, so staff had to go elsewhere to get ID bands printed and multiple wristbands were held in nurse's pockets.

Case 15.3: Equipment and communication failure leading to delay in collection (ADU)

A patient required a blood transfusion for intraoperative bleeding. The EBMS handheld device in theatre was not responding or working after several attempts. Maternity's handheld device was missing. The ICU's handheld device would not print a barcode for use on the collection slip. The clinical team tried to bleep the laboratory several times, but there was no answer. The bleep number was confirmed with the switch board but again no answer. Two colleagues went to pathology and banged on the door until someone answered to gain access to the blood refrigerator for this patient's blood which was needed urgently.

Access cards

The purpose of controlling access to IT systems is to ensure that staff are appropriately trained and competent and to provide an audit trail. The following example demonstrates the risks of sharing access cards or a computer log-in that gives the wrong level of access. Information required to access systems should be secure but not overly complicated such that it could be forgotten when used infrequently.

Case 15.4: Someone else's access card used to get emergency blood (RBRP)

The transfusion laboratory rejected two pre-transfusion samples, so theatre needed to use emergency blood from the remote blood refrigerator. The theatre nurse did not have access to Haemobank because their personal barcode was not working. The hospital transfusion laboratory advised them to seek another staff member with access. This was misinterpreted as being told to use someone else's barcode. O D-negative red cells were removed, and the component transfused in theatre.

Downtime procedures – when equipment doesn't function as intended

There have been several examples this year, repeating the previous experiences, of errors that occur because systems are down and the contingency processes in place are not robust enough – or staff have not been trained in down-time procedures. Equipment failures may introduce unsafe practices which may make sense to the staff at the time but are demonstrated to introduce errors, partly due to over-reliance on the electronic systems or technology and partly due to lack of knowledge about why systems are needed. An illustrative example is given below.

Case 15.5: New LIMS (RBRP)

The department went live with a new LIMS which included a new label printer. As the labels printed, they came out successively, with the first printed label on the bottom when they are removed from the printer. The BMS was unfamiliar with the new design of the labels and, although they checked the patient details, they omitted the bag number check and transposed the bag labels, which were both for the same patient. Immediate action was taken to ask all staff to only print one label at a time and complete that labelling before printing labels for further units. Additionally, quotes were sourced for software which could mandate a 'bag and tag' scan prior to release to prevent such an incident re-occurring.

Functionality, alerts and warnings – LIMS and EBMS

There has been little change from previous years in the problems with flags, alerts and warnings. The problems arise from the configuration of systems so that the warnings are not seen at the time where they are needed or in a format that does not convey the appropriate action to take.

The most common category, particularly for patients needing irradiated or CMV-negative components, is the failure to communicate the need for a specific transfusion requirement so that a flag is not set at all or updated in a timely manner.

Miscommunication and lack of availability or interoperability of systems contribute to errors with selection of phenotyped red cells either to prevent sensitisation or to match a patient with red cell antibodies. Interoperability issues could be with the legacy systems or unlinked records within and between hospital sites.

Case 15.6: Wrong platelets transfused despite multiple alerts (IBCT-WCT)

Platelet components were issued to two patients on the same ward with exactly the same surname, and very similar hospital numbers. The nurse collecting received an audible alert on the blood-tracking system stating, 'stop contact blood bank for advice' and the screen stated that the unit was assigned to a different patient and to return the component to storage. The nurse sought advice from the laboratory and was told to continue with collection. The patient developed a fever and returning the platelets to the agitator resulted in another alert that the platelets were 'already in storage'. The system therefore 'quarantined' the unit. Later, on scanning the platelet component out a second time the blood-tracking system gave an audible alert 'stop contact blood bank for advice and the screen stated that the unit was 'unsuitable for use'. The BMS again advised to continue with collection. The two-person independent pre-administration check did not prevent transfusion to the wrong patient.

Case 15.7: Failure to use a legacy system to look for red cell antibodies (IBCT-SRNM)

Two units of red cells were provided by electronic issue, but legacy system checks were omitted. The patient met all EI criteria according to testing on current LIMS which had been in place since August 2021. The historical anti-K and anti-C were recorded on the legacy system but were not discovered until 'end of testing' form check was performed. These checks should be performed daily because data migration from the legacy system may have been planned but had not yet taken place. There were ongoing staffing capacity issues that could have contributed to the incident.

Learning point

- IT supports safe practice, but only if it is configured, designed, maintained and used correctly

Recommended resources

SHOT SCRIPT resources
https://www.shotuk.org/resources/current-resources/script/

SHOT Laboratory and IT webinar 2020
https://www.shotuk.org/resources/current-resources/webinars/

SHOT Bite No. 13: Information Technology and Transfusion (2020)
https://www.shotuk.org/resources/current-resources/shot-bites/

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REACTIONS IN PATIENTS

16 Febrile, Allergic and Hypotensive Reactions (FAHR) n=294

Authors: Catherine Booth and Jayne Peters

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.

Abbreviations used in this chapter

BSH	British Society for Haematology	**IHN**	International Haemovigilance Network
FAHR	Febrile, allergic and hypotensive reactions	**ISBT**	International Society for Blood Transfusion
FFP	Fresh frozen plasma	**PAS**	Platelet additive solution

Key SHOT message

- Inappropriate use of steroids and antihistamines continue to be seen with staff not using the patient's symptoms and signs to differentiate allergic from febrile reactions. These reactions are distinct and require different investigations and treatment

Recommendations

The recommendations from previous years continue to be relevant and are included here again:

- Give appropriate targeted treatment and if needed, preventative cover for future transfusion (Soutar et al. 2023), as indicated below:

Table 16.1: Targeted treatment for febrile and allergic transfusion reaction

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 PAS) 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

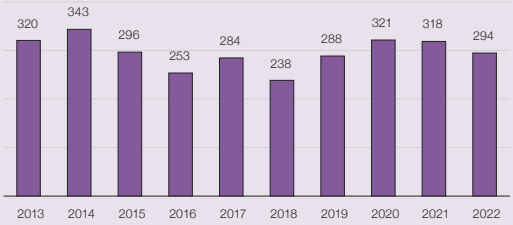
- Transfusion teams should audit appropriateness of treatment given for acute transfusion reactions
- Transfusion reaction reporting forms should be designed to help reporters classify the type of reaction, to guide appropriate investigation
- The possibility of a febrile or allergic reaction should be explained to patients/guardians when taking consent for transfusion with provision of relevant patient information leaflets

Action: Hospital transfusion teams

Headline data 2022

Number of reports n=294
Deaths n=1
Major morbidity n=77

FAHR reports by year



Demographic data

Male n=151
Female n=142
Unknown n=1

Adults n=257
Paediatric n=35
Unknown n=2

Blood component data

Red cells n=140
Platelets n=114
Plasma n=22
Cryoprecipitate n=8
Multiple components n=10

Introduction

Reactions are classified according to the ISBT/IHN definitions, which are summarised below in Table 16.2, available online (ISBT/IHN 2011) and have been adopted by the BSH (Soutar et al. 2023). Mild reactions are not reportable to SHOT.

Table 16.2: 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*

As the reporting categories on SABRE can cause confusion, since 2022, the SHOT definitions document has been updated to clearly map which category to select when submitting a report.

Total number of FAHR reactions n=294

After 2 years with increasing number of reports of febrile reactions, the number reported in 2022 is similar to 2019 and previous years.

In 11 cases, the reporter deemed that transfusion was not clinically indicated according to the relevant BSH guidelines. In a further 28 cases this was 'unknown' and in another 7 cases, not stated. Febrile, allergic or hypotensive reactions are unpredictable and largely unpreventable, illustrating the importance of giving transfusion only when there is no suitable alternative.

Deaths related to transfusion n=1

There was 1 death possibly related to transfusion (imputability 1). A patient in his late 50s with relapsed leukaemia suffered an allergic reaction during a platelet transfusion, followed by airway obstruction requiring intubation and then cardiac arrest. Prior to the transfusion the patient was gravely unwell, being managed in the intensive care unit and had recently received emergency chemotherapy. Various factors may have contributed to the acute deterioration and outcome in this patient.

Major morbidity n=77

The ISBT/IHN classification of a severe reaction has been used to define major morbidity.

Reactions are categorised in Table 16.3.

Table 16.3: Classification of FAHR in 2022

	Moderate	Severe	Death	Total
Febrile	118	14	0	132
Allergic	62	54	1	117
Mixed allergic/febrile	25	7	0	32
Hypotensive	11	2	0	13
Total	**216**	**77**	**1**	**294**

NB: in 15 of the 77 reactions classified as severe this was primarily because the patient was admitted/kept in overnight/re-presented to hospital after discharge

Reactions in IgA deficient patients n=5

There were 5 reactions reported in patients who were subsequently discovered to have severe IgA deficiency (IgA levels <0.07g/L). Three were confirmed to have anti-IgA antibodies; in the other 2 the result was not stated. Three occurred within the first 15 minutes of transfusion and the remaining 2 within 30 minutes. Four were febrile reactions involving marked systemic upset, with other features including hypo- or hypertension, myalgia and vomiting. One presented with significant hypotension alone. None of the reactions had allergic features.

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 (NHSBT 2019).

Anaphylactic reactions n=36

Thirty-six severe allergic reactions were reported which required the use of adrenaline. Seventeen were routine transfusions, 17 occurred on general wards and 2 in an outpatient or day care setting. Children were disproportionately represented: 9/36 (25.0%) cases were in patients under 18 years.

One reaction followed a prophylactic transfusion of platelets prior to a bone marrow biopsy (contrary to guidelines) (BSH Estcourt et al. 2017) and 1 followed transfusion of cryoprecipitate postoperatively to a non-bleeding patient with marginally low fibrinogen. A patient given a red cell transfusion for iron deficiency anaemia suffered a cardiac arrest due to probable anaphylaxis, resulting in hypoxic brain injury.

All clinical areas administering blood components need to be equipped and staff trained to manage a severe acute reaction and transfusion decisions must be made after taking into account risks and benefits to patients. Where transfusions are concerned, less is often more.

Type of reaction by component

This remains similar to previous Annual SHOT Reports; see Figure 16.1. Red cells are usually associated with febrile-type reactions, 96/140 (68.6%) whereas plasma components and platelets more commonly cause allergic reactions, 26/30 (86.7%) and 62/114 (54.4%) respectively.

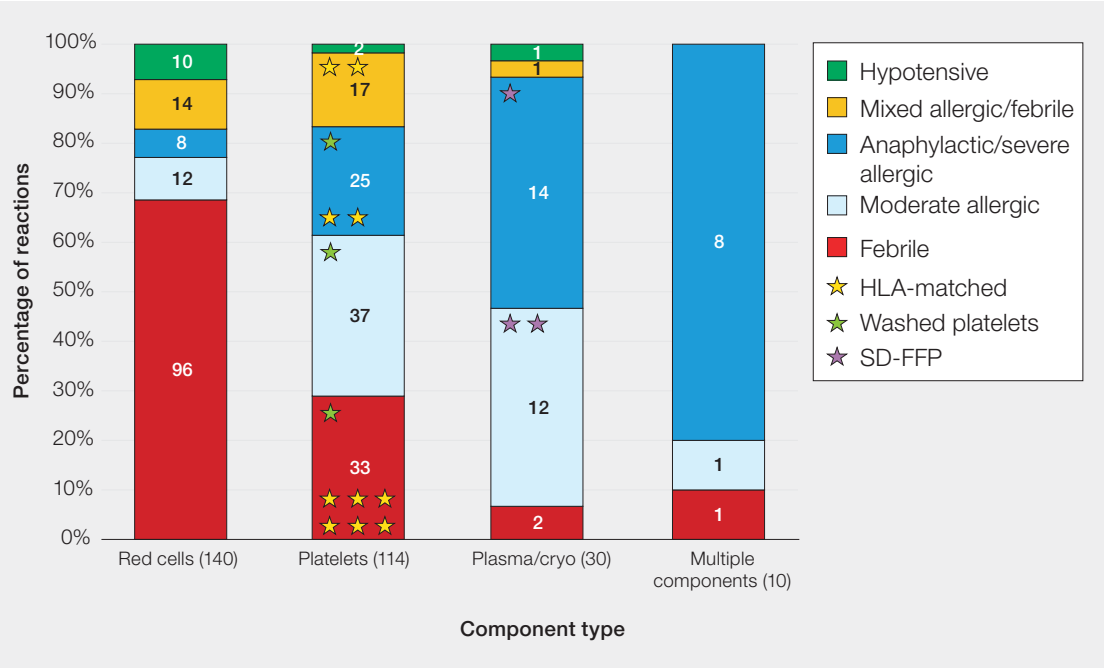


Figure 16.1: Reactions by component type

HLA=human leucocyte antigen; cryo=cryoprecipitate; SD-FFP=solvent detergent treated fresh frozen plasma

The overall incidence of reactions of all types combined is greater for apheresis (46/137,932=0.033%) than for pooled (33/147,904=0.026%) platelet components. Fewer allergic reactions were reported with pooled platelets in PAS than apheresis platelets, which is linked to the lower plasma content (Figure 16.2) (BSH Estcourt et al. 2017).

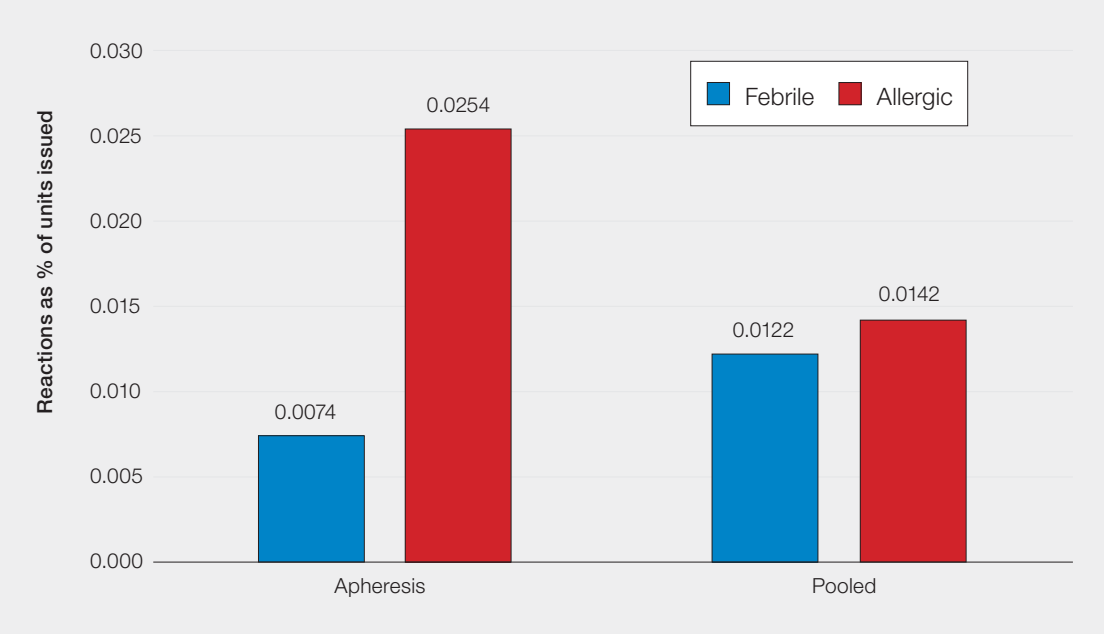


Figure 16.2: Incidence of reactions as a percentage of platelet units issued

Analysis of reactions remains comparable to previous years in the following characteristics (Table 16.4).

Table 16.4: Characteristics of FAHR

Recipient or transfusion characteristic	Percentage
Age distribution	88% of patients were aged 18 years or over
Sex	52% were male
Urgency of transfusion	62% were given routinely
Timing of transfusion	72% occurred within standard hours
Location	61% were on wards and 14% in outpatient/day case units

Over the last 3 years, a higher proportion of reactions have been reported occurring during standard working hours. This might reflect a move away from transfusing outside standard hours except in emergencies, in line with recommendations.

Treatment of reactions

An antihistamine with or without steroid continues to be used inappropriately to treat reactions with only febrile/inflammatory type symptoms and/or signs; see Table 16.5. In addition to no evidence of benefit, the repeated use of steroids may further immunosuppress already immunocompromised patients and increase the risk of side effects such as infection.

Table 16.5: Reported treatment of febrile reaction

Year	Number of febrile reactions	Medication stated	Antihistamine & /or steroid
2022	132	130/132 (98.5%)	61/130 (46.9%)
2021	174	155/174 (89.1%)	61/155 (39.3%)
2020	166	140/166 (84.3%)	58/140 (41.4%)
2019	146	130/146 (89.0%)	62/130 (47.7%)
2018	103	88/103 (85.4%)	39/88 (44.3%)

Subsequent management

A plan for subsequent treatment of febrile reactions was only given in 15 cases, likely reflecting that many patients are not expected to need further transfusion. While only 4 reports explicitly gave a plan to use antihistamine with or without steroids to treat a subsequent pure febrile reaction (Table 16.6), a further 3 stated 'premedication'. The largest planned management category was use of washed blood components, 6/15 (40.0%).

Table 16.6: Planned treatment of subsequent febrile reactions

Year	Number where treatment stated	Antihistamine +/- steroid stated
2022	15	4/15 (26.7%)
2021	18	3/18 (16.7%)
2020	33	7/33 (21.2%)
2019	42	7/42 (16.7%)
2018	27	8/27 (29.6%)

Case 16.1: Misclassification of a febrile reaction results in inappropriate immediate and future management

A child with aplastic anaemia receiving a platelet transfusion developed a fever of 39.2°C with rigors, hypertension and tachycardia. There were no allergic features. He was given an antihistamine and hydrocortisone and a plan was made for prophylactic chlorphenamine before future platelet transfusions.

Learning points

- Antihistamines and steroids have no role in treating or preventing febrile reactions
- Chlorphenamine is a sedating antihistamine and repeated prophylactic dosing may potentially have an adverse effect on a child receiving regular platelet transfusions

Investigation

Laboratory investigations should be tailored to the reaction type. If a febrile reaction is sufficiently severe to warrant discontinuing transfusion completely, repeat compatibility testing should be performed. Repeat compatibility testing is not required in reactions with purely allergic features (Soutar et al. 2023).

Transfusion was discontinued completely in 95 of the 132 febrile reactions. In 22/95 of these (23.2%), there was no mention of repeat compatibility testing.

Of the 117 reactions with purely allergic features, 47/117 (40.2%) were unnecessarily investigated with repeat compatibility testing and in 29/117 (24.8%) blood cultures were taken from the patient. The unit was sent for culture in 3 cases.

Case 16.2: Unnecessary investigations for an allergic reaction

A male in his 30s with thalassaemia, who had a history of allergic reactions in other settings, developed rash, urticaria, facial swelling and mild hypotension after 60mL of his third unit of red cells had been transfused. Transfusion was discontinued, he was given an antihistamine and hydrocortisone and his symptoms settled. He was investigated with IgA levels, mast cell tryptase, repeat group and screen, direct antiglobulin test and blood cultures, none of which showed any abnormality.

Learning points

- Allergic symptoms during transfusion are not caused by red cell antibodies or bacterial sepsis
- Unnecessary investigations add to the demand on the laboratory at a time when staffing is almost universally stretched

Conclusion

Febrile, allergic and hypotensive reactions are an unavoidable and unpredictable risk relating to transfusion. While most are minor, anaphylaxis can be life-threatening, and this emphasises the need to ensure that transfusion is only given when clinically indicated and there is fully informed patient consent. Suboptimal management of acute transfusion reactions continue to be reported, particularly the inappropriate use of antihistamine and/or steroids to treat febrile reactions (in 46.9% of cases). There is a lack of selectivity in investigations following the event, with compatibility testing frequently performed unnecessarily following allergic reactions. The key message remains the need to use the patient's symptoms and signs to distinguish febrile from allergic reactions and to tailor investigation and management accordingly.

Recommended resources

SHOT Bite No. 5: FAHR
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: FAHR
https://www.shotuk.org/resources/current-resources/videos/

JPAC – Guidance for UK health professionals on consent for blood transfusion
https://www.transfusionguidelines.org/transfusion-practice/consent-for-blood-transfusion/guidance-for-healthcare-practitioners-involved-in-this-role

References

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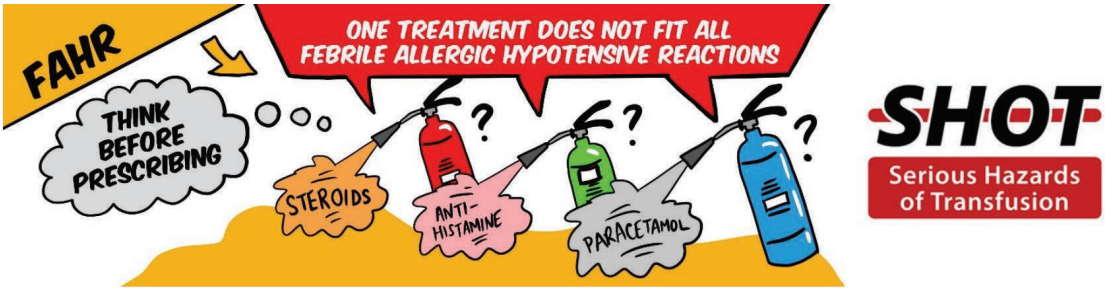


Pulmonary Complications of Transfusion n=212

17

Author: Shruthi Narayan

With contributions from the SHOT Pulmonary Working Expert Group members

Abbreviations used in this chapter

ARDS	Acute respiratory distress syndrome
BNP	B-type natriuretic peptide
BP	Blood pressure
BSH	British Society for Haematology
COPD	Chronic obstructive pulmonary disease
CPAP	Continuous positive airway pressure
CT	Computed tomography
CXR	Chest X-ray
ECG	Electrocardiogram
FFP	Fresh frozen plasma
GI	Gastrointestinal
GP	General practitioner
Hb	Haemoglobin
HLA	Human leucocyte antigen
HNA	Human neutrophil antigen
ICU	Intensive care unit
ISBT	International Society of Blood Transfusion
IRC	International revised consensus
LV	Left ventricle
MHRA	Medicines and Healthcare products Regulatory Agency
NBTC	National Blood Transfusion Committee
RLL	Right lower lobe of the lung
TACO	Transfusion-associated circulatory overload
TAD	Transfusion-associated dyspnoea
TRALI	Transfusion-related acute lung injury
WEG	Working expert group

Key SHOT messages

- Pulmonary complications of transfusion remain a leading cause of transfusion-related mortality and morbidity, contributing to more than 50% of transfusion-related deaths reported to SHOT from 2013 to 2022
- Categorising pulmonary complications can be challenging. Staff need to be precise in clarifying what is meant when the various terms are used
- Preventable risk factors, in particular fluid overload, are often identifiable regardless of the final classification. Structured incident investigation may be useful to ensure that risk factors and preventative actions are identified

The recommendations from previous years continue to be relevant and specific recommendations are also covered in the individual chapters.

Recommendations (repeat from previous years)

- All cases with pulmonary complications up to 24 hours post transfusion should be reported to SHOT with as much information as possible to ensure adequate inference and effective learning

Action: All SHOT reporters, NBTC, hospital transfusion teams

- Risk assessment of all patients needing transfusions will help institute appropriate, timely mitigating actions to prevent or reduce the severity of pulmonary complications. Prompt recognition with appropriate investigations and accurate diagnosis will help improve morbidity and mortality

Action: All staff involved in transfusion

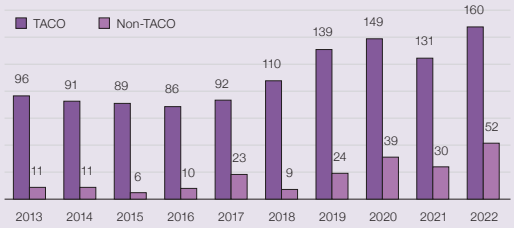
Pulmonary complications post transfusion continue to contribute significantly to death and major morbidity. Patients with respiratory complications are often elderly with multiple co-morbidities which could all contribute to the complication post transfusion. Pulmonary complications present diagnostic and therapeutic challenges with mainly supportive measures available and paucity of specific therapies.

There is an increasingly upward trend in the number of pulmonary complications reported to SHOT in the last decade.

Headline data 2022

Number of reports n=212
Deaths n=15
Major morbidity n=37

Pulmonary reports by year



Demographic data

Male n=98
Female n=114
Adults n=198
Paediatric n=8
Unknown n=6

Blood component data

Red cells n=162
Platelets n=13
Plasma n=7
Granulocytes n=3
Cryoprecipitate n=1
Multiple components n=26

All cases included in the TACO chapter are those that meet the validated ISBT TACO surveillance definition (Wiersum-Osselton et al. 2019). In this year's Annual SHOT Report, all the pulmonary reactions which do not meet the ISBT TACO criteria are covered in a single chapter similar to last year (Narayan et al. 2022). These cases have been primarily classified using the IRC TRALI classification (Vlaar et al. 2019). Categorisation of these reactions is challenging as is evident from the extensive reclassification of cases following submission and has been explained further in the subsequent chapters. A recent Australian study looking at the impact of revised definitions of TACO and TRALI on haemovigilance reporting found that while the revised TACO definition appears to capture more cases than the former definition, there was no significant difference in the number of TRALI cases using the IRC TRALI classification as compared to the Canadian Consensus Conference definition (Yuan et al. 2021).

As has been highlighted previously and evident in most cases, mechanisms for post-transfusion pulmonary complications are multifactorial and complex, involving both transfusion-specific and patient-specific factors. The respiratory deterioration is a common end point for multiple pathophysiological mechanisms. Unwell patients therefore have the highest risk of transfusion but may also have the highest need for transfusion. Reported TACO cases are increasing and most patients with pulmonary complications were at risk of fluid overload or had features of fluid overload even if TACO criteria were not met.

It is important that the relative risks and benefits of transfusion should be weighed up carefully in all patients receiving a transfusion but particularly those with other morbidities. Pre-transfusion TACO risk assessment should be used sincerely rather than as a tick box exercise as this can prompt appropriate actions to mitigate the risk. While the evidence for effectiveness of this pre transfusion is still awaited, it is clear from some of the cases that the checks were not done properly, with missed opportunities for mitigating interventions.

A systematic review of safety checklists concluded 'safety checklists appear to be effective tools for improving patient safety in various clinical settings by strengthening compliance with guidelines, improving

human factors, reducing the incidence of adverse events, and decreasing mortality and morbidity. None of the included studies reported negative effects on safety' (Thomassen et al. 2014).

There is of course work to do in identifying patients at risk of pulmonary complications prior to transfusion, in particular patterns of comorbidity. It will not be possible to prevent all respiratory deteriorations with a temporal relationship to transfusion but at least those that can be prevented may be identified through pre-transfusion checks. Future goals might be to improve understanding of which patients with inflammation are sensitive to fluid, how to prevent any adverse impact, effectiveness of measures currently advocated and identify which reactions to investigate for leucocyte antibodies.

Blood components should be administered only after careful consideration of the patient's unique risk of a transfusion complication versus the physiologic benefit of the planned transfused blood component. Staff need to be vigilant when transfusing critically ill patients. 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.

Less is often more with regards to transfusion.

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Vlaar APJ, Toy P, Fung M, et al. A consensus redefinition of transfusion-related acute lung injury (TRALI). *Transfusion* 2019;**59(7)**:2465-2476. doi: 10.1111/trf.15311.

Wiersum-Osselton J, Whitaker BL, Grey S, et al. Revised international surveillance case definition of transfusion associated circulatory overload (TACO): a classification agreement validation study. *Lancet Haematol.* 2019;**6(7)**:e350-e358. doi:10.1016/ S2352-3026(19)30080-8.

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17a Transfusion-Associated Circulatory Overload (TACO) n=160

Author: Sharran Grey

Definition:

TACO is defined as acute or worsening respiratory compromise and/or acute or worsening pulmonary oedema during or up to 12 hours† of 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 17a.1 for details of required and additional criteria for a surveillance diagnosis

Key SHOT messages

- The number of TACO cases reported in 2022 is the highest to date. Although cases continue to increase, there is likely to be a level of under-reporting
- The continued adoption of the TACO checklist is encouraging although analysis of the data shows it is still under-used or used ineffectively
- TACO continues to be a major cause of transfusion-related mortality and morbidity

Recommendations (new)

- Patients who develop respiratory distress during or up to 24 hours following transfusion where transfusion is suspected to be the cause must be reported to SHOT. The TACO definition criteria can be used as guidance, but this should not be restrictive. SHOT experts can transfer cases between categories

Action: All staff involved in transfusion

Recommendations (ongoing)

- A formal pre-transfusion risk assessment for TACO should be undertaken whenever possible for all patients receiving blood transfusion (especially if older than 50 years or weighing less than 50kg) and mitigating actions taken, as TACO is the most commonly reported cause of transfusion-related mortality and major morbidity

Action: All staff authorising transfusion

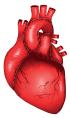
- A structured incident review should be undertaken for every case of TACO to ensure optimum organisational and individual patient safety measures are in place to protect patients from TACO as far as possible (see 'Recommended resources')

Action: Trust/Health Board governance and clinical risk departments, all staff investigating transfusion incidents

- Use weight-adjusted red cell dosing to guide the appropriate number of units required, for all non-bleeding adult patients, ideally using tools which also highlight inappropriate transfusion (Grey et al. 2018, National Comparative Audit 2017)

Action: All staff authorising transfusion

The TACO pre-transfusion risk assessment infographic (Figure 17a.1) was updated in the 2020 Annual SHOT Report to make it suitable for incorporation into clinical documents. No further update was required this year.

TACO Checklist	Patient Risk Assessment	TICK
	Does the patient have a diagnosis of 'heart failure' congestive cardiac failure (CCF), severe aortic stenosis, or moderate to severe left ventricular dysfunction?	
	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 hypoalbuminaemia?	
	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 can be investigated, treated or resolved?		

If Proceeding with Transfusion: Assign Actions	TICK
Body weight dosing for red cells	
Transfuse a single unit (red cells) and review symptoms	
Measure fluid balance	
Prophylactic diuretic prescribed	
Monitor vital signs closely, including oxygen saturation	

Name (PRINT):	
Role:	
Date:	**Time (24hr):**
Signature:	

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

TACO=transfusion-associated circulatory overload

Figure 17a.1: TACO pre-transfusion checklist

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

Table 17a.1: TACO surveillance definition (adapted from Wiersum-Osselton et al. 2019)

Introduction

The number of cases reported in 2022 is the highest to date and is an increase of 29 cases from 2021 (n=131). 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=8

There were 8 deaths related to the transfusion, of which 1 was definitely related (imputability 3), 1 was probably related (imputability 2) and 6 were possibly related (imputability 1) (Table 17a.2).

Major morbidity n=25

There were 25 cases of major morbidity cases in 2022, this is similar to 2021 when there were 23 cases reported.

Table 17a.2: Demographic overview of cases

Demographic	Number of reports
Deaths (imputability 3, definite)	1
Deaths (imputability 2, likely)	1
Deaths (imputability 1, possible)	6
Major morbidity outcome	25
Age	Range: newborn – 97 years (3 aged under 18 years) Median: 72 years
Gender	91 female: 69 male
Body weight (adults)	Female (n=56): average 66.6kg (range: 33.1-105kg) Male (n=33): average 77.9kg (range: 63-125kg)
Top 4 medical specialties	Haematology=32, general medicine=19, acute medicine=18, gastroenterology=10
Bleeding patients (indication code R1 or 'massive bleeding' indicated)	19
Non-bleeding patients (other indication codes or not stated)	141

Commentary

TACO is more commonly reported in elderly, non-bleeding patients but is seen across all age groups and is consistent with the data from previous years. There were 3 cases in the under-18 age group, (newborn to age 17 years). TACO was reported more in adult female patients compared to male. Weight was provided in 33 adult female cases, with an average of 66.6kg (33.1-105kg). Weight was provided in 34 adult male cases, with an average of 77.9kg (63-125kg). This difference may account for the apparent higher incidence of TACO in female patients and underlines the risk of TACO in lower-weight patients and the importance of weight-adjusted red cell dosing. Adult medical specialties and haematology continue to be the most common specialties where TACO is reported, and this should be considered when targeting TACO education and mitigation plans.

Use of the TACO risk assessment

The recommendation for a formal pre-transfusion TACO risk assessment was introduced in the 2015 Annual SHOT Report (Bolton-Maggs et al. 2016). A question regarding the use of the TACO risk assessment and mitigating actions was added to the SHOT questionnaire for the 2019 reporting year. An overview is shown in Figure 17a.2. The TACO risk assessment was not used in 60.6% (97/160) cases. This is a similar level compared to 2021.

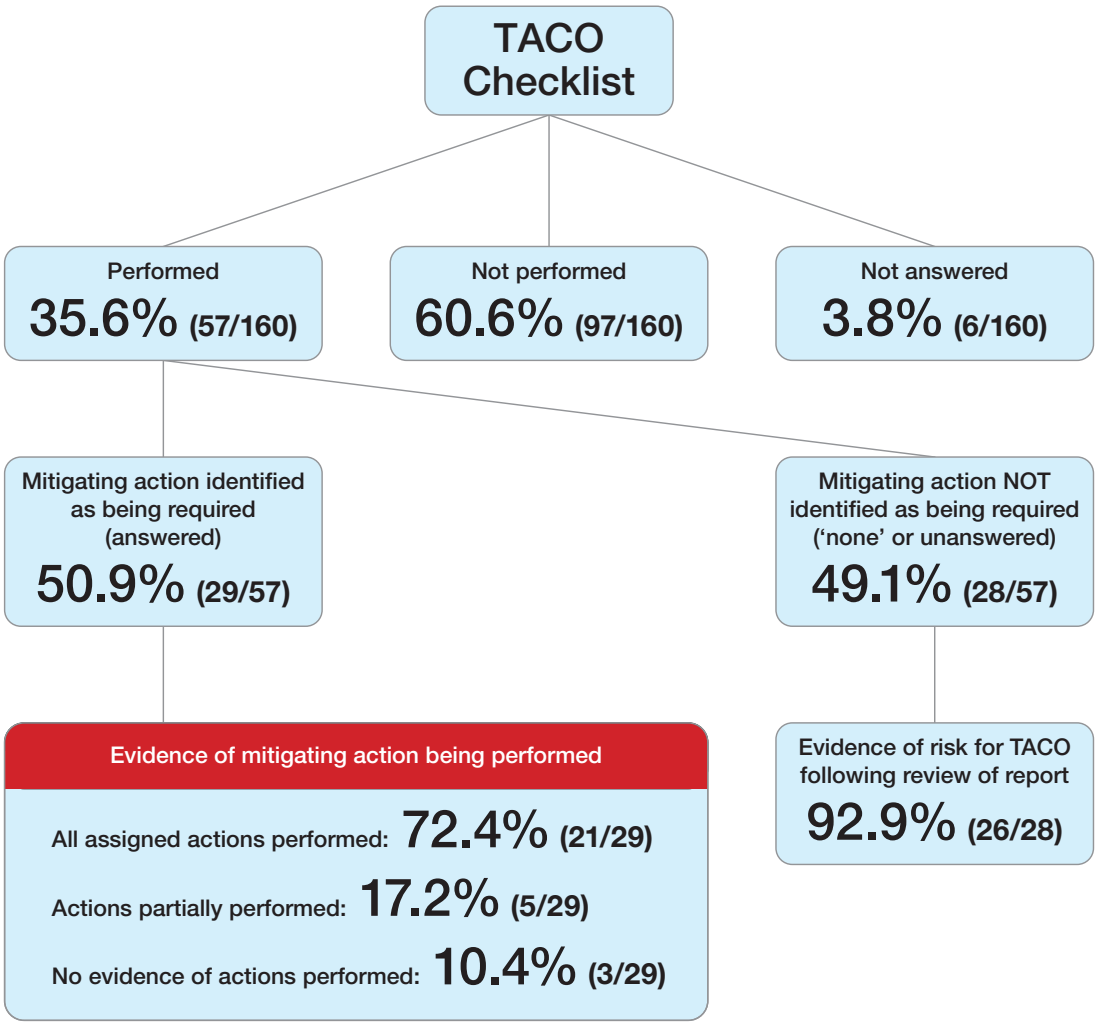


Figure 17a.2: Use of the checklist to identify patients at risk of TACO and implementation of mitigating actions

The TACO checklist was reported to have been used in only 57/160 (35.6%) cases. It is disappointing that the checklist is not universally utilised as there may have been missed opportunities to reduce the risk of TACO. This has been a SHOT recommendation since 2016 and is also highlighted in the BSH guideline on the administration of blood components (BSH Robinson et al. 2018). Where a TACO checklist was performed 29/57 (50.9%), it demonstrated the need for a mitigating action and in most cases, these were taken. In some cases, additional measures could also have been instigated. There were 3 cases where assigned actions had not been carried out and 5 where the actions were only partially completed. Where a TACO checklist was performed and it was determined a mitigating action was not required, a review of these reports showed that 26/28 (92.9%) did in fact have at least one risk factor for TACO. It is important to recognise that while the TACO risk assessment does not guarantee avoidance of TACO, it can provide a means of identifying patients at risk. This helps apply strategies to reduce risk and help make safe transfusion decisions. It is not clear from the data whether this is due to improper use of the TACO checklist or whether this reflects lack of clinical knowledge to perform the risk assessment.

TACO cases with evidence of excessive red cell volume to meet the target Hb

There were 68 cases where a pre-and post-transfusion Hb was provided. In 18/68 (26.5%) cases there was evidence of excessive red cell transfusion to meet the Hb target. Of these 17/18 (94.4%) had a Hb above 100g/L. In 2 cases these were inappropriate transfusions based on the pre-transfusion Hb level.

The number of units transfused, and body weight were provided in 10/68 (14.7%) of these cases. Excluding the two inappropriate transfusions the number of units transfused was excessive based on the patient's weight and pre-transfusion Hb level in 6/10 cases. In 2/10 cases patients with severe chronic

anaemia only required minimal transfusion to alleviate the symptoms of anaemia. Three and six units of red cells were transfused in these cases. This underlines the importance of weight-adjusted red cell dosing to avoid the risks of overtransfusion.

Cases involving severe chronic anaemia

Severe anaemia was added to the TACO checklist following a signal previously observed in the data (Narayan et al. 2019). Non-bleeding adult patients with severe chronic anaemia are particularly vulnerable to TACO even in the absence of additional risk and comorbidities that are known to predispose TACO.

In 39/160 cases there was a Hb <60gL. Of these, 7/39 cases were severe anaemia due to haemorrhage or erroneous Hb measurement. The remaining 32/39 cases were severe chronic anaemia and 7 had clear evidence of iron deficiency. There is still evidence that iron replacement (including intravenous iron) is not being administered to patients with iron deficiency anaemia. Transfusion of excessive volumes of red cells, lack of consideration of patients with low body weight, and evidence of aiming for a Hb target that is intended for the correction of acute anaemia increase the risk of TACO in these patients. Patients with severe chronic anaemia should receive only minimal red cell transfusion with the aim of alleviating symptoms as opposed to aiming for Hb correction to meet a target Hb level.

Case 17a.1: Severe chronic iron deficiency anaemia in a patient with low body weight

A female patient in her 80s with a low body weight (49kg) was asymptomatic and haemodynamically stable with severe microcytic hypochromic anaemia (Hb44g/L) with no clinical signs of pulmonary oedema on the chest X-ray or clinical examination. Three units of red cells were transfused over a period of 15 hours because the attending doctor was aiming for a post-transfusion Hb of 70-90g/L. The patient developed respiratory compromise (desaturation from 100% on room air to 71%, with dyspnoea, wheeze, and tachypnoea). There were new cardiovascular changes: tachycardia (heart rate 131bpm) and hypertension (blood pressure 204/96mmHg). Fluid balance was not clearly documented. Additional fluid was not involved. A diuretic was given but the patient deteriorated and died, therefore a diuretic response could not be evaluated. There was clear evidence of overtransfusion as the post-transfusion Hb was 111g/L. The patient did not otherwise have comorbidities predisposing circulatory overload. The post-transfusion chest X-ray showed pulmonary oedema.

This was a complex case which was referred to the coroner. The post-mortem examination report described pulmonary oedema and congestion of the lungs. The histopathology findings on the lung tissue were interpreted as TRALI by the histopathologist due to the presence of fibrinous exudate and neutrophil polymorphs in the alveoli which is indicative of an inflammatory process. The symptoms, signs and the clinical context met the haemovigilance criteria for TACO and was reported as such by the hospital to SHOT and per legal obligations to the MHRA. As TRALI had been cited in the post-mortem report there was an obligation to report this to the Blood Service. A clinical assessment for TRALI was performed and it was agreed the case met the TACO criteria, not TRALI. Blinded opinion was sought from the two other members of the SHOT Pulmonary Complications of Transfusion WEG who also agreed this was TACO. All agreed that a TRALI investigation (involving the testing of recipient and donors) was not indicated based on the clinical assessment criteria for pulmonary complications of transfusion. A TRALI assessment had only been initiated based on the interpretive comments in the histopathology and the post-mortem reports.

The purpose of considering a TRALI investigation was not to differentiate TACO and TRALI for the purpose of determining the cause of death, rather a potential public health concern should any of the donors have a clinically significant HLA or HNA antibody that could potentially cause a similar reaction in another recipient. A TRALI investigation would normally require testing of the recipient to demonstrate a match between donor antibody and recipient tissue-type. The only biological specimen available were paraffin blocks of lung tissue. As testing procedures are validated on blood samples (not tissue in paraffin histology blocks), any results would be unvalidated and reliability unknown. The absence of HLA/HNA antibodies in the donors would exclude antibody-mediated TRALI, however if present it could not be excluded if recipient typing was not possible.

The conclusions regarding the type of pulmonary complication of transfusion differed as haemovigilance criteria and histopathology are each based upon different evidence however it was agreed the patient had a pulmonary complication of transfusion. The understanding of the pathogenesis of TACO is incomplete and it is widely agreed that there may be an inflammatory aspect, and therefore the presence of fibrinous exudate and neutrophil polymorphs in the alveoli of the lung does not exclude TACO. A negative TRALI investigation would not exclude 'antibody-negative' TRALI, and indeed TACO and TRALI may co-exist (Bosboom et al. 2019).

The patient was at risk of TACO due to her low body weight and severe anaemia. A TACO risk assessment would have identified this and should have prompted single unit/weight-adjusted red cell dosing, prophylactic diuretic etc. Despite this, the attending doctor was aiming for a significantly higher target Hb as would have been appropriate if the patient had stable acute anaemia. The patient had asymptomatic severe chronic iron deficiency and therefore a small volume red cell transfusion (to improve any symptoms of anaemia and minimise risk of cardiac ischaemia), followed by intravenous iron replacement was indicated.

Cases with evidence of a structured investigation

Previous data suggested there was a lack of structured investigation following cases of TACO, resulting in missed opportunities to mitigate the risk of TACO and to improve transfusion safety for all patients. The TACO structured investigation tool was first launched in the 2020 Annual SHOT Report and continues to be a recommendation this year. The pulmonary reactions questionnaire in the SHOT database (Dendrite) has been updated to include a question as to whether it was performed. The template was used by only 37/160 (23.1%) of reporters in 2022. A structured review and incident investigation should be undertaken for every case of TACO to optimise organisational and individual patient-safety measures.

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 other risk factors and comorbidities that predispose to TACO

Conclusion

The continued adoption of the TACO checklist is encouraging though analysis of the data shows it is still under-used or used ineffectively. There has been some uptake of the TACO structured assessment tool, but the data suggest that there is significant lack of structured investigation following cases of TACO and this results in missed opportunities to mitigate the risk of TACO and to improve transfusion safety for all patients. Overtransfusion of red cells also remains an issue which could be minimised by weight-adjusted or single unit transfusion in non-bleeding patients. The transfusion management of patients with severe chronic anaemia is concerning and resulted in a patient death this year due to excessive transfusion. There are several strategies now available to mitigate the risk of TACO based on many years of haemovigilance data. Everyone involved in the transfusion process has a professional duty to protect patients from TACO wherever possible.

With an increasing number of TACO cases reported to SHOT year-on-year, including instances of preventable deaths, a TACO safety alert is being planned to be released UK-wide by SHOT through the MHRA. This will help promote implementation of measures to enhance safety and facilitate appropriate transfusion decisions. The NBTC indication codes are also being reviewed currently and an updated version is expected to be released soon. Identifying risk-factors for TACO in vulnerable patients prior to transfusion helps initiate appropriate mitigating measures. Some TACO deaths are preventable.

Recommended resources

Example of weight-adjusted red cell dosing implemented in clinical practice
www.rcdcalculator.co.uk

TACO Incident Investigation Guidance Tool
https://www.shotuk.org/resources/current-resources/

TACO Checklist: in risk assessment/checklist alternative format for incorporation into clinical documents
https://www.shotuk.org/resources/current-resources/

SHOT Bite No. 11: Respiratory Symptoms During Transfusion
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: TACO
https://www.shotuk.org/resources/current-resources/videos/

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/)

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Pulmonary complications of transfusion (non-TACO) n=52

17b

Author: Tom Latham

With contributions from the Pulmonary WEG members

Definition:

Cases where there is a respiratory deterioration within 24 hours of transfusion which does not meet ISBT TACO criteria, and which is not explained by the recipient's underlying condition.

Key SHOT messages

- Pulmonary complications are often multifactorial, and classification of these cases is challenging
- Fluid overload is often suspected as a contributing factor even if cases do not meet TACO criteria
- Classification of a case as TRALI using international criteria does not imply or depend on the presence of leucocyte antibodies in the donor

Recommendation

- A structured TACO investigation tool should be used for all pulmonary complications

Action: All staff involved in investigating transfusion reactions

Introduction

Pulmonary reactions which do not meet the ISBT TACO criteria are discussed in this chapter. Cases have been primarily classified using the IRC TRALI classification (Table 17b.1) (Vlaar et al. 2019). Due to the complexity of these reactions, there was extensive reclassification of cases following submission and review by the pulmonary WEG members. Further details can be found in the supplementary information on the SHOT website (https://www.shotuk.org/shot-reports/report-summary-and-supplement-2022/).

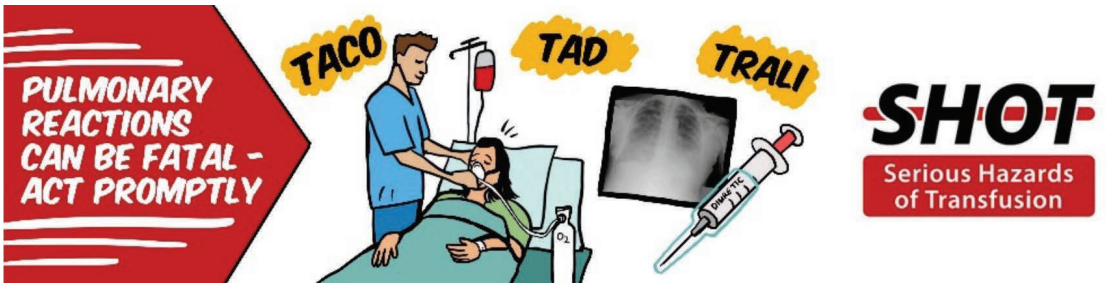


Table 17b.1 International classification of pulmonary complications

Table 7 Comparison table to assist with pulmonary reaction classification

	TRALI Type I	TRALI Type II	ARDS	TRALI/TACO	TACO	TAD
Hypoxemia	Present	Present	Present	Present	May be present but not required	May be present but not required
Imaging evidence of pulmonary edema	Documented	Documented	Documented	Documented	May be present but not required	May be present but not required
Onset within 6 hr	Yes	Yes	Yes	Yes	Yes*	No*
ARDS risk factors	None	Yes—with stable or improving respiratory function in prior 12 hr	Yes—with worsening respiratory function in prior 12 hr	None, or if present, with stable or improving respiratory function in prior 12 hr	Not applicable	Not applicable
LAH†	None/mild	None/mild	None/mild	Present or not evaluable	Present	May be present but not required

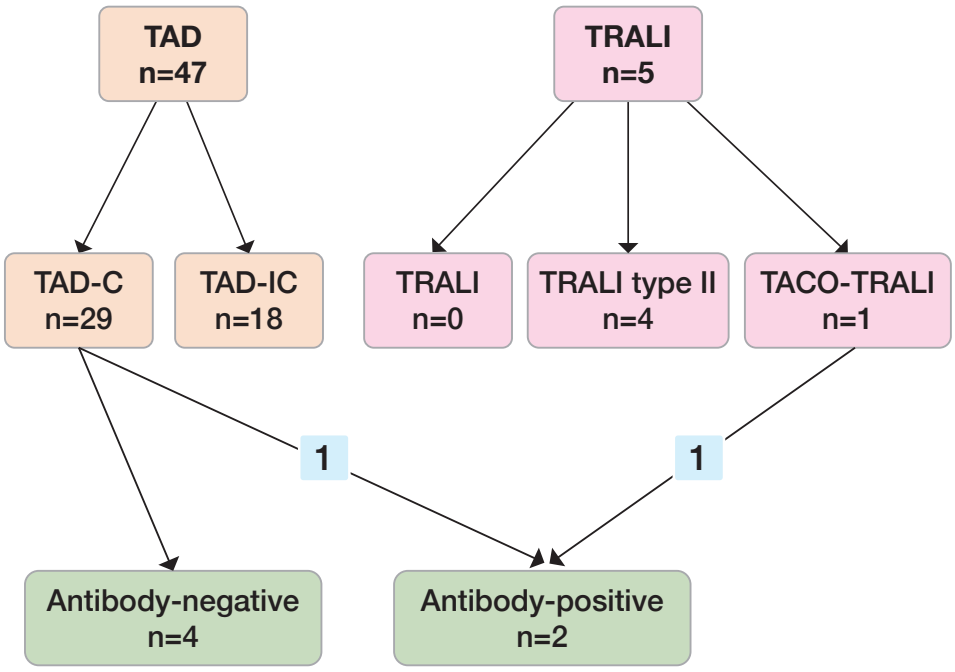
*Some definitions of TACO allow onset up to 12 hours posttransfusion. However, our current recommendation is that 6 hours be used. If pulmonary edema occurs greater than 6 hours following the transfusion and is clinically suspicious for a temporal association with transfusion, the case should be classified as TAD as is currently done in many hemovigilance systems.

†LAH is difficult to assess. When LAH is suspected, we recommend using objective evaluation to determine if it is present. Objective criteria include imaging (e.g., echocardiography) or invasive measurement (e.g., pulmonary artery catheter pressure measurement). However, clinical judgment is often required and, if this is needed, should be used for case classification as follows: TRALI and/or TACO = respiratory insufficiency at least partially explained by hydrostatic lung edema resulting from cardiac failure or fluid overload or unable to fully assess the contribution of hydrostatic lung edema resulting from cardiac failure or fluid overload; TACO = respiratory insufficiency explained by hydrostatic lung edema resulting from cardiac failure or fluid overload.

Reproduced from Vlaar et al. 2019

The final classification of cases is summarised in Figure 17b.1. The TAD category is subclassified into TAD-IC, the cases which could not be classified because of incomplete information reported, and TAD-C, the cases where there was sufficient information to judge that the case did not meet either TACO or TRALI criteria.

Figure 17b.1: Final classification of non-TACO cases



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

Deaths related to transfusion n=7

There were 7 deaths reported this year. A summary is presented in Table 17b.2. All patients were unwell prior to transfusion, and it is not clear how much the transfusion contributed to the reaction. The cases classed as definitely related (imputability 3), or probably related (imputability 2), were both classified as TAD-IC but were suggestive of fluid overload. There were no deaths due to antibody-associated TRALI.

Table 17b.2: Summary of pulmonary complication deaths

Case	Category	Imputability	Products transfused	Explanatory features	Underlying disease	Imaging	Difficulty classifying
1	TAD-IC	1, possible	2 red cell units	Cardiac failure, peripheral, aspiration pneumonia, low albumin, liver impairment, renal impairment. Crackles on chest examination	Fall/anaemia	Not performed	Absent imaging. Insufficient criteria for TACO
2	TAD-C	1, possible	2 red cell units	Cardiac failure, lung infection, COPD, low albumin	Terminal malignancy	L basal shadowing	Insufficient criteria for TACO.
3	TAD-C	1, possible	1 apheresis platelets	Neutropenic sepsis, pneumonia, low albumin, peripheral oedema	Lymphoma	Bilateral worsening	Donor antibody negative. Does not fit TRALI as deteriorating state.
4	TAD-IC	3, definite	2 red cell units	Low albumin. Rise in BP and crackles on chest examination	Multiple sclerosis, Hb68g/L	Not performed	Insufficient criteria for TACO, absent imaging
5	TAD-IC	2, probable	4 FFP, 2 cryoprecipitate	Liver disease, ascites, low albumin, pre-existing lung abnormality (collapse, ground glass shadowing)	Liver disease	Bilateral pulmonary oedema	Insufficient criteria for TACO, hypoxia likely but not reported
6	TAD-IC	1, possible	3 red cell units	Decompensated liver disease, low albumin, COPD, infection, cardiac ischaemia	GI bleed	Not performed	Absent imaging
7	TRALI type II	1, possible	13 red cell units, 12 FFP, 4 cryoprecipitate 2 pooled platelets	Decompensated liver disease, ascites, renal failure, low albumin, COVID-19, lobar pneumonia	Massive haemorrhage-traumatic arterial puncture	Bilateral pulmonary oedema	Meets TRALI type II criteria but multiple explanations. Not investigated for donor antibody in view of large number of donors

Case 17b.1: Major haemorrhage in a patient with multiple comorbidities, meeting TRALI criteria

A male patient in his 50s with decompensated liver disease, renal failure, ascites, COVID-19 and RLL pneumonia was transfused 13 red cell units, 12 FFP, 4 cryoprecipitate, and 2 platelets following a puncture of the inferior epigastric artery during ascites drainage. There was sudden development of 'very high ventilation requirements' with 'ARDS like picture' on CXR. He was mechanically ventilated for 18 days but died as result of respiratory compromise.

This case is representative of the difficulty in classifying pulmonary complications. The case met the IRC criteria for TRALI type II since there was hypoxia, bilateral chest imaging changes rapidly after transfusion and the pre-transfusion respiratory state was described as 'stable'. There were multiple other risk factors for developing ARDS even if the transfusion had not occurred. Causation was almost impossible to establish; investigating the donors for antibodies was unlikely to be helpful since there would be a high chance of finding leucocyte antibodies if over 40 random donors were investigated. Prolonged ventilation does not favour a classical antibody-mediated TRALI as the sole cause of death since antibody-mediated TRALI is normally self-limiting.

Case 17b.2: Suspected fluid overload in an outpatient transfusion

A female patient in her 50s with multiple sclerosis attended for an outpatient red cell transfusion. The reason for the Hb of 68g/L was not recorded. During the second unit of red cells, she developed severe respiratory distress, with systolic blood pressure 196mmHg, flushing, wheeze and crepitations. There was no improvement with diuretics and adrenaline. Care was not escalated because of a pre-existing resuscitation order. The case was reported as TACO, with 'death directly and solely caused by transfusion'.

The case remains strongly suggestive of fluid overload but there was insufficient clinical information to meet ISBT TACO or TRALI criteria. The reporters recognised that a TACO checklist was not part of their transfusion policy and awareness of TACO was poor. These issues were addressed following an investigation. Low albumin and low Hb were identifiable risk factors for fluid overload, but the severity of the reaction was unexpected given the pre-transfusion risks. It was not clear whether the preventative actions were commensurate with the identifiable risks and would have prevented the reaction.

Major morbidity n=12

There were 12 cases (2 TRALI, 9 TAD-C and 1 TAD-IC) associated with major morbidity as they required ICU admission or ventilation. Of these, 5 were considered to be probably related to the transfusion (imputability 2). A summary can be found in the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/). Two cases with leucocyte antibodies are detailed in the following section.

A similar picture is seen of recipients with multiple comorbidities. The case below is described since it demonstrates a specifically identifiable risk for transfusion despite classification as TAD.

Case 17b.3: Rapid transfusion of patient with megaloblastic anaemia

A female in her 30s was admitted with megaloblastic anaemia and a Hb31g/L, undetectable folate levels and low B12 levels. She was transfused three units of red cells, the second unit over 20 minutes. Desaturation was noted during the second unit and the transfusion was stopped during the third unit. The CXR showed features of fluid overload, but the case did not meet TACO criteria. The patient was admitted to ICU but made a full recovery.

This case was classified as TAD as there were insufficient features to meet TACO criteria but appears to be the classical picture of overtransfusion in megaloblastic anaemia. Patients with B12 or folate deficiency can have impaired myocardial function and may not tolerate transfusion well. Transfusion can often be avoided since the haemoglobin typically responds rapidly to haematinic replacement. There were 2 similar cases in this year's Annual SHOT Report.

Learning point

- Patients with megaloblastic anaemia are at risk of fluid overload and transfusion should be avoided if possible. If transfusion is necessary because of severe features of anaemia, a single unit or weight-adjusted red cell dosing should be given with close monitoring

TRALI and leucocyte antibody cases

In 2022, cases have been classified as TRALI using the IRC definition. In contrast to previous SHOT classifications, the presence of leucocyte antibodies plays no part in this definition. Antibodies however remain an established cause of TRALI, and one which is potentially preventable. Cases which were positive for antibodies (HLA or HNA) are therefore presented in parallel. The terminology 'plausibility' used in Table 17b.3 indicates whether it is plausible that the features of the reaction were caused by leucocyte antibodies.

Cases meeting TRALI criteria n=5

Table 17b.3: Cases meeting TRALI criteria

Case	Category	Plausibility	Products transfused	Explanatory features	Underlying disease	Antibody	Outcome
1	TRALI type II	Plausible	1 apheresis platelets	Unexplained breathlessness prior to transfusion	Neuroblastoma	Not tested	Mechanical ventilation, full recovery
2	TRALI type II	Implausible	1 red cell unit	Cardiac failure, sepsis, consolidation on CXR	Surgery for perianal abscess	Not tested	Symptoms resolved within 30 minutes
3	TRALI/TACO	Plausible	1 red cell unit	Low albumin, cardiac failure (LV assist device), positive fluid balance	GI bleed	HLA I and II	CPAP, improved after 6 hours
4	TRALI type II	Equivocal	Pooled granulocyte	Pre-existing bilateral consolidation	Neutropenic sepsis	Not tested	Increased oxygen, full recovery
5	TRALI type II	Equivocal	13 red cell units, 12 FFP, 4 cryoprecipitate 2 pooled platelets	Decompensated liver disease, ascites,renal failure, low albumin COVID-19, lobar pneumonia	Massive haemorrhage - traumatic arterial puncture	Not tested	Death possibly related to transfusion

Case 17b.4: Reaction to granulocytes fulfilling TRALI criteria

A male patient in his 40s with neutropenic sepsis and ALL developed acute breathlessness, fever, and hypoxia 6 hours after a granulocyte transfusion. Diffuse bilateral shadowing was reported on CXR. The patient made a full recovery with increased oxygen provision only.

There were 3 cases of pulmonary reactions to granulocytes reported this year. In many cases the reaction represents the therapeutic effect of granulocytes responding to underlying infection, for example with rapid development of unilateral consolidation. This case meets TRALI criteria, but the distinction seems arbitrary, and the rapid subsequent recovery would favour a therapeutic effect rather than a classical antibody-mediated TRALI reaction. Febrile and pulmonary reactions are very common after granulocyte transfusion. Investigating donors for antibodies is unlikely to be helpful in establishing causation because of the large number of donors involved, and the need to consider antibody cross-reacting with any of the donations in the pool, not only the recipient (who by definition is not likely to have circulating neutrophils).

Case 17b.5: Antibody-positive case at high risk for TACO

A male recipient in his 60s with a left ventricular assist device, renal impairment and low albumin experienced dyspnoea, wheeze, hypoxia, and an increase in temperature approximately 1 hour into transfusion of red cells for anaemia due to GI bleeding. He had also received 1L crystalloids and had a 1.2L positive fluid balance. The CXR showed bilateral pulmonary congestion and there was no initial improvement with diuretic. He was transferred to ICU and received CPAP and a furosemide infusion. He had improved after 6 hours and was transferred back to the ward the following day. HLA class I and II antibodies were found in a female donor.

The case does meet TRALI criteria, but the patient was clearly at high risk of fluid overload and had established heart failure. The relatively short period of hypoxia is not typical of an antibody-mediated TRALI. The case was classified in the IRC scheme as 'TACO and TRALI cannot be distinguished'.

Cases with leucocyte antibodies n=2

Six cases reported this year were tested for antibodies, 2 of these had donors with antibodies that matched the recipient. Both were classed as 'major morbidity'. One case, Case 17b.5 is described under TRALI above, the 2nd did not meet TRALI criteria.

Case 17b.6: Antibody-positive case which does not fit TRALI criteria

A female in her 60s who was post allogeneic transplant attended for an outpatient red cell transfusion. She had recently been started on antibiotics by her GP and was slightly breathless prior to transfusion. She became hypoxic during transfusion, developed atrial fibrillation and had a small troponin rise. There was an improvement within 2 hours following administration of diuretics, and she needed non-invasive ventilation. The chest CT scan showed peribronchial ground glass shadowing in keeping with bronchopneumonia. Subsequent investigations showed she was positive for influenza A. A female red cell donor was positive for HLA A2 and B27 which matched the recipient.

The case was classified as TAD-C since the imaging features and clinical course were not those of TRALI. The HLA antibodies were likely to be incidental; HLA class I antibodies are thought to have a weaker association with TRALI than HLA class II and HNA antibodies.

Commentary

The pattern of pulmonary complication reports is similar to previous years, with many recipients having multiple possible explanations for a respiratory deterioration. Figure 17b.2a summarises the presence of alternative factors in the cases reported. The median number of explanatory factors in this year's cases was 3. Figure 17b.2b shows that many patients had pre-existing cardio-respiratory disturbance identifiable on pre-transfusion observations or had pre-existing features of fluid overload. Control data for general transfusion recipients would be needed to investigate whether any of these factors are risk factors for pulmonary deterioration, but as a general principle the benefits of transfusion should be carefully considered against the risks when transfusing unwell patients.

Features on imaging and features of the reaction itself are summarised in Figures 17b.2c and 17b.2d. Unsurprisingly, increased respiratory rate and fall in oxygen saturation were present in the majority of cases, however it is notable that there was an improvement with diuretics in a majority of cases where it was reported, supporting the idea that fluid overload is a contributory factor in many cases which do not satisfy formal TACO criteria.

There is clearly an unmet need for explanation, as 38% of cases were referred as 'likely' or 'certain' that 'the blood product caused the reaction'. Classification appears difficult as there are many transfers between categories. Classifying cases as TAD, and particularly TAD-IC arguably does not meet this need. Table 17b.4 shows the proportion of reports which supplied information necessary to provide a TRALI classification or which could help to support a TACO classification, showing that these data are often difficult for reporters to supply. Use of a structured TACO investigation tool as suggested in previous Annual SHOT Reports may help improve classification accuracy (Narayan et al. 2021).

Classification of reactions is not an end, but a means to aid understanding. There does not seem to be any easily apparent difference either in terms of underlying factors or reaction features between cases classified as TRALI or TAD. The distinction between TACO, TRALI and TAD often seems dependant on the interpretation of the wording of the IRC, rather than reflecting genuine differences in pathophysiology. Given that it seems likely that many of these cases are multifactorial, it is perhaps unrealistic to expect that fitting cases into a small number of categories provides sufficient information capacity to capture the important features of interest.

The key aim of haemovigilance remains one of prevention, and the approach of 'preventing what we know can be prevented' still applies. The number of antibody-associated TRALI cases remains very

low and there are even fewer cases which unambiguously seem to be transfusion reactions. Fluid overload is the other well-defined mechanism which is potentially preventable, and there is still work to do in identifying at risk cases. Only 33% of cases had a TACO checklist performed prior to transfusion (Table 17b.5) despite previous SHOT recommendations. Perhaps more concerning are cases where the checklist did not identify a patient as at risk despite gross features of fluid overload, suggesting the checklist may simply be being completed as a tick box exercise in some cases. Further work is required to establish whether the presence of multiple risk factors, in particular fever or inflammation, should warrant additional intervention to prevent fluid overload.

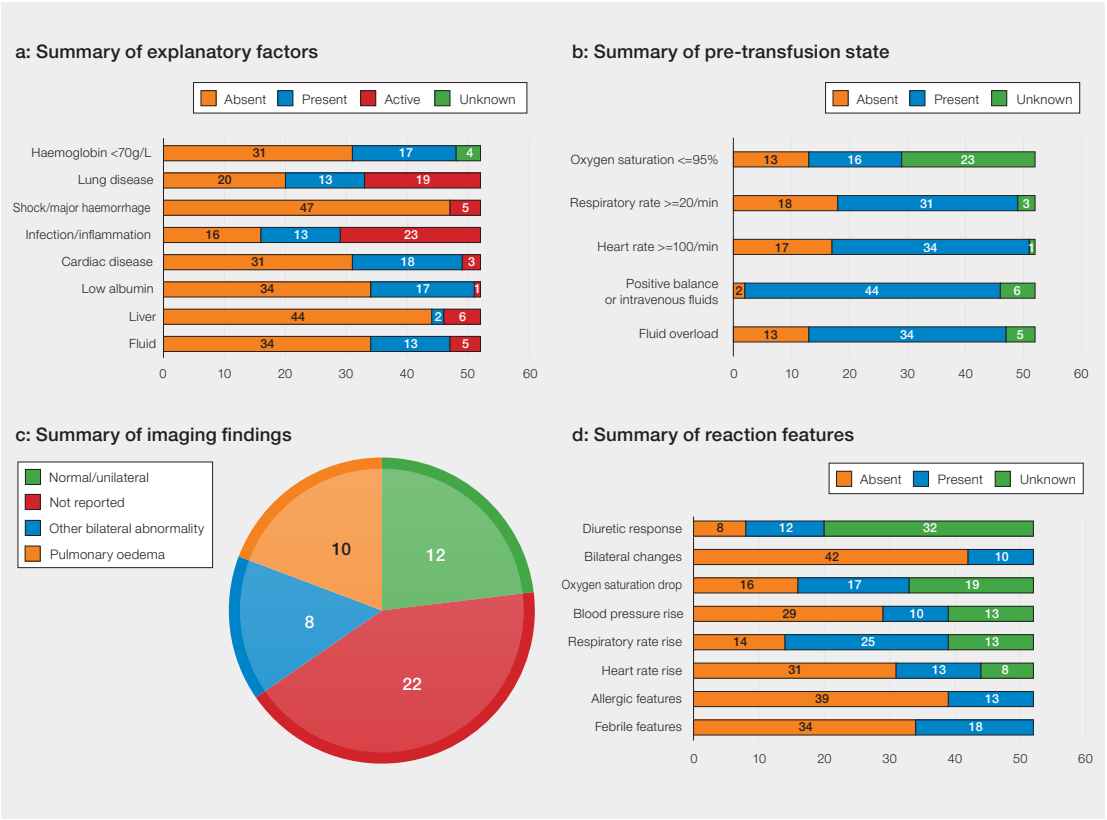


Figure 17b.2: Clinical features of pulmonary cases

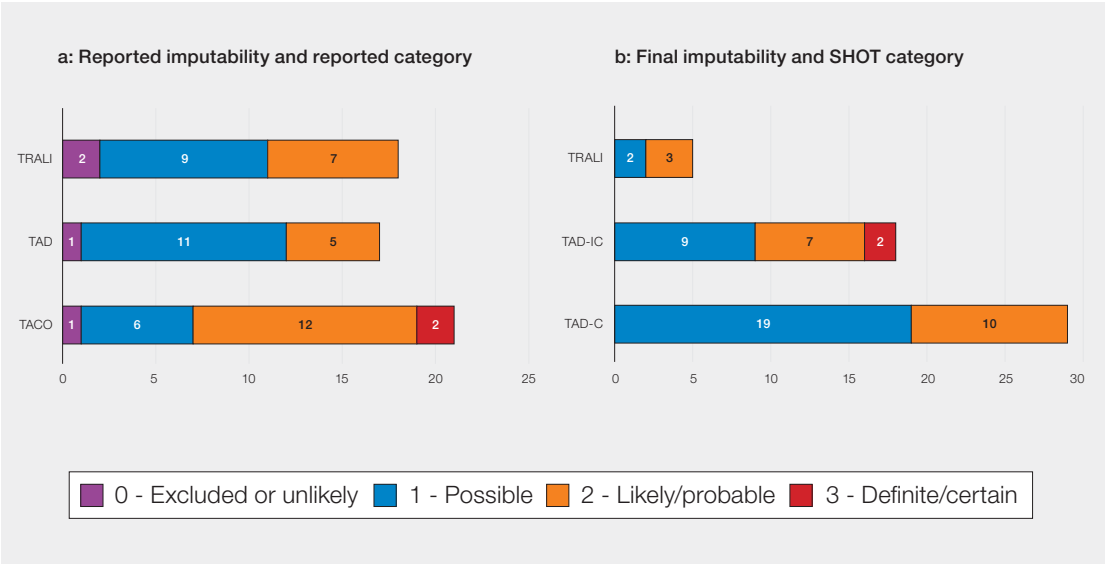


Figure 17b.3: Imputability of pulmonary cases

Table 17b.4: Submission rates for criteria necessary for classification

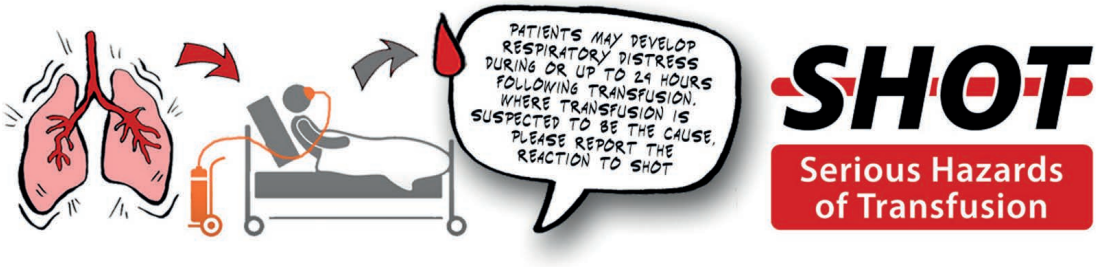
Necessary for classification	% responses submitted
Respiratory state	34%
Timing	100%
Post-transfusion SaO2	77%
Post-transfusion CXR	52%
Helpful for classification	
BNP	3%
Fluid balance	24%
Post-transfusion BP	82%
ECG	13%
Echo	8%
Name, dose and timing of diuretic	50%
Volume of diuresis	48%
Effect on respiratory systems	50%

Table 17b.5: Concordance with previous SHOT recommendations

SHOT recommendations	% reported	% 'yes'
TACO checklist	92%	33%
Risks identified	32%	40%
TACO investigation	89%	20%
Features identified	11%	0%

Conclusion

Pulmonary deterioration following transfusion remains common. The implications of the recently introduced international definitions of TRALI and TACO are still under investigation, and it appears difficult for reporters to supply information necessary to classify cases using these definitions. Preventable factors, particularly risk factors for fluid overload, can often be identified and offer opportunities for further preventative interventions.



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Haemolytic Transfusion Reactions (HTR) n=49

18

Authors: Tracey Tomlinson and Anicee Danaee

Definitions:

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.

Abbreviations used in this chapter

AHTR	Acute haemolytic transfusion reactions
BSH	British Society for Haematology
DAT	Direct antiglobulin test
DHTR	Delayed haemolytic transfusion reactions
ED	Emergency department
EPO	Erythropoietin
Hb	Haemoglobin
HTR	Haemolytic transfusion reactions
IAT	Indirect antiglobulin test
ICU	Intensive care unit
IV	Intravenous
IVIg	Intravenous immunoglobulin
LDH	Lactate dehydrogenase
NHSBT	National Health Service Blood and Transplant
RCI	Red cell immunohaematology
Sp-ICE	Specialist Services electronic reporting using Sunquest's Integrated Clinical Environment

Key SHOT messages

- Cases of hyperhaemolysis remain under-reported to SHOT
- SHOT continues to receive reports of HTR in sickle cell patients who have records of confirmed red cell antibodies available on national databases such as Sp-ICE

Recommendations

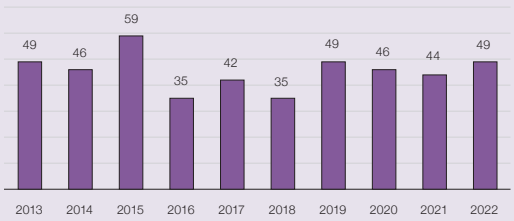
- All staff involved in the transfusion of patients at risk of hyperhaemolysis should be able to recognise, manage and seek specialist help for these cases. They should inform the local transfusion teams of any confirmed cases to facilitate SHOT reporting
- Processes need to be in place to share antibody and transfusion history. This will support safe transfusion, and the investigation and treatment of HTR, in patients who present at different hospitals with symptoms of haemolysis post transfusion

Action: All staff involved in transfusing patients

Headline data 2022

Number of reports n=49
Deaths n=1
Major morbidity n=11

HTR reports by year



Demographic data

Male n=16
Female n=33
Adults n=44
Paediatric n=5

Blood component data

Red cells n=48
Platelets n=0
Plasma n=0
Multiple components n=1
Other n=0

Number of cases n=49

A total of 49 cases have been included, 11 acute, 29 delayed reactions and 9 cases of hyperhaemolysis. The total number of reactions reported is comparable to 2021 (44 cases) and 2020 (46 cases).

All reported cases occurred following red cell transfusions.

Age range and median

The age range was 5 to 80, with a median age of 42. This is shown in Figure 18.1, broken down further by gender. HTR were reported in 5 paediatric patients. Two thirds, 33/49 (67.3%) of the reactions occurred in female patients.

Figure 18.1: Age range in males and females experiencing an HTR

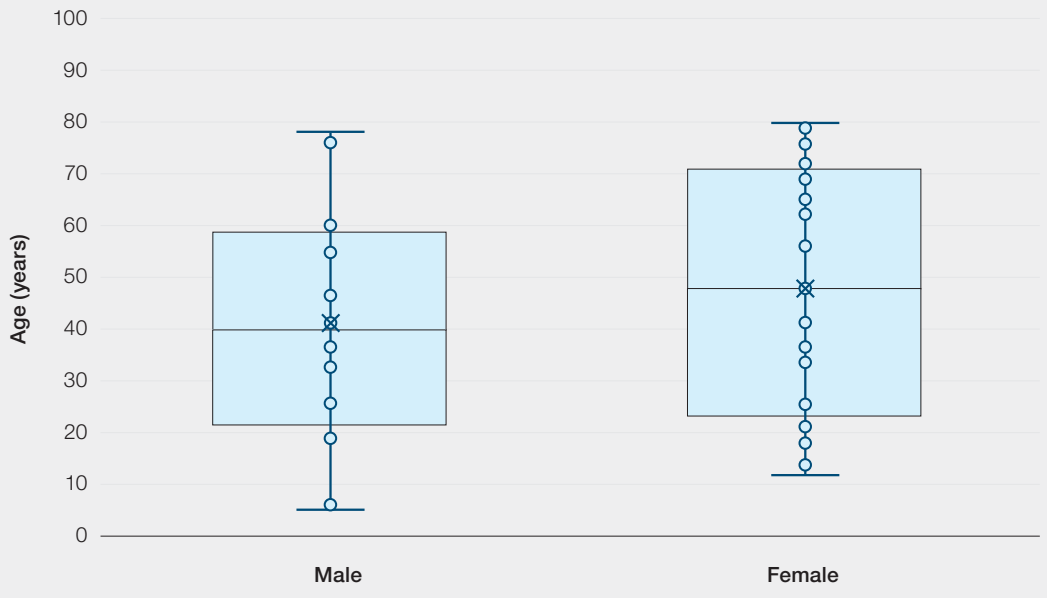


Figure 18.1 is a box and whisker diagram showing the median age and the age range of patients experiencing a HTR reported to SHOT separated by gender. The middle bar in the shaded box indicates the median age, the outer bars of the box represent the upper and lower quartiles. The lines extending from the boxes (whiskers) indicate the lowest and highest values.

Deaths related to transfusion n=1

There was 1 death in a sickle cell patient attributed to the transfusion reaction (imputability 2, probable). This was a young female patient in her 20s who was admitted with suspected sickle crisis and was subsequently diagnosed with hyperhaemolysis. The patient was admitted to ICU where they rapidly deteriorated.

Major morbidity n=11

There were 11 cases reported in which the patient suffered major morbidity. SHOT considers that all reported cases of probable hyperhaemolysis, where there is a significant fall in Hb, should be considered as major morbidity. Following application of this criterion 8 cases of hyperhaemolysis reported with 'minor morbidity' were upgraded.

Hyperhaemolysis n=9

The majority of hyperhaemolysis cases reported (8/9) occurred in patients with sickle cell anaemia. One further case of hyperhaemolysis was reported in a patient with non-Hodgkin lymphoma in their 70s.

While the number of hyperhaemolysis cases reported was comparable to previous years, it is strongly suspected that hyperhaemolysis is still under-reported to SHOT. This is partially attributed to the fact that hyperhaemolysis can be difficult to diagnose with symptoms showing many similarities to DHTR and vaso-occlusive crisis (Adkins et al. 2020). In contrast to other HTR, hyperhaemolysis has been reported to be accompanied by a decrease in the patient's absolute reticulocyte count and an increase in the ferritin level (Win et al. 2019).

Hyperhaemolysis can be either acute or delayed. 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). Three cases reported the reactions occurred within the first 7 days post transfusion. Of these, 1 patient was DAT-positive in both the pre-transfusion and post-transfusion samples however this was the patient with non-Hodgkin lymphoma and these patients are often DAT-positive.

Treatment in hyperhaemolysis

There are no published recommendations on the treatment of hyperhaemolysis. There is paucity of published randomised clinical trials in the effectiveness of the available interventions, however, eculizumab has been licensed to treat ongoing brisk haemolysis (NHS England 2020). Since 2020 SHOT has requested reporters to provide information on how these patients were managed. Generally, patients are treated with a combination of IVIg, steroids and EPO. A summary of the treatment methods reported is provided in Table 18.1, which demonstrates that huge variation exists within this field.

Treatment type	2020	2021	2022
No treatment information provided	1	2	1
IVIg, IV Steroids & EPO	1	2	6
IVIg and IV Steroids	3	2	1
IVIg only	1	1	-
IV Steroids only	2	-	-
IVIg and EPO	1	-	1

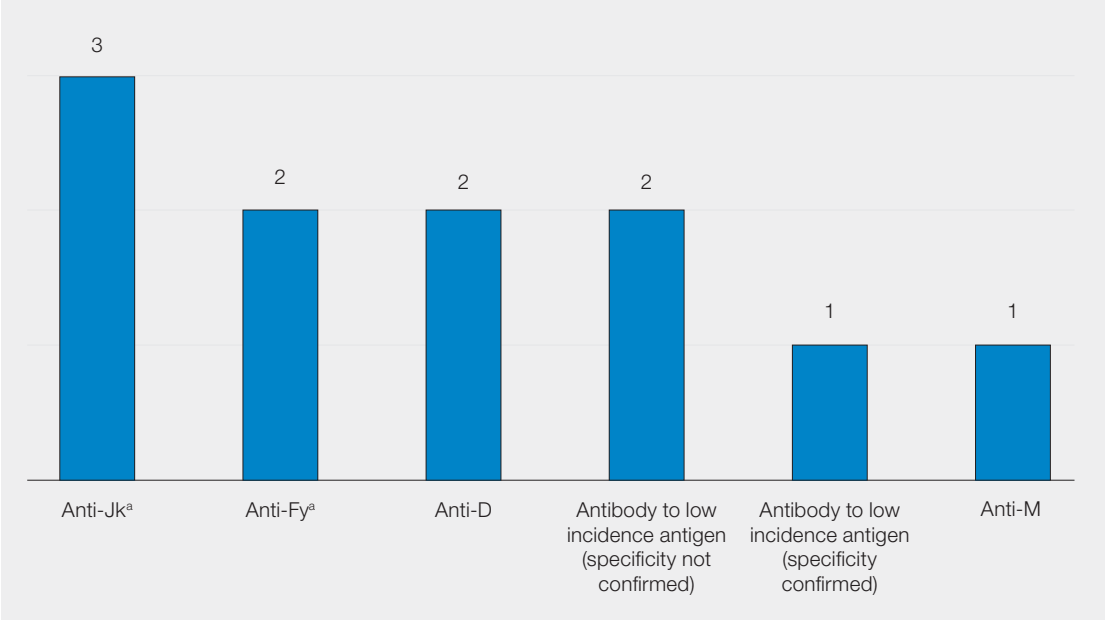
Table 18.1: Treatment methods used for hyperhaemolysis cases reported to SHOT 2020-2022

Clinical and laboratory signs and symptoms

Acute haemolytic transfusion reactions n=11

There were 11 cases reported. Alloantibodies to red cell antibodies were identified in all 11 cases. The alloantibodies implicated as shown in Figure 18.2.

Figure 18.2: Alloantibodies reported in AHTR in 2022



In 9 cases the implicated antibody was not detected in the pre-transfusion sample.

In 3 cases the patient received urgent transfusion of antigen-positive blood with the agreement of the transfusion medics. All 3 patients made a full recovery. 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. This decision must be made on an individual basis and in conjunction with concessionary release procedures (BSH Milkins et al. 2013).

Symptoms of fever, rigors and chills were reported in 8/11 AHTR, with symptoms of dyspnoea, tachycardia and hypertension also being reported at the time of the transfusion. In 5/11 cases, patients also reported dark urine.

Learning point

- Lifesaving transfusion should not be withheld in urgent clinical situations for patients with a history of alloantibodies. In such instances where suitable antigen-negative blood is not available, it may be necessary to transfuse blood components which are positive for a confirmed antibody. These decisions must be made only after liaising with specialist transfusion staff and balancing the risks versus benefits for the patient

Delayed haemolytic transfusion reactions n=29

No clinical symptoms of a transfusion reaction were reported in 7/29 DHTR cases submitted to SHOT and in all 29 cases a lack of sustained Hb increment following transfusion was described.

Alloantibodies were detected in 27/29 of the DHTR reported and in 21 of these cases, alloantibodies were detected in the post-transfusion plasma that were not detected pre transfusion.

Anti-Jk^{a} remains the most frequently implicated antibody in DHTR (Figure 18.3).

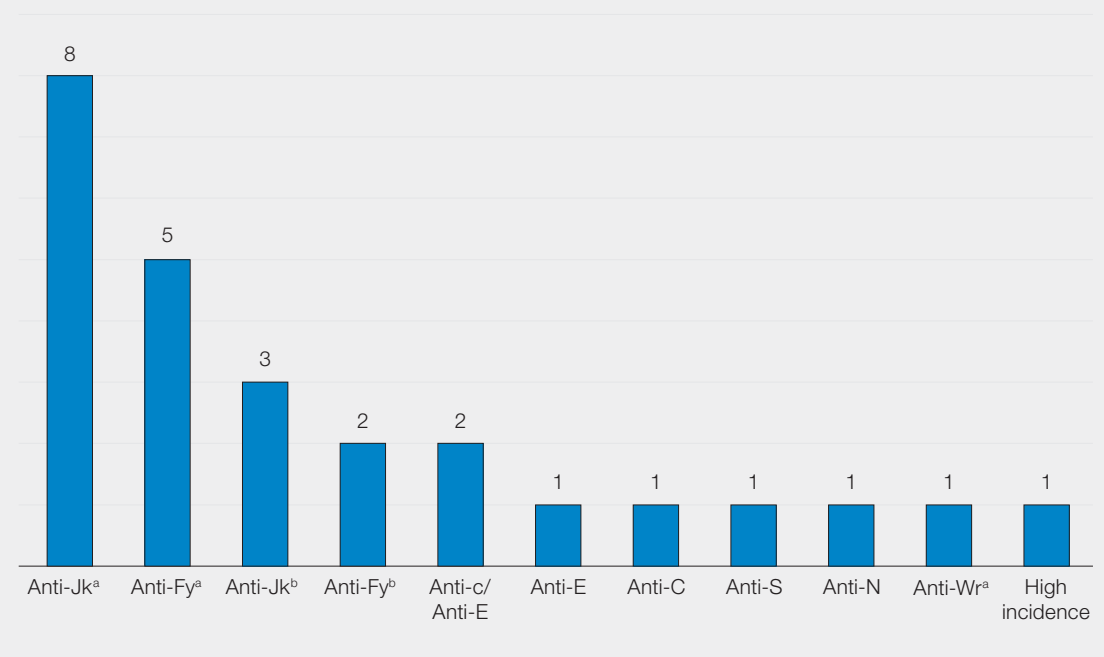


Figure 18.3: Antibody specificities implicated in DHTR

DHTR in shared care patients

In contrast to previous years, 6 cases were reported in which the patient had received the transfusion at a different hospital to the one that they presented to with symptoms of HTR. In all cases the investigation of the reaction was complicated by difficulties in obtaining details of the patient's history and pre-transfusion serology results.

Case 18.1: Diagnosis of DHTR delayed due to supply of incorrect transfusion history

A patient presented at the ED feeling unwell and experiencing thigh pain and pyrexia. The patient reported receiving a recent transfusion but when the previous hospital was contacted, they stated that the patient had only received plasma products. Laboratory results were suggestive of haemolysis with a high bilirubin, raised LDH, positive DAT and haemoglobinuria. An anti-E antibody was detected in the group and screen sample. The patient's Hb dropped to 60g/L overnight. The transfusion practitioner at the previous hospital later confirmed that the patient had received four units of red cells in her last transfusion episode at the hospital of which at least one was confirmed as positive for the E antigen.

Case 18.2: Clinical notes stated patient history not available on a haemoglobinopathy patient

Anti-S was detected in an initial sample and three units of S-negative red cells were issued by IAT crossmatch. The patient was being monitored as having a high risk for hyperhaemolysis when classical symptoms indicative of a DHTR were reported, including a falling Hb, high bilirubin, raised LDH, positive DAT and haemoglobinuria. The post-transfusion sample was DAT-positive and anti-Jk^{b} plus another possible IAT-reactive antibody were detected in addition to the anti-S. Samples were referred to the reference laboratory who confirmed they had previously investigated this patient in 2015 when they confirmed the presence of anti-Jk^{b}. This result was available on Sp-ICE. Investigation into the reaction by the hospital found that the patient had a clinical note on record stating that the ward had attempted to obtain the patients previous history, but this had not been available.

The hospital had no process in place to check patients on Sp-ICE and are looking at improving this process following this incident.

Sp-ICE was launched by NHSBT in November 2013 as a national database of patient antibody data. Initially RCI reports from 2011 were migrated to Sp-ICE but a later project uploaded reports from referrals from 31st October 2006 onwards. In 2016 the usefulness of Sp-ICE or similar national databases was discussed with a key SHOT recommendation that hospitals should take active steps to check these databases for those patients at high risk of experiencing transfusion reactions such as those with sickle cell anaemia. This recommendation was repeated in 2017, 2018, 2019 and 2021. However, each year SHOT continues to receive reports of HTR in sickle cell patients who have confirmed antibody history available on Sp-ICE. While Sp-ICE seems to be a helpful tool in helping to prevent DHTR often challenges in the blood transfusion laboratory make it difficult to use the database.

Rejected reports

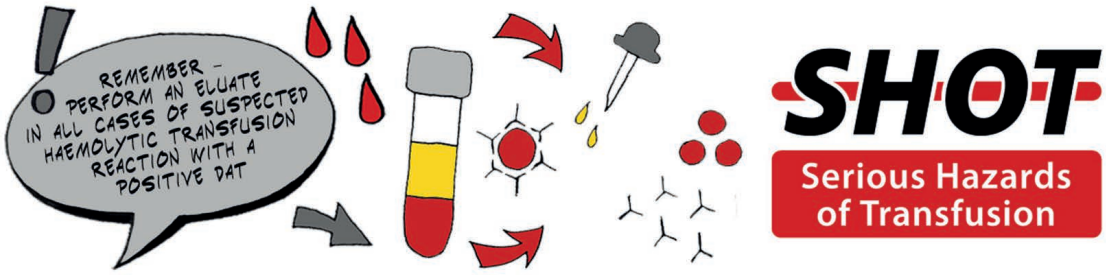
Three reports were submitted due to the detection of a new antibody specificity post transfusion, but with no detectable signs of haemolysis or other changes in the patient's serology e.g., development of a positive DAT. These cases were therefore considered as primary sensitisation to a new antibody rather than an HTR. SHOT stopped collecting data on sensitisation events in 2015, however diagnosis of HTR remains challenging and therefore the SHOT team can be contacted for advice if the reporter is unsure on whether a case is reportable to SHOT or not.

Learning point

- Identification of a new antibody without any clinical or laboratory signs of haemolysis is not indicative of HTR

Conclusion

HTR are recognised as an important cause of transfusion-associated reactions and may be subclinical, mild, or fatal. DHTR and hyperhaemolysis continue to pose diagnostic and therapeutic challenges. HTR are largely preventable and adherence to established protocols for prompt identification and timely management, as well as reporting them, remain the cornerstone of management of HTR. Patient databases such as Sp-ICE can provide vital antibody history for antibodies where the level has dropped below the detectable titre. Hospitals should have local polices to decide which patients to check on Sp-ICE or equivalent databases in the UK. All patients with laboratory evidence of haemolysis should be evaluated and followed up clinically. Procedures for investigation of transfusion reactions should be compliant with the BSH guidelines covering investigation and management of acute transfusion reactions (BSH Tinegate et al. 2012). Patients receiving transfusions should be educated about the signs and symptoms of transfusion reactions and know when and how to seek medical help.



Recommended resources

SHOT Bite No. 8: Massive Haemorrhage Delays
SHOT Bite No. 15: Hyperhaemolysis
https://www.shotuk.org/resources/current-resources/shot-bites/

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19 Uncommon Complications of Transfusion (UCT) n=13

Author: Shruthi Narayan

Definition:

Occurrence of an adverse effect or reaction temporally related to transfusion, which cannot be classified according to an already defined transfusion event and with no risk factor other than the transfusion, and no other explanation.

Serious reactions in this category are reportable to the European Union as 'uncategorised unintended responses'.

Abbreviations used in this chapter

BP	Blood pressure	**TACO**	Transfusion-associated circulatory overload
BSH	British Standards for Haematology	**UCT**	Uncommon complications of transfusion
DAT	Direct antiglobulin test	**UK**	United Kingdom
Hb	Haemoglobin	**USA**	United States of America
NICE	National Institute for Health and Care Excellence		

Key SHOT messages

- It is important that atypical complications noted in patients post transfusion continue to be reported to SHOT. This category includes those that are temporally correlated to transfusion but with non-specific clinical features that cannot be classified into any of the other known categories. This will help understand of these complications better, identify risk factors, and develop risk-reduction strategies
- All appropriate investigations should be carried out in case of any suspected transfusion reactions as per BSH guidelines (BSH Tinegate et al. 2012)
- Reporters must submit all relevant information including results from any investigations done when reporting the incident to SHOT to help categorise and assign imputability to reported cases

Recommendation

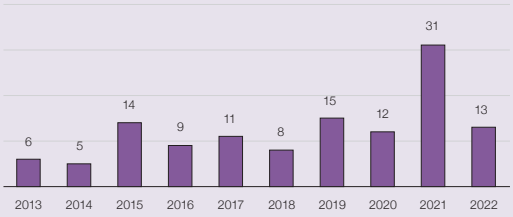
- Reporters are encouraged to continue to report cases with unusual reactions to transfusion

Action: All staff involved in transfusion

Headline data 2022

Number of reports n=13
Deaths n=1
Major morbidity n=1

UCT reports by year



Demographic data

Male n=7
Female n=6
Adults n=11
Paediatric n=2

Blood component data

Red cells n=8
Platelets n=5
Plasma n=0
Multiple components n=0
Other n=0

Introduction

This category includes cases with reactions reported in patients with a temporal relation to transfusions but cannot be classified into other categories. These are uncommon and uncategorisable. Patients often have multiple comorbidities which may have contributed to the transfusion complication. Reporting and reviewing these will help in our ever-evolving understanding of these cases and will help improve patient safety in transfusion by implementing appropriate risk-reduction measures. Occasionally, error reports that do not fit under other categories are included here 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 19.1: A sick patient with multiorgan dysfunction deteriorated following a red cell transfusion

A male patient in his mid-30s with pituitary hypogonadism, decompensated alcoholic liver disease and COVID-19 was receiving a red cell transfusion when he became tachycardic, tachypnoeic with increased work of breathing and increasing oxygen requirement. Arterial blood gases showed a deranged metabolic state. The transfusion was stopped, with increased ventilatory and vasopressor support. The laboratory investigation of the transfusion reaction showed no discrepancies or incompatibility, and the donor unit was tested and found to be suitable for transfusion. The pre- and post-transfusion group and screen samples had negative antibody screens, but had a 1+ IgG reaction on the DAT. No serological evidence of a transfusion reaction was noted by the laboratory. The patient had initially stabilised after stopping the transfusion but later died of multiorgan failure.

This was clearly a sick patient with multi-organ dysfunction with several contributory factors and highlights the challenges of managing transfusion support in such patients.

Major morbidity n=1

Case 19.2: Hypertension during red cell transfusion

A female patient in her early 60s with adenocarcinoma of the lung became hypertensive during a two-unit red cell transfusion as a day case. Observations taken pre transfusion were within normal range and the TACO risk assessment did not reveal any risk factors. The highest BP record noted was 200/103mmHg. The patient continued to feel well with no pulmonary symptoms, and the rest of the observations remained in range. Furosemide was administered as prescribed, and the patient

was admitted to the ward for overnight monitoring. The patient recovered uneventfully. It was noted that the pre-transfusion Hb was 92g/L raising the question of the need for transfusion support in this patient and an avoidable complication/admission.

Red cell transfusions are frequently overused and are associated with increased risk of patient harm and added healthcare costs, without conferring additional value. Conservative blood use, often referred to as 'restrictive transfusion practice,' is recommended in stable, non-bleeding patients by NICE and the Choosing Wisely campaigns in Canada, the UK, and the USA (see references at the end of the chapter).

Other cases n=11

Several other cases were reported in this category and have been detailed in the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).

Conclusion

Transfusion reactions range from clinically benign, to life-threatening and can be acute or delayed. The nature of the reaction may not be immediately apparent, as many reactions begin with non-specific symptoms. Patients receiving transfusions often have complex underlying clinical conditions, the symptoms of which may mimic a transfusion reaction. Close monitoring and prompt management of patients experiencing symptoms or signs consistent with an acute transfusion reaction is vital to minimise the impact of the reaction and optimise patient safety. As evident from the cases included in this section, it is often challenging to attribute imputability of the patient's reaction/complication to transfusion when there are multiple ongoing medical and surgical issues in the patient. But all cases need to be reviewed to ensure that learning from these events helps inform and improve practices.

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SHOT
Serious Hazards of Transfusion

Transfusion-Transmitted Infections (TTI) n=2

20

Authors: Chloe Davison, Heli Harvala and Su Brailsford

Definition:

Include 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.

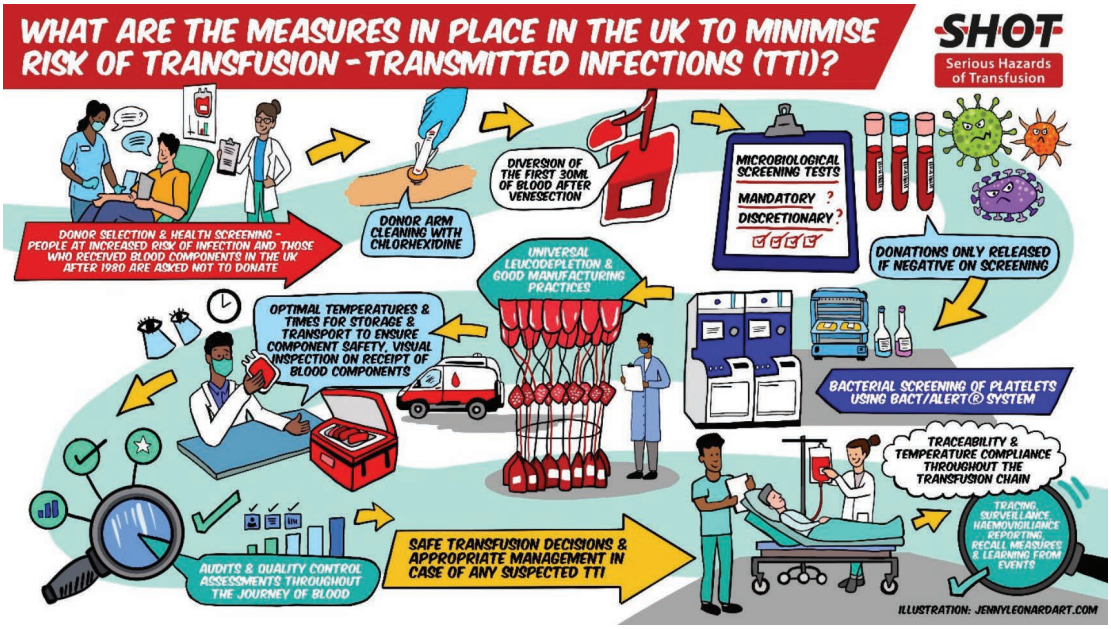
AND

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.



Abbreviations used in this chapter

ALT	Alanine transaminase
BSH	British Society for Haematology
CMV	Cytomegalovirus
DNA	Deoxyribonucleic acid
EIAR	Emerging infectious agents report
EU	European Union
FAIR	For the assessment of individualised risk
FDA	Food and Drug Administration
FFP	Fresh frozen plasma
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HEV	Hepatitis E virus
HIV	Human immunodeficiency virus
HTLV	Human T cell lymphotropic virus
JPAC	Joint UKBTS Professional Advisory Committee
MHRA	Medicines and Healthcare products Regulatory Agency
NAT	Nucleic acid testing
IVIg	Intravenous immunoglobulin
NHSBT	National Health Service Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
OBI	Occult hepatitis B virus (HBV) infection
PTR	Post-transfusion reactions
RNA	Ribonucleic acid
SaBTO	Advisory Committee on the Safety of Blood, Tissues and Organs
SACTTI	Standing Advisory Committee on Transfusion Transmitted Infection
SAR	Serious adverse reaction
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SNBTS	Scottish National Blood Transfusion Service
TTI	Transfusion-transmitted infections
UK	United Kingdom
vCJD	Variant Creutzfeld Jakob Disease
WBS	Welsh Blood Service
UKHSA	United Kingdom Health Security Agency

Key SHOT messages

- Suspected TTI should be discussed with infectious disease and/or virology colleagues to confirm the diagnosis and reported to the appropriate UK Blood Service as soon as possible for it to be fully investigated
- The UK Blood Services store a sample from every blood donation for at least three years. Testing can be done on these samples during this time if a TTI is suspected
- It is important that all healthcare professionals consenting patients for blood transfusion have up-to-date knowledge of blood donation testing, and the extremely small but potential risk of routine testing not detecting an infection in a donor that may enter the blood supply. For HBV, HCV and HIV this has been estimated to be less than 1 in 1 million donations tested

Introduction

This chapter describes suspected TTI incidents investigated by the UK Blood Services and reported to the NHSBT/UKHSA Epidemiology Unit's surveillance scheme in 2022. Additionally, we report on investigations where the UK Blood Services identify infection in a repeat donor and lookback to their previous donation(s) for evidence of transmissions to recipients.

A full description of the findings from the Epidemiology Unit surveillance schemes are available here: https://hospital.blood.co.uk/diagnostic-services/microbiology-services/epidemiology/ Epidemiology - Hospitals and Science - NHSBT (blood.co.uk)

Summary of reports in 2022

During 2022, UK Blood Services investigated 115 suspected bacterial incidents, 1 suspected parasitic incident and 8 suspected viral incidents. The outcomes are given in Figure 20.1.

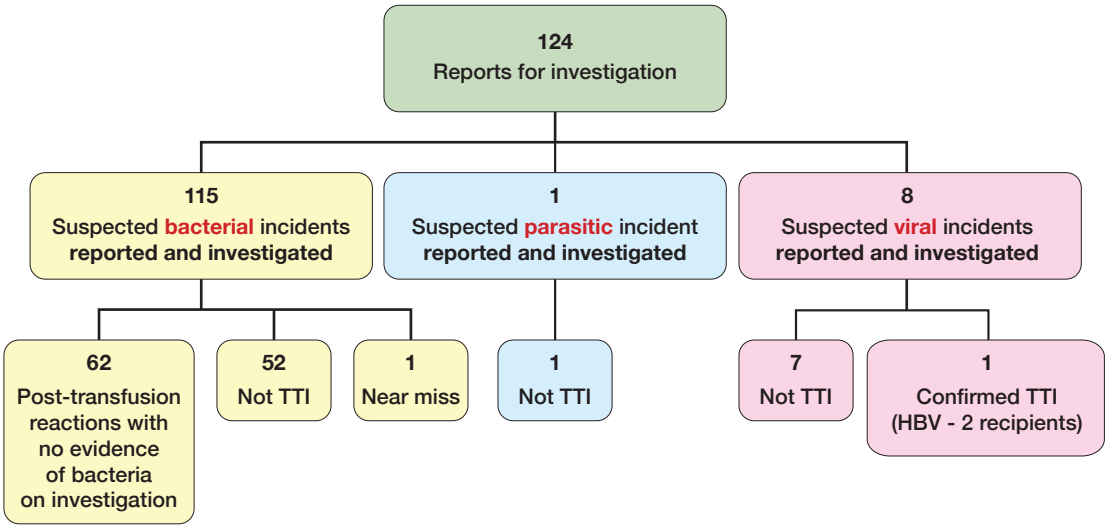


Figure 20.1: Outcome of suspected TTI investigated by the Blood Services in England, Northern Ireland, Scotland and Wales reported to the NHSBT/UKHSA Epidemiology Unit by the end of 2022

TTI=transfusion-transmitted infection; HBV=hepatitis B virus

Please note:

- A PTR occurs when a recipient develops a reaction and bacteria were suspected. However, no bacteria were cultured in the recipient, units or donor(s); i.e. no evidence of any bacterial contamination
- A confirmed TTI is as above with evidence that the virus/bacterium is indistinguishable on molecular typing between patient and donor/donation
- A probable TTI is as above, but where molecular typing cannot be carried out to confirm this
- Not a TTI is defined as an investigation that concluded the infection in the recipient was NOT caused by transfusion, either as no infected donors identified (after all donors traced) or bacteria/virus identified in the recipient, but all units cleared (no bacteria/virus in the unit and/or implicated donors)
- A near miss is defined as either an infection was identified in the unit due to be transfused however the unit was NOT used in transfusion (e.g. bacterial growth seen in 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 unit before it is transfused

Deaths related to transfusion n=0

None of the patients with confirmed TTI were reported to have died after being transfused, following investigations in 2022.

Major morbidity n=2

The recipient involved in the confirmed HBV TTI from an OBI donor had progressive kidney disease and underwent HBV testing following a liver function screen which revealed an increased ALT. The patient had extensive immunosuppression and therefore started antiviral treatment. A second recipient was diagnosed with a chronic HBV infection following a lookback investigation. They had moderate to severe fibrosis of the liver, which was multifactorial in origin and were also started on antiviral medication.

Bacterial TTI reports 2022

In 2022, none of the reported suspected bacterial TTI investigations were concluded to be confirmed, probable or possible. One investigation was concluded to be a near miss and the organism identified to be *Staphylococcus aureus* (Figure 20.1).

The four UK Blood Services all use the BacT/ALERT system for bacterial screening which has been successful in reducing the risk of bacterial TTI (McDonald et al. 2017). The details of which are described in Table 20.1.

Case 20.1: Near miss bacterial TTI (*Staphylococcus aureus*)

An apheresis platelet pack was returned to the Blood Service before being transfused, following the observation of clumps within the pack by the hospital transfusion laboratory. On return, small white flakes could be seen in the pack. Routine bacterial screening was reported as negative. BacT/ALERT bottles were also returned for further culture and investigation. Samples from the pack itself were positive for Staphylococcus aureus in both anaerobic and aerobic bottles on two occasions. S. aureus was also isolated from a swab from the implicated donor. Molecular typing confirmed the donor and pack isolates were a single strain. The donor was informed and removed from the donor panel.

A recall was issued for the associated platelet pack, but it had already been transfused. The recipient showed no adverse reaction or signs of bacterial TTI. There were no issues noted with this pack and bacterial screening remained negative. Evidence of bacteria in an individual unit from an apheresis donation does not necessarily indicate that the other units produced from the same donor will also show evidence of bacteria.

Bacterial TTI 1996-2022

Screening of platelet components cannot guarantee the absence of bacterial contamination. Packs are released for issue as 'negative-to-date', which can be before bacteria have multiplied sufficiently to trigger detection on screening. There have been 11 such near misses, all but one in platelet components, reported between 2011 and 2022. Overall, out of a total of 44 bacterial transfusion-transmissions to individual recipients, 37 (34 incidents) have been caused by the transfusion of platelets, and 7 by red cells (Table 20.6) since reporting began in 1996.

Haemovigilance systems for bacterial TTI are passive, relying on clinical colleagues to suspect and report TTI. Current BSH guidance recommends that patients are advised to report any symptoms that occur within 24 hours of transfusion (BSH Tinegate et al. 2012) although patients with confirmed bacterial TTI generally become unwell very rapidly, often during transfusion.

Table 20.1: Bacterial screening methods used by the UK Blood Services

	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

Viral TTI reports 2022

In 2022, one suspected viral TTI investigation was concluded to be a confirmed HBV transmission from an OBI donor. This led to the identification of a second confirmed HBV TTI through lookback.

The number of viral TTI investigated in 2022 includes 4 reports where a CMV non-tested blood component was used in a situation where CMV tested ones should have been used, hence retrospective CMV testing is completed. These investigations are not further examined in the text of this chapter due to them not fulfilling the definition of a TTI. They are instead described in Chapter 9, Incorrect Blood Component Transfused (IBCT).

Case 20.2: Confirmed HBV transmission from a donor with occult HBV infection - recipient 1

Recipient 1 (50-60 years) had progressive kidney disease. They were diagnosed with an acute asymptomatic HBV infection in early 2022, four months post transfusion. HBV testing was performed following a liver function screen which revealed an increased ALT.

Blood transfusion was considered the most likely source of infection. They had received 28 units of FFP over 2 months in 2021. Six of the 28 donors were non-returning donors and their implicated donations all tested negative for anti-HBc and HBV DNA. Of the returning donors, 21 of 22 tested

negative for anti-HBc, and one donor tested positive with HBV DNA detected in their implicated donation on retesting by individual donation NAT. Post-donation testing had returned negative by pooled NAT.

Based on these investigations, one returning donor was identified with an occult HBV infection characterised with a very low viral load in the absence of HBV surface antigen. The donor was aged >50 and of other white ethnicity. The donor reported an accident leading to a hospitalisation when at the time liver function was investigated due to a slow recovery, no other significant history was disclosed. Based on their history, they were eligible to donate but have now been permanently deferred.

Case 20.3: Confirmed HBV transmission from a donor with occult HBV infection - recipient 2

Subsequent lookback investigations into red cell components made from the donation in Case 20.2 identified a second HBV infected recipient. Recipient 2 (70-80 years) had severe fibrosis due to non-alcoholic fatty liver disease. Nine months post transfusion, the recipient was tested and found to be positive for HBsAg, HBeAg and anti-HBc. HBV DNA was also detected at a very high level. They had tested negative for HBsAg in May 2017, and no other source or risk factors for HBV were identified. Following their positive test, the patient was started on antiviral treatment.

Sequencing analysis showed high similarity between the virus obtained from the implicated donor and the two recipients, and confirmed transfusion as the source.

Viral TTI 1996-2022

The year of transfusion may be many years before the year in which the incident is investigated and reported to SHOT due to the chronic nature, and possible late recognition, of some viral infections. Since 1996, 43 confirmed transfusion-transmitted viral infections have been documented in the UK, involving 35 donors. Among these, HBV (n=15) and HEV (n=15) were the most reported proven viral TTI. For HBV, this is partly because the 'window period', where an infectious donation from a recently infected donor cannot be detected by the screening tests, is longer than for HCV or HIV, despite NAT screening of blood donations.

The first transmissions of OBI confirmed by DNA sequencing in the UK were identified in 2022. Previously, 5 reports had been made of an HBV infection in recipients who had received components from donors with OBI in England; in these cases, transmission could not be confirmed because of a lack of sequencing information. However, implementation of sample concentration techniques (i.e. ultracentrifugation of large volumes of plasma) has made it possible to obtain viral sequences from samples containing very small amounts of viral DNA.

All except 2 of the 15 HEV transmissions were reported before the HEV RNA screening was introduced in April 2017 in the UK (Harvala et al. 2022). 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 to minimise donations from those infected.

Lookback investigations

Lookback investigations are considered when the UK Blood Services identify markers of infection in a donation from a repeat donor. This may be due to seroconversion or the introduction of a new test. The archive sample of their most recent screen-negative donation is requested for retrospective re-testing and if identified as positive, a full clinical lookback will be instigated. This means the associated components are traced, recipients are identified, and advice is given regarding follow-up and testing. For lookbacks involving OBI donors, all previous donations available for retesting are considered regardless of the screening result. In NHSBT, samples of donations are stored for three years.

In England in 2022 there was 1 HEV, 4 syphilis and 3 OBI lookback investigations. The HEV lookback involved an apheresis platelet donation where two components were made. No transmission was identified and both recipients died of unrelated causes. The 4 syphilis lookbacks involved 7 donations and 12 components: 5 recipients had died, 6 tested negative and one wasn't transfused. The 3 OBI lookbacks involved 16 donations and 30 components. Three donations had positive archive tests, which

had 6 associated components. Five components were transfused; one has follow-up in progress. Three recipients have testing results outstanding, one had died and one tested positive, as described in Case 20.3. In Scotland there is one pending HBV lookback investigation.

A HEV lookback investigation in Wales followed a donation positive for HEV RNA. The donor's most recent donation, made 6 weeks prior to the index donation, was found to contain HEV RNA on retrospective testing. This donation was a double apheresis platelet donation and manufactured into 8 neonatal platelet components. Fortunately, all neonatal components were time expired and not transfused to any patients. This case could have potentially led to adverse effects for several recipients of the donated components and has resulted in the WBS commencing ID HEV NAT testing on all apheresis donations in November 2022.

Non-investigated reports

Some reports made to NHSBT are not investigated due to various biological and practical factors.

Examples include:

- If a recipient tests positive only for antibodies to infection, it is possible that passive transfer of antibodies occurred. The presence of antibodies can reflect past infection. To clarify this NHSBT finds out if they received IVIg or blood transfusion, and if so, repeat the testing 4-6 weeks after the transfusion date. If it is the passive transfer of antibodies, then reactivity should resolve within this time, and they no longer have any evidence of infection
- In cases where only IgM antibodies are detected, reactivity for RNA/DNA and seroconversion (e.g., IgG) would also need to be confirmed before investigations commenced. This is because IgM assays are often cross-reactive and non-specific, so isolated IgM reactivity is not usually diagnostic
- In cases 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 is very low at less than 1 per million donations tested (Table 20.2) (JPAC 2021). 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 OBI.

Table 20.2: The estimated residual risk (and 95% confidence interval) that a donation made in the HBV, HCV and HIV infectious window period related to acute infection is not detected on testing UK: 2019-2021

	HBV	HCV	HIV
Number per million donations	0.39	0.02	0.03
95% confidence interval	*(0.07-0.98)*	*(0.00-0.09)*	*(0.00-0.08)*
At 1.9 million donations per year, testing will miss a potentially infectious window period donation every:	1 year	35 years	18 years

Far fewer TTI are observed in practice than the estimated risks in Table 20.2 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 screening process

Every blood donation in the UK is screened for HBV, HCV, HEV, HIV and syphilis. Details on screening and surveillance methods can be found on the NHSBT website using the following link: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/27719/nhsbt-ukhsa-data-sources-and-methods-2021.pdf

In 2022, following a SaBTO review (SaBTO 2022a), hepatitis B core antibody testing was rolled out across the UK to supplement current HBV screening in blood donors with the aim to reduce the risk from occult hepatitis B infection where HBsAg is not detectable and DNA levels may fluctuate below the levels of pooled testing (Harvala et al. 2021). While lookback investigations involving the testing of archive samples from donors with OBI will continue in England, lookback investigations into the archive samples of hepatitis B core antibody-positive donors are planned to begin in the UK in 2023. The WBS changed to individual HEV NAT screening for apheresis donors during November 2022.

Testing and selection of donors

The HEV screening process is currently under review by SaBTO (SaBTO 2022a).

Since the implementation of FAIR (For the Assessment of Individualised Risk) in summer 2021, there has been no evidence that FAIR has impacted recent viral infections or blood safety. While syphilis in first-time donors has continued at a higher rate in 2022, this is not thought to be because of FAIR but reflects the sustained higher level among the general population.

Parasitic TTI

In 2022, there was one parasitic TTI investigation for toxoplasmosis. This was concluded to not be a TTI.

Emerging infections

The EIAR produced by the NHSBT/UKHSA Epidemiology Unit is distributed monthly. This is reviewed by the SACTTI Horizon Scanning Team and may lead to further risk assessment and changes to the donor selection guidelines, or other blood safety measures, where necessary. Please see the horizon scanning position statement on the JPAC website: https://www.transfusionguidelines.org/document-library/position-statements

In 2022, the monkey pox outbreak was monitored carefully to ensure that existing Blood Service safety measures were sufficient. Arbovirus outbreaks and spread, particularly within Europe, continued to be monitored carefully with a 28-day deferral implemented for donors visiting the areas in France affected by dengue outbreaks. There were no known cases of transfusion-transmitted SARS-CoV-2 infections reported to the Blood Services in 2022 and there is still no evidence that SARS-CoV-2 is a TTI.

Variant Creutzfeldt Jakob disease (vCJD) 2022

There were no vCJD investigations in 2022.

vCJD 1996-2022

Three vCJD incidents (Table 20.3) 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 (SaBTO 2013).

One of these measures, the provision of imported plasma for individuals born on or after 1st January 1996, was withdrawn in September 2019. This followed a recommendation by SaBTO based on evaluation of the risk of transmission of vCJD. Other risk-reduction measures, such as leucodepletion, remain in place (SaBTO 2019).

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 (TMER 2021). In 2022 both the FDA in the United States and the Australian Red Cross Lifeblood announced the removal of their blood donor deferral for people who had spent time in the UK between 1980 and 1996 (AABB 2022) with the FDA also removing the deferral for people who have received a transfusion in the UK since 1980. Further review of CJD safety measures in the UK is planned (SaBTO 2022b).

Table 20.3: number of confirmed TTI incidents, by year of transfusion and infection in the UK, reported to SHOT between October 1996 and December 2022 (Scotland included from October 1998)

Year of transfusion	Bacteria	HAV	HBV	HCV	HEV	HIV	HTLV	Parvovirus (B19)	Malaria	vCJD or prion	Total
Pre 1996	0	0	1	0	0	0	2	0	0	0	3
1996	0	1	1	1	0	1(3)	0	0	0	1	5 (7)
1997	3	0	1	1	0	0	0	0	1	2	8
1998	4	0	1	0	0	0	0	0	0	0	5
1999	4	0	2 (3)	0	0	0	0	0	0	0 (1)	6 (8)
2000	7	1	1	0	0	0	0	0	0	0	9
2001	5	0	0	0	0	0	0	0	0	0	5
2002	1	0	1	0	0	1	0	0	0	0	3
2003	3	0	1	0	0	0	0	0	1	0	5
2004	0	0	0	0	1	0	0	0	0	0	1
2005	2	1	1	0	0	0	0	0	0	0	4
2006	2	0	0	0	0	0	0	0	0	0	2
2007	3	0	0	0	0	0	0	0	0	0	3
2008	4 (6)	0	0	0	0	0	0	0	0	0	4 (6)
2009	2 (3)	0	0	0	0	0	0	0	0	0	2 (3)
2010	0	0	0	0	0	0	0	0	0	0	0
2011	0	0	1 (2)	0	1 (2)	0	0	0	0	0	2 (4)
2012	0	0	0	0	2	0	0	1	0	0	3
2013	0	0	0	0	0	0	0	0	0	0	0
2014	0	0	0	0	1 (2)	0	0	0	0	0	1 (2)
2015	1	0	0	0	5 (6)	0	0	0	0	0	6 (7)
2016	0	0	0	0	0	0	0	0	0	0	0
2017	0	1	0	0	0	0	0	0	0	0	1
2018	0	0	0	0	1	0	0	0	0	0	1
2019	0	0	0	0	1	0	0	0	0	0	1
2020	0	0	0	0	0	0	0	0	0	0	0
2021	0	0	1 (2)	0	0	0	0	0	0	0	1 (2)
2022	0	0	0	0	0	0	0	0	0	0	0
Total number of incidents (recipients)	**41 (44)**	**4**	**12 (15)**	**2**	**12 (15)**	**2 (4)**	**2**	**1**	**2**	**3 (4)**	**81 (93)**

Year of transfusion	Red blood cells	Pooled platelets	Apheresis platelet	Fresh frozen plasma	Cryoprecipitate	Total
Pre 1996	3	0	0	0	0	**3**
1996	5	1	0	1	0	**7**
1997	6	1	1	0	0	**8**
1998	2	1	2	0	0	**5**
1999	5	3	0	0	0	**8**
2000	1	5	3	0	0	**9**
2001	0	4	1	0	0	**5**
2002	2	1	0	0	0	**3**
2003	1	1	3	0	0	**5**
2004	1	0	0	0	0	**1**
2005	1	3	0	0	0	**4**
2006	0	1	1	0	0	**2**
2007	2	1	0	0	0	**3**
2008	0	2	4	0	0	**6**
2009	1	0	2	0	0	**3**
2010	0	0	0	0	0	**0**
2011	2	0	0	2	0	**4**
2012	1	0	0	2	0	**3**
2013	0	0	0	0	0	**0**
2014	1	0	0	1	0	**2**
2015	1	3	1	1	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	1	0	0	1	0	**2**
2022	0	0	0	0	0	**0**
Total number of recipients	**36**	**27**	**21**	**8**	**1**	**93**

Table 20.4: Number and type of implicated components from confirmed TTI recipients, by year of transfusion in the UK, reported to SHOT between October 1996 and December 2022 (Scotland included from October 1998)

	Bacteria	HAV	HBV	HCV	HEV	HIV	HTLV I	Parvovirus (B19)	Malaria	vCJD or prion	Total
Outcomes											
Death due to, or contributed to, by TTI	11	0	0	0	2	0	0	0	1	3	**17**
Major morbidity	29	3	15	2	9	4	2	1	1	1	**67**
Minor morbidity	4	1	0	0	4	0	0	0	0	0	**9**
Implicated component types											
Red blood cells	7	1	11	2	4	2	2	1	2	4	**36**
Pooled platelets	21	2	1	0	2	1	0	0	0	0	**27**
Apheresis platelets	16	1	1	0	3	0	0	0	0	0	**21**
Fresh frozen plasma	0	0	2	0	5	1	0	0	0	0	**8**
Cryoprecipitate	0	0	0	0	1	0	0	0	0	0	**1**

Table 20.5: Outcome of confirmed TTI incidents and implicated components by infection in the UK, reported to SHOT between October 1996 and December 2022 (Scotland included from October 1998)

Accompanying notes for Table 20.3, 20.4 and 20.5

- Where applicable, number of recipients are included in bracket
- No blood donation screening has been ever in place for vCJD, HAV or parvovirus B19
- 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 both malaria transmissions, 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 figure
- The year of transfusion may be prior to year of report to SHOT due to delay in recognition of chronic infection
- The 2 HIV incidents 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 patient with prion disease 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

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21 Post-Transfusion Purpura (PTP) n=1

Author: Tom Latham

Definition:

Post-transfusion purpura is defined as thrombocytopenia arising 5-12 days following transfusion of cellular blood components (red cells or platelets) associated with the presence in the patient of antibodies directed against the HPA (human platelet antigen) systems.

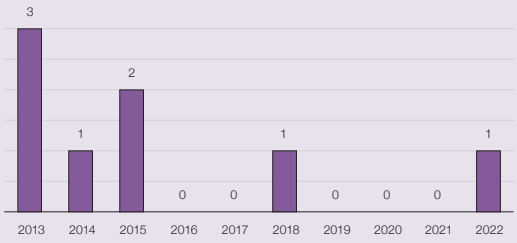
Abbreviations used in this chapter

Hb	Haemoglobin	**IVIg**	Intravenous immunoglobulin
HPA	Human platelet antigen	**PTP**	Post-transfusion purpura

Headline data 2022

Number of reports n=1
Deaths n=0
Major morbidity n=1

PTP reports by year



Demographic data

Male n=0
Female n=1
Adults n=1
Paediatric n=0

Blood component data

Red cells n=1
Platelets n=0
Plasma n=0
Multiple components n=0
Other n=0

Introduction

There was 1 case of post-transfusion purpura reported this year, the only case since 2018.

Deaths related to transfusion n=0

There were no deaths reported related to PTP in 2022.

Major morbidity n=1

Case 21.1: Post-transfusion purpura

A female patient in her 70s with cholangiocarcinoma was transfused two units of red cells as an outpatient prior to a liver biopsy. Seven days later she developed bruising and was found to have a

platelet count of 8. There were no features of sepsis, and no history of medication exposure, even transiently. She had further transfusions of red cells and platelets which produced poor increments. Platelet count gradually increased and had returned to normal 10 days after presentation. IVIg treatment was not given. Platelet antibodies were not detected either at presentation or on a repeat sample 6 weeks later. Tests revealed her platelet phenotype as HPA 5b5b and had potential to form anti-HPA 5a. In view of the possible diagnosis of PTP, transfusion was avoided, with erythropoietin used to support her Hb. No further transfusion support was needed before she died of her malignancy 6 months later.

The time course here was classical for PTP and there were no other identified reasons for the transient but severe fall in platelets. Despite the absence of antibodies, this was included as a PTP case. There was the potential to make an anti-HPA 5a antibody. In the context of neonatal thrombocytopenia, low-affinity antibodies which are not detectable by standard techniques have been described in cases where there is a strongly suspicious history, and it is plausible that a similar phenomenon has occurred here (Hawkins et al. 2019).

Learning point

- PTP may be suspected if the history is classical, but HPA antibodies are not detected, if the recipient HPA genotype suggests there is potential to form antibodies. Low affinity antibodies are postulated as a possible mechanism

Conclusion

Post-transfusion purpura has become extremely rare since the introduction of universal leucodepletion. There have been 8 cases reported to SHOT over the last 10 years including this case. It remains an important diagnosis for clinicians to be aware of, since the mainstay of management is transfusion avoidance, in addition to IVIg administration.

The diagnosis of PTP can be elusive given its substantial symptomatic overlap with other thrombocytopenic syndromes. Under-diagnosis and under-reporting make the true incidence of disease difficult to define (Hawkins et al. 2019). Staff need to be able to recognise these delayed immunological transfusion reactions so that appropriate actions can be taken. PTP has a temporal relationship to a transfusion and clinicians must recognise this and investigate appropriately. Although the low platelet counts are transient, major haemorrhage resulting from the thrombocytopenia can lead to patient death and major morbidity. Avoiding unnecessary transfusions, monitoring patients for delayed reactions and educating patients about these potential risks are vital (Narayan et al. 2021).

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SHOT
Serious Hazards of Transfusion

SPECIAL CLINICAL GROUPS

22 Cell Salvage (CS) n=20

Author: Sarah Haynes

Definition:

Any adverse events or reactions associated with cell salvage (autologous) transfusion methods, including intraoperative and postoperative cell salvage (washed or unwashed).

Abbreviations used in this chapter

AAA	Abdominal aortic aneurysm	**HTC**	Hospital Transfusion Committee
BCSH	British Committee for Standards in Haematology	**ICS**	Intraoperative cell salvage
		Ig	Immunoglobulin
cffDNA	Cell free fetal DNA	**IV**	Intravenous
FFP	Fresh frozen plasma	**LDF**	Leucocyte depletion filter
FMH	Feto-maternal haemorrhage	**WHO**	World Health Organisation

Key SHOT messages

- Cell salvage related incidents continue to be under-reported
- Preventable errors accounted for 10/16 adverse events
- Of the adverse reactions, hypotensive reactions were seen in 3/4 cases

Recommendations

- Where cell salvage has been planned, teams should ensure the availability of trained staff and adequate resources for the procedure. Review current training needs for all staff involved in the process and address any deskilling by update training

Action: Cell salvage leads, theatre leads, anaesthetic and surgical specialty leads

- Review suitability of cell salvage documentation (paper or electronic) and its appropriate use. Ensure the record of cell salvage is accessible and complete, particularly in relation to communicating pertinent details at handover

Action: Cell salvage leads, theatre teams, hospital transfusion teams

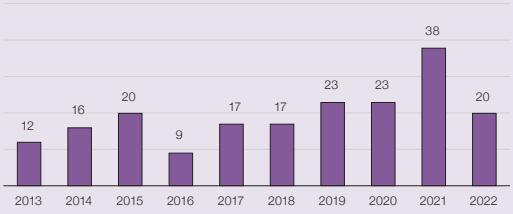
- Establish clear responsibilities and lines of reporting for cell salvage incidents. Review pathways and structure for governance and communicate these processes to all stakeholders

Action: Cell salvage leads, theatre leads, HTC, clinical governance leads

Headline data 2022

Number of reports n=20
Deaths n=0
Major morbidity n=0

CS reports by year



Demographic data

Male n=8
Female n=12
Adults n=19
Paediatric n=0
Unknown n=1

Blood component data

Red cells n=20
Platelets n=0
Plasma n=0
Multiple components n=0
Other n=0

Introduction

There were 20 cell salvage incidents analysed in 2022. All incidents related to the use of ICS. The reports were submitted from 15 different hospitals, with one hospital submitting 5 reports, one 2 reports, and the remaining 13 hospitals submitting a single incident each.

All reported incidents were in adult patients, with an age range of 26 to 89 years, with 12 females and 8 males.

Unlike previous years, reports were spread between surgical disciplines, with most surgeries being planned as opposed to emergencies (Table 22.1).

There were 16 adverse events, of which 10 were attributable to preventable error, and 4 adverse reactions comprising 3 episodes of hypotension and 1 allergic reaction. Hypotensive reactions on reinfusion of cell salvaged blood remain the most commonly reported reaction.

Table 22.1. Cell salvage cases by speciality

Specialty	Elective	Emergency	Total
Gynaecology	2	1	**3**
Hepatobiliary	1	0	**1**
Obstetrics	5	0	**5**
Orthopaedic	5	0	**5**
Spinal	1	0	**1**
Trauma	0	1	**1**
Urology	2	0	**2**
Vascular	1	1	**2**
Total	**17**	**3**	**20**

Deaths related to transfusion n=0

There were no deaths related to cell salvage in 2022.

Major morbidity n=0

There were no incidents that resulted in major morbidity in 2022.

Cell salvage adverse events n=16

There were 10 preventable incidents, 4 equipment failures and 2 other adverse events.

Procedural errors n=10

There were 3 cases where inappropriate substances were aspirated into the blood collection causing cell salvage to be abandoned. In a further case intermittent machine failures were found to have resulted from user error and resolved by installing a new consumable set correctly.

In 3 cases, reported from one hospital, inadequate documentation, and inability to access process records on the device called into question the quality of the salvaged red cells. In all 3 (2 orthopaedic, 1 gynaecology) there was no means of verifying at handover as to whether a partial bowl had been double washed. A contributory factor on 2 occasions was powering down the cell salvage device 'mid-processing' to move it from theatres to recovery to continue processing of the collected blood. Despite these concerns the processed red cells were reinfused in all cases.

Problems with reinfusion of cell salvaged blood were reported in 3 cases. In an orthopaedic case a fat reduction filter was not primed correctly (using reverse priming) causing it to fail and the infusion abandoned. In another incident a standard solute giving set, instead of a blood transfusion giving set, was used to reinfuse 461mL of salvaged red cells. Inadequate documentation was also noted in this case as the reinfusion start time had not been recorded. And in a third case, despite the blood bag not being labelled with the patient's details and no blood authorisation documentation being completed, a 473mL reinfusion went ahead regardless.

Learning points

- Procedure documentation must be contemporaneous, reliable, and complete
- Moving a device mid-procedure is not advisable. If power is lost to a device mid-procedure, staff should have sufficient training to be able to recall processing records on the cell salvage device

Equipment failure n=4

There were 4 incidents in which cell salvage devices or disposables failed or malfunctioned. In the first case, cell salvage was employed in an elective caesarean section. Ongoing failures of the on-board suction system persisted, despite attempts to troubleshoot, requiring a replacement machine to be introduced. Inevitably, some of the 2L intraoperative blood loss was not captured, reducing the efficiency of the process with only 391mL of red cells being reinfused.

In a 2nd case, cell salvage was set up for AAA surgery in a man in his 70s. Blood loss was rapid, and a large volume (over 3L) was quickly collected in the reservoir. Despite the best efforts of the theatre staff present, the device could not be initiated to process the blood. At this point cell salvage was abandoned and suction switched to a waste container. Ongoing massive blood loss and activation of the MHP resulted in transfusion of 11 units of red cells and four units of FFP. The patient died despite supportive measures. Failure of cell salvage was not deemed to be a contributory factor in the patient's death.

In the 3rd case, complete failure of the cell salvage device in an elective caesarean section meant that the 2.4L blood loss was not compensated and a two-unit allogeneic red cell transfusion was required. The reporter stated that the hospital's cell salvage machines were over 10 years old and in need of replacement.

The last incident related to quality concerns with black particles seen in the reinfusion bag after processing blood collected in an elective total hip replacement.

Other adverse events n=2

There were 2 further adverse incidents. In the 1st, which occurred outside core hours, a cardiac arrest call was put out for a postoperative gynaecology patient. The lady in her 60s, who was a Jehovah's Witness, was returned to theatre for an emergency laparotomy. Blood loss was collected, but there was no trained cell salvage operator available to process the blood. Additionally, the saline used as washout in the surgical field was not IV grade making the blood collected unusable. The patient was transferred to ICU and made a full recovery.

In the 2nd case, failures in communication resulted in a near miss but highlighted the need to discuss patient specific concerns and the use of cell salvage at team brief and at handover.

Case 22.1: Failure to communicate risks inadequate anti-D Ig prophylaxis

A woman in her 20s underwent an elective caesarean section in which cell salvage was to be used. Prior to surgery there was no discussion within the theatre team about the women's blood group, which was D-negative. The patient received a transfusion of 251mL of salvaged red cells whilst in theatre, something not communicated to the midwife at handover. This was later discovered when the patient herself told the midwife she had received her own blood back and the fact verified by review of the anaesthetic chart. No maternal sample had been taken for Kleihauer testing even though over 45 minutes had elapsed since the transfusion. A review of the cffDNA result however showed that the baby was also D-negative meaning that no anti-D Ig prophylaxis was required.

A failure in communication in this case risked a patient having inadequate anti-D Ig prophylaxis. BCSH guidelines (BCSH Qureshi et al. 2014) state that where ICS is used during caesarean section in D-negative, previously non-sensitised women, and where cord blood group is confirmed as D-positive (or unknown), a minimum dose of 1500IU anti-D Ig should be administered following the re-infusion of salvaged red cells, and a maternal sample should be taken for estimation of FMH 30–45 minutes after reinfusion in case more anti-D Ig is indicated. It is also recommended that clinicians inform the transfusion laboratory if ICS has been used to ensure that the correct dose of anti-D Ig is issued. It was fortunate in this case that a previous cffDNA test had shown the child to be D-negative, a result that was only reviewed in retrospect.

Learning point

- Communication around the use of cell salvage is key. The WHO Surgical Safety Checklist team brief allows patient specific concerns to be discussed prior to surgery. Any ICS infusions should be documented and notified at handover to recovery staff so that the patient is cared for appropriately. The transfusion laboratory should also be notified of cell salvage use in D-negative mothers

Cell salvage adverse reaction n=4

There were 3 hypotensive reactions reported. All were associated with the use of LDF to mitigate the risk of cancer dissemination, with citrate anticoagulation. All patients experienced transient symptoms which were corrected and made full recoveries.

A woman in her 50s underwent complex gynaecological surgery. On reinfusion of cell salvaged blood her BP dropped to 68/30mmHg. The transfusion was stopped, the patient was given fluids and vasoconstrictors and blood pressure normalised. On resumption of the reinfusion, a similar drop in blood pressure occurred and the cell salvage infusion abandoned. The patient received three units of allogeneic red cells intraoperatively but it was difficult to say if any of these could have been avoided if cell salvage had been successful.

Severe hypotension was also noted in a man in his 60s undergoing spinal surgery with malignancy.

A woman underwent a nephrectomy and experienced marked hypotension on infusion of salvaged red cells. The transfusion was stopped, the patient stabilised and the LDF removed and replaced with a 40-micron filter. In total 900mL of salvaged red cells were reinfused. The woman was a Jehovah's Witness, and the reinfusion was hence significant.

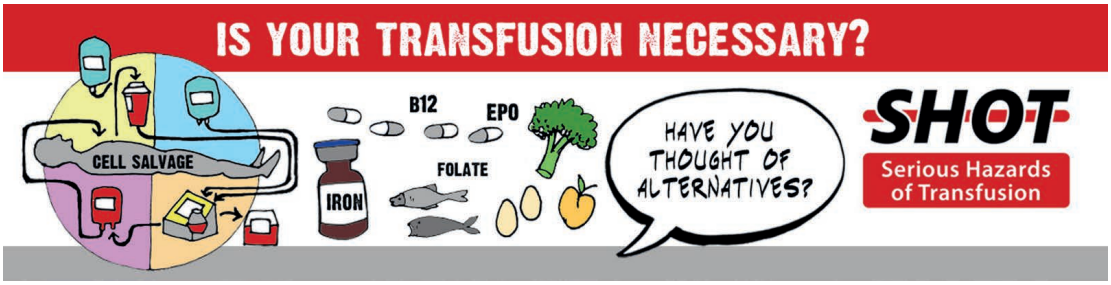
The 4th reaction was in a woman in her 30s undergoing an elective caesarean section. Following the reinfusion of 50mL of salvaged blood, the patient developed redness tracking along the vein and spreading across the forearm with white wheals. The infusion was stopped, the affected area on her arm delineated, and hydrocortisone administered. The reaction diminished over time with the patient being fine throughout apart from discomfort and itching at the reaction site.

Conclusion

It is concerning that most incidents reported this year were preventable. Staff were provided with refresher training in cases where procedural errors were identified. A number of new training resources related to blood transfusion, including a module on cell salvage, have been recently been released and are accessible to NHS staff through the e-learning for Healthcare website (see 'Recommended resources'). Appropriate staff training and competency-assessment are essential to ensure safe delivery of cell salvage.

Inaccurate documentation and labelling appear to be a theme this year, particularly in relation to communicating important information at handover. The appropriate management of patients receiving cell salvaged blood is vital as unexpected clinical reactions can and do happen. The 3 hypotensive reactions described here bring the total to 34 incidents reported to SHOT since 2010. It is anticipated that this under-represents the true picture.

In the recent UK Cell Salvage Action Group survey (in press), only 58% of organisations (53/90) reported cell salvage incidents to SHOT compared to 92% reporting through local incident reporting systems. Only 30% stated that they report machine and disposables failures to the MHRA Yellow Card Scheme or equivalent in devolved countries. Incidents were most commonly investigated through theatres, transfusion practitioners and ICS leads, with governance being provided by the Hospital Transfusion Committee/Team, Clinical Governance or Patient Safety Committee. Cell salvage contributes significantly to perioperative patient blood management. Hospitals should strive to achieve the same rigor in safety and governance as any other transfusion practice.



Recommended resources

E-learning for Healthcare
https://www.e-lfh.org.uk/programmes/blood-transfusion/

WHO Surgical Safety Checklist
https://www.who.int/teams/integrated-health-services/patient-safety/research/safe-surgery/tool-and-resources

UK Cell Salvage Action Group
https://www.transfusionguidelines.org/transfusion-practice/uk-cell-salvage-action-group

References

BCSH Qureshi H, Massey E, Kirwan D, et al. BCSH guideline for the use of anti-D immunoglobulin for the prevention of haemolytic disease of the fetus and newborn. *Transfus Med*. 2014;**24(1)**:8-20. https://doi.org/10.1111/tme.12091 [accessed 30 April 2023].

The UK Cell Salvage Action Group. Intraoperative Cell Salvage: Survey of Equipment and Practice across the UK in 2019. (2023) (in press).

Paediatric Cases n=151

23

Authors: Anne Kelly and Helen New

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.

Abbreviations used in this chapter

ADU	Avoidable, delayed and under/overtransfusion	**NEC**	Necrotising enterocolitis
BSH	British Society for Haematology	**NM**	Near miss
CS	Cell salvage	**RBRP**	Right blood right patient
CMV	Cytomegalovirus	**SaBTO**	The Advisory Committee on the Safety of Blood, Tissues and Organs
EI	Electronic issue		
FAHR	Febrile, allergic and hypotensive reactions	**SCD**	Sickle cell disease
FFP	Fresh frozen plasma	**SRNM**	Specific requirements not met
Hb	Haemoglobin	**TACO**	Transfusion-associated circulatory overload
HSCT	Haemopoietic stem cell transplant	**TAD**	Transfusion-associated dyspnoea
HSE	Handling and storage errors	**TANEC**	Transfusion-associated NEC
HTR	Haemolytic transfusion reactions	**TRALI**	Transfusion-related acute lung injury
IBCT	Incorrect blood component transfused	**TTI**	Transfusion-transmitted infection
Ig	Immunoglobulin	**UCT**	Uncommon complications of transfusion
MHP	Major haemorrhage protocol	**WCT**	Wrong component transfused

Key SHOT messages

- Paediatric reports account for 263/3499 (7.5%) of all reports to SHOT including NM and RBRP. More than a third of reports involved neonates
- Five of the 8 overtransfusion reports were due to errors in administration and 3 were due to prescribing errors
- Transfusion delays with paediatric major haemorrhage continue to be reported. Ten of 22 delayed transfusions involved communication failure within teams and between clinical and laboratory areas
- The decision around whether to irradiate components for patients with known or suspected DiGeorge syndrome is based upon assessment of immune function and not all children with DiGeorge will require irradiated blood components
- The paediatric transfusion formula remains the best way to calculate the volume of red cells for transfusing a child

Recommendations

- Local guidelines for management of iron and haematinic deficiency in children should be developed and implemented
- Transient abnormalities of coagulation and platelet number are common following exchange transfusion and transfusion should only be given if within guidelines (BSH New et al. 2016, 2020)
- Specific paediatric MHP are required, and all members of staff involved need to be aware of their roles

Action: Hospital transfusion teams and paediatricians; Royal College of Paediatrics and Child Health; paediatric and nursing educators

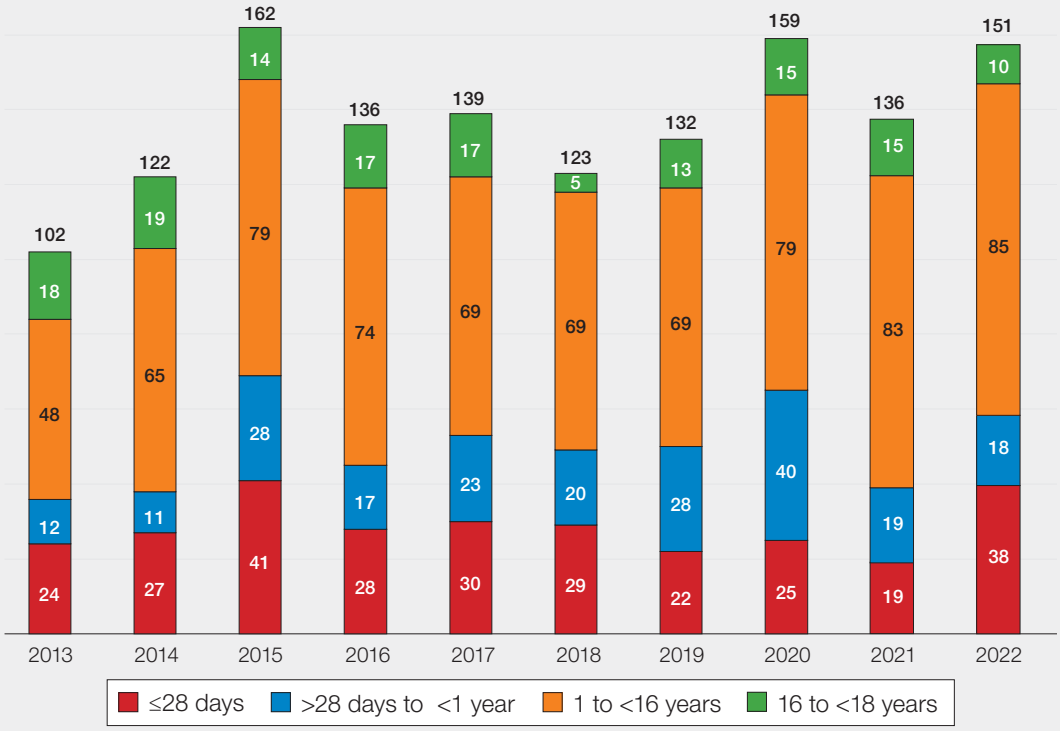
Introduction

Numbers of reports in 2022 are similar to those reported in 2020 and have increased compared to last year (151 vs 136). Paediatric cases were 151/1869 (8.1%) of total cases excluding NM and RBRP and 263/3499 (7.5%) if NM and RBRP are included. More than a third of reports involved neonates <28 days of age and infants <1 year old.

Once again there is over-representation of paediatric cases within the FAHR, ADU and IBCT categories. It is notable that this year in ADU, as well as overtransfusion, delay in transfusion is also over-represented.

The balance between clinical vs laboratory error was similar to last year with 60/101 errors being primarily clinical (59.4%) and 41/101 mainly laboratory (40.6%). Overall, in both adults and children the proportion of total clinical versus laboratory error reports was 918/1278 (71.8%) clinical. In children the two categories with the highest numbers of clinical errors were ADU and HSE. This is likely to reflect the complexities of both prescription and administration in these age groups.

Figure 23.1: Trends in paediatric reports 2013-2022



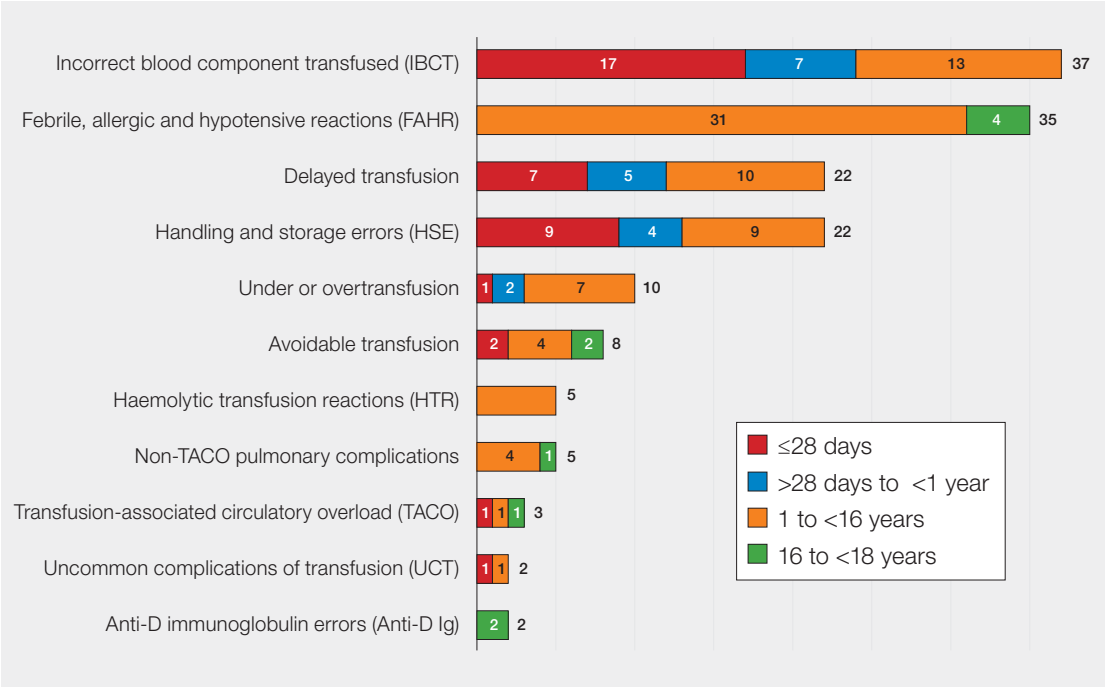


Figure 23.2: Summary of paediatric cases by category and age 2022

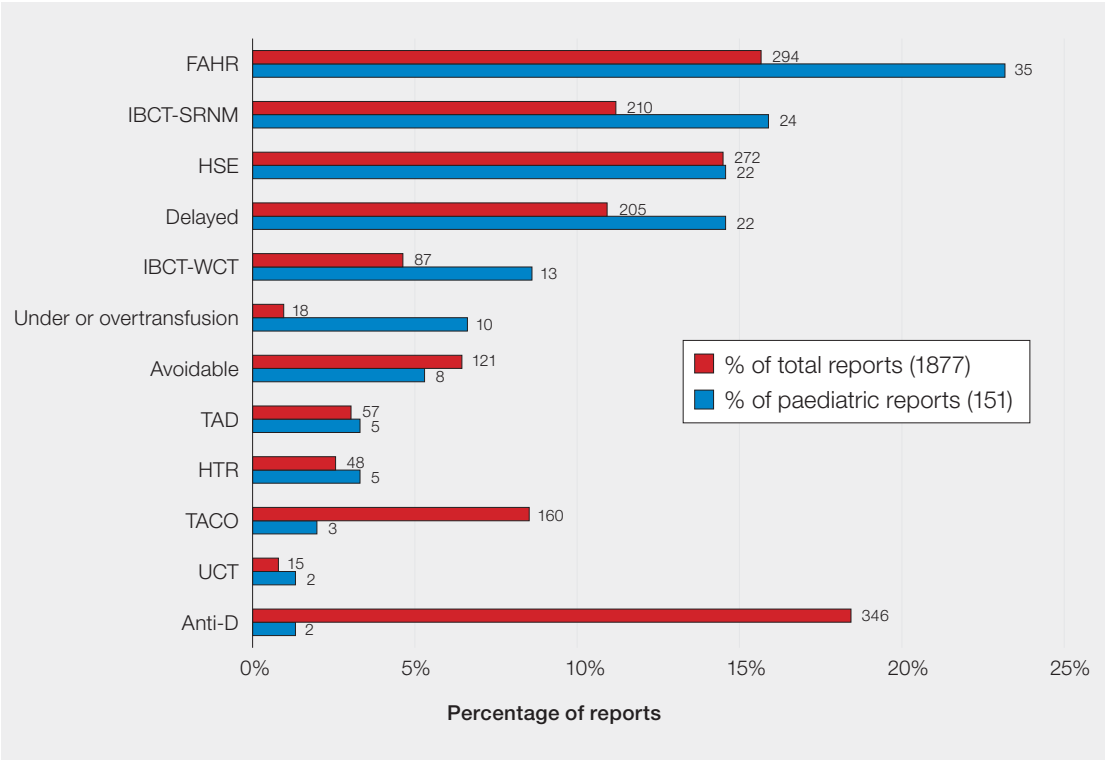


Figure 23.3: Percentages of paediatric and total reports in each category

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

Deaths related to transfusion n=0

There were no cases which met the criteria for transfusion-related deaths.

Major morbidity n=18

There were 18 cases of major morbidity associated with transfusion. Once again, the largest category

was in FAHR with 11 reports. There were also 2 cases of non-TACO pulmonary complications, 1 case of TACO, and a delayed HTR resulting from a new allo anti-Fy^a in a teenager with SCD. One child developed a subdural haematoma following a delay in platelet transfusion. The child had also sustained a head injury and it is therefore not clear to what extent the transfusion delay contributed to the bleed.

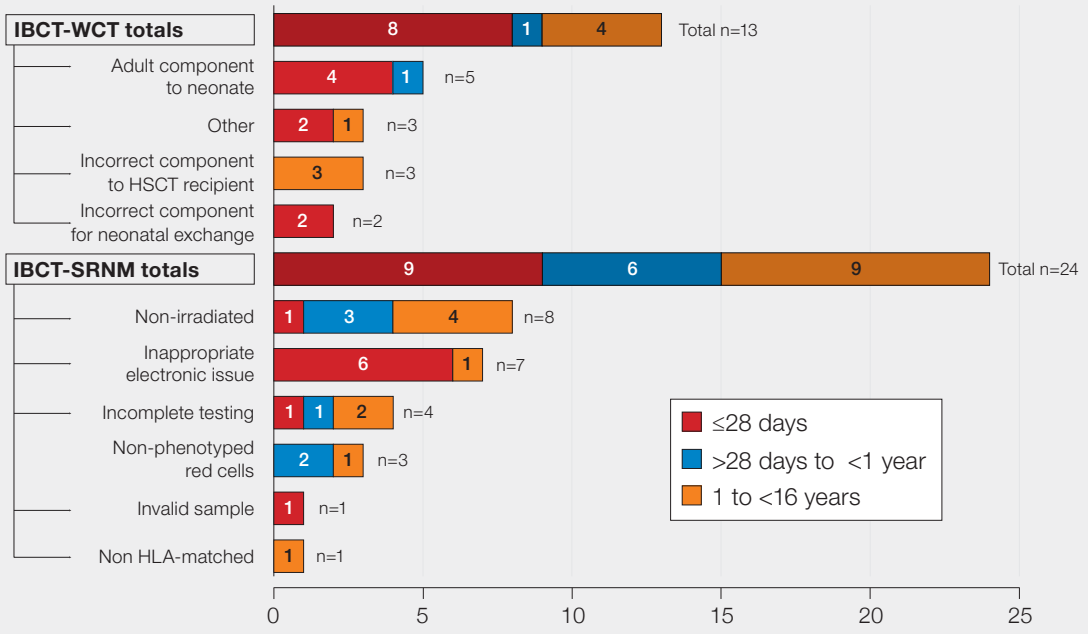
Error-related reports n=101

There was an increase in error-related reports compared to 2021 (101 vs 83). This increase was noticeable in IBCT (in particular IBCT-SRNM), HSE and ADU.

Incorrect blood component transfused (IBCT) n=37

The total number of reports remains similar to previous years. For IBCT-WCT half of reports are classified as clinical and half laboratory. However, for IBCT-SRNM there are significantly more laboratory reports compared to clinical ones. For a more detailed discussion of the IBCT laboratory errors see Chapter 9, Incorrect Blood Component Transfused (IBCT).

Figure 23.4: Breakdown of incorrect blood component transfused reports



IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; HSCT=haemopoietic stem cell transplant; HLA=human leucocyte antigen

IBCT-wrong component transfused (WCT) n=13

IBCT-WCT clinical errors n=7

Clinical teams should understand that there is a difference between adult and neonatal specification components in order to reduce errors in emergency situations.

Adult specification component to infant or neonate n=5

There were 5 cases where adult specification units were given to children under the age of 1 year, 4 of these were neonates. In 3 of these cases the units were red cells given for emergency neonatal resuscitation and in 1 case (described below) an adult platelet unit was used for a neonate.

Case 23.1: Preterm baby received an adult platelet component

A preterm baby who had sepsis and low platelets required an emergency platelet transfusion. An

adult platelet component was incorrectly collected from the transfusion laboratory. The neonatal intensive care unit team noted that the unit was much larger than usual and did not have the standard compatibility label. As it was the same blood group as the patient it was decided to transfuse to the baby. Part way through the transfusion the laboratory rang to inform the ward team of the error. Of note the unit was not CMV-negative.

Components which are provided for neonatal and infant use have additional safety requirements in view of the vulnerability of this patient group. It is recommended that these components are used for infants under 1 year of age (BSH New et al. 2016).

Incorrect component to HSCT recipient n=1

The transfusion laboratory was not informed of the transfusion requirements of a child who was post HSCT and as a result a D-positive component was given to a D-negative infant.

Other n=1

The final clinical case involved a maternal crossmatch sample which was labelled with the details of another mother.

IBCT-WCT laboratory errors n=6

There were 6 cases which were due primarily to laboratory errors.

Incorrect component for neonatal exchange transfusion n=2

Two of these cases involved the incorrect component provision for neonatal exchange transfusion. The 1st case involved a baby with haemolytic disease of the newborn secondary to anti-A. The patient received a neonatal large volume transfusion unit instead of a neonatal exchange specification component. The 2nd case involved a baby with a congenital haemolytic anaemia (hereditary pyropoikilocytosis) who was given an exchange transfusion using a non-exchange red cell component following incorrect ordering by the laboratory. On this occasion, a clinical decision was taken to avoid delay by using the non-exchange component provided as the only difference was in haematocrit and anticoagulant.

Incorrect component to HSCT recipient n=2

In 2 cases children whose requirements had changed following allogenic HSCT received the wrong component. The first received a D-positive platelet transfusion instead of D-negative. Fortunately, at this time the child had not engrafted and was still grouping as D-positive. In the 2nd case a teenager received group A rather than group O red cells as the biomedical scientist failed to check the laboratory information management system flag and issued based on the pre-transplant ABO group.

Other n=2

A neonate received group O plasma when only one historical group was present. The other case was a child who had previously reacted to apheresis platelets. The patient subsequently tolerated a pooled unit without any clinical reaction and was accidentally given a further apheresis unit and had a mild reaction.

IBCT-specific requirements not met (SRNM) n=24

IBCT-SRNM clinical errors n=6

Failure to provide irradiated components n=5

Five cases involved failure to provide irradiated components. Two of these were children who had previously received purine analogue (fludarabine). In 2 cases there was failure to provide irradiated components to children around the time of HSCT or harvest.

The final case is described below and was a failure to communicate a diagnosis of DiGeorge syndrome by the clinical team.

Case 23.2: Failure to provide irradiated blood component for a potentially immunodeficient infant with DiGeorge syndrome

Clinicians failed to communicate the diagnosis of DiGeorge syndrome to the laboratory for a child who was a few months of age, and they did not receive irradiated red cells. Of note the transfusion was urgent due to haematemesis. The child had not previously been known to the hospital and no assessment of immune function was recorded.

Learning points

- The 2020 BSH irradiation guidelines provide guidance on appropriate assessment of immune function in patients with known or suspected DiGeorge syndrome to rationalise the requirement for irradiated components (BSH Foukaneli et al. 2020)
- For children less than 2 years old and where there is time for immunological assessment prior to transfusion, if the T-lymphocyte count is >400cells/microlitre of which 30% are naïve T cells, there is no need for irradiated components. In the absence of assessment demonstrating adequate immunity, they should receive irradiated components
- For children over the age of 2 without any significant history of infections or history consistent with severe T-lymphocyte associated immunodeficiency irradiated components are not required

Failure to provide phenotyped component n=1

The transfusion laboratory was not aware of the thalassaemia diagnosis for a patient who subsequently made two allo antibodies (anti-c and anti-E) and had therefore not been receiving phenotyped, antigen-negative units.

IBCT-SRNM laboratory errors n=18

Inappropriate electronic issue (EI) n=7

In 4 cases, EI was used for neonates inappropriately. One case was a post liver transplant patient (of note this child also should have received irradiated blood components). One infant had inappropriate EI as there was maternal anti-E. This child should have received crossmatched antigen-negative red cells.

Failure to provide irradiated components n=3

There were 3 cases with a failure to provide irradiated components mainly due to laboratory errors. These were a child pre HSCT, a child with potential immunodeficiency and an infant who had received a previous intrauterine transfusion.

Incomplete testing n=4

There were 3 cases of incomplete testing due to missing maternal antibody checks and 1 case of a missing authorisation step.

Failure to provide phenotyped component n=2

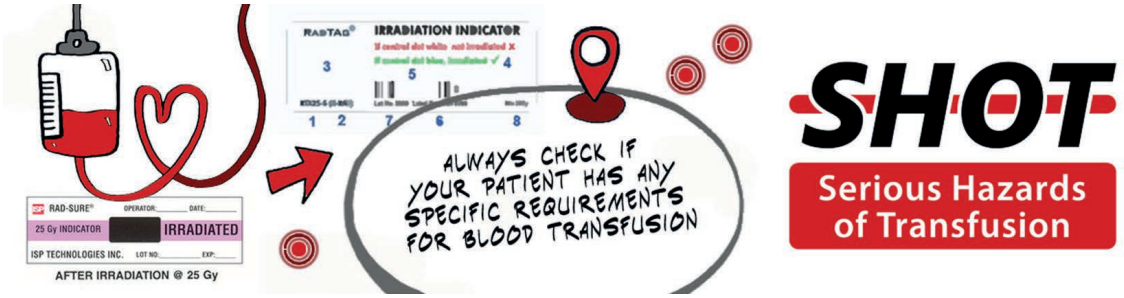
One child with SCD and 1 neonate with a known maternal anti-M did not receive phenotyped/antigen-negative red cells.

Invalid sample n=1

One child had red cells issued and the group and screen sample was more than 7 days old.

Failure to provide HLA matched component n=1

One child accidentally received non-HLA matched platelets.



Avoidable, delayed, under or overtransfusion (ADU) n=40

Avoidable transfusions n=8

The classification of avoidable cases follows that of the main ADU chapter (Chapter 11b, Avoidable Transfusion), and the majority fell within the category of a decision made upon the basis of inaccurate results. Of these, 6 cases were transfused following either an old result (n=3) or an inaccurate result such as platelet clumping (n=3). These cases highlight the importance of looking at the trend in a patient's results and asking for a repeat sample if results are unexpected or inconsistent with the clinical status.

The other 2 cases were both examples of flawed decision-making. The first was an example of treating a number without looking at the clinical status of the patient and is summarised below.

Case 23.3: Management of abnormal results following exchange transfusion

A term neonate received an exchange transfusion for hyperbilirubinemia. Following the procedure, the fibrinogen was found to have dropped to 0.8g/L. The neonate was given cryoprecipitate but was well with no bleeding and with no invasive procedure planned.

Learning point

- Transient abnormalities of coagulation and platelet count are common following exchange transfusion. In the absence of bleeding, these do not usually require correction by transfusion and BSH guidance should be followed (BSH New et al. 2016, 2020)

Another case was again a flawed decision to transfuse, with two units of red cells for iron deficiency given to a teenager without checking the full blood count. The pre-transfusion Hb was 60g/L and the second red cell unit could have been replaced by iron therapy.

There was a further case reported in which a second red cell unit could have been avoided. As this case involved delay in provision of the blood component, it is included in the delay section.

Delayed transfusions n=22

Delay to transfusion has again been prominent for paediatric recipients.

In 3 cases the delays were around the management of major haemorrhage; 2 of these were due to failure to activate the MHP by switchboard and 1 was a delay in obtaining the red cells from the emergency refrigerator.

Further discussion on MHP can be found in Chapter 11a, Delayed Transfusions, and the supplementary material for that chapter (https://www.shotuk.org/report-summary-and-supplement-2022/). One of the cases involving MHP is detailed below.

Case 23.4: Failure to activate MHP

A teenage patient was admitted with major bleeding. There was a delay in provision of FFP due to the switchboard team activating two trauma calls rather than activating the MHP call. This meant that a porter was not sent to collect the blood components.

Learning points

- It is vital that all staff involved in the MHP process are aware of the actions required
- MHP practice/simulation is important to ensure that potential problems are identified and rectified

Communication was a common theme in cases with transfusion delays. Ten cases involved problems with communication within teams and between clinical and laboratory areas.

There were 6 laboratory delays, 2 of which were due to broken refrigerators which was not communicated to clinical staff. There was a delay in provision of FFP for a child as the thawing devices were all in use for other patients at the time.

There were multiple factors involved in the delay of provision of red cells to a child with iron deficiency and this is discussed below.

Case 23.5: Management of iron deficiency

A teenager presented with symptomatic iron deficiency anaemia with Hb 65g/L. There was a delay in obtaining red cells due to problems with sample labelling, which resulted in the need for repeat samples and failure to request the red cells. This caused many hours of delay before the first unit was commenced.

Of note two red cell units were requested for this patient, the second unit could have been replaced with iron.

Learning point

- Asymptomatic children with haematinic deficiency anaemia can be safely managed with appropriate supplementation avoiding the need for transfusion. Children without significant co-morbidities and chronic anaemia can often tolerate a very low Hb without issues

Another case involved a delay in platelet provision for a child due to a request for apheresis platelets. It is important to note that following the SaBTO recommendation in 2019 either pooled or apheresis platelets may be used for children (SaBTO 2019).

Case 23.6: Delay to provision of platelets

There was a delay in provision of platelets to a child with an acute lymphoblastic leukaemia. This delay was due to communication issues around when the unit was required. The prescriber had specified that apheresis platelets should be provided.

Learning point

- For children >1 year of age either standard apheresis or pooled platelets may be used (BSH New et al. 2020)

The final case also involved confusion in the different components available for children.

Case 23.7: Delay in provision of red cells for a child with SCD due to incorrect exchange unit ordered

A young child with SCD required a red cell exchange. A neonatal exchange unit was erroneously requested for the child. This resulted in a delay in provision of the red cells.

Clinical and laboratory staff must be aware of the different transfusion component requirements based on age and indication. Components for red cell exchange transfusions differs according to age group. This case is counted in the numbers for ADU but could also have been included in IBCT-WCT as the child did receive neonatal specification units.

SHOT
Serious Hazards of Transfusion

Overtransfusion n=8

There were 8 cases of overtransfusion (age range 18 days to 5 years). Five of the 8 overtransfusion reports were due to errors in administration and 3 were due to prescribing errors. One had a haemoglobin disorder and received excessive red cells due to miscommunication.

One administration error involved cell salvage in a child undergoing elective cardiac surgery and is described below. The blood component was transfused at the incorrect rate in 3 cases with administration errors and were due to staff misreading the prescription. The final case was due to a pump programming error.

Case 23.8: Error with infusion line clamps resulted in overtransfusion following cell salvage

During transfer from theatres to the paediatric intensive care unit the clamps on the infusion line were left open which resulted in an overtransfusion and at too high a rate. The child required venesection/ dilutional exchange to reduce the Hb from 173g/L to 148g/L over the next 12 hours.

Of the 3 prescription errors, 1 involved prescribing 40mL/kg of platelets for an infant. This child subsequently required furosemide for pulmonary symptoms. One involved the prescription of a full unit of platelets for a child and the final report was of an over prescription of red cells and is described below.

Case 23.9: Overtransfusion due to prescription of incorrect volume

One unit of red cells was prescribed for a child with neuroblastoma. The increased volume compared to usual was noticed by the parent. The reporter commented that a full red cell unit had been prescribed rather than 15mL/kg. The child had received 290mL (25mL/kg).

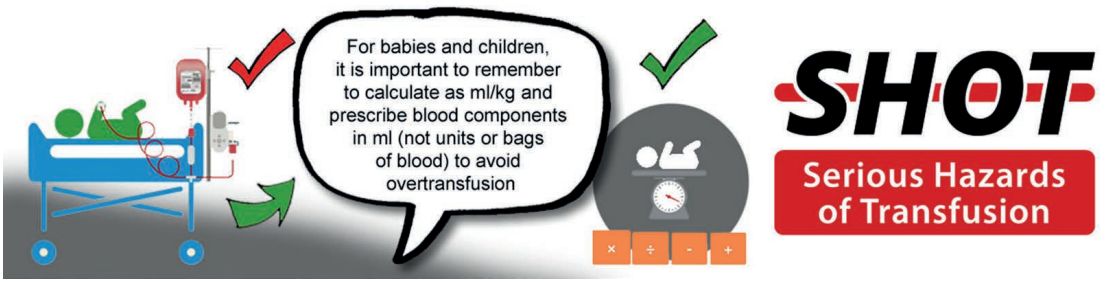
Of note 15mL/kg is a relatively high volume for a top-up transfusion in a non-bleeding child. It would be predicted to raise the post-transfusion haemoglobin by approximately 40g/L. In contrast, transfusion of a single unit to an adult is approximately 4mL/kg transfusion.

Learning points

- Volume of red cells to be transfused to children is best determined by utilising the paediatric transfusion formula. BSH guidelines (New et al. 2016) recommend aiming for a Hb 20g/L above transfusion threshold for non-bleeding patients and those without chronic anaemia (and maximum 1 red cell unit as for adults). The Hb rise expected if this formula is used is equivalent to approximately 8mL/kg transfusion
- The formula for estimating the volume of red cells required for transfusion is included here:

$$\text{Volume required (mL)} = \frac{(\text{Target/desired Hb (g/L)} - \text{current Hb (g/L)}) \times \text{weight (kg)} \times 4}{10}$$

- To reduce errors and prevent overtransfusions, clinicians should double check that the calculated final volume is not >20mL/kg for top-up transfusions



Undertransfusion n=2

There was 1 case where a severely thrombocytopenic child did not receive a platelet transfusion at the time of a nasogastric tube placement because a count of $16x10^9$/L was misheard as 60; the cut off for transfusion pre-procedure was a count of $50x10^9$/L. They were transfused later in response to bleeding.

The 2nd case was a major haemorrhage in a large infant with sepsis and bleeding. Standard adult components had been requested but neonatal components (platelets and FFP) were provided which were significantly less than the volume required for the child.

Cell salvage (CS) n=0

In 1 case, errors with cell salvage resulted in significant overtransfusion in the patient and has been discussed in the overtransfusion section.

Handling and storage errors (HSE) n=22

Clinical errors contributed to 20 HSE errors.

In 12 of these there were issues around the time to transfuse which were related to programming of pumps. The case below illustrates the complexities particularly in the neonatal age group. One case resulted in overtransfusion but as it did not result in patient harm, it is included in the HSE figures. There was 1 case of a component being administered with incompatible fluids.

Case 23.10: Infusion pump programming error in a neonate

A preterm baby received red cell transfusion at only 1.4mL/hour instead of 5mL/hour for the first 2.5 hours of a transfusion. The member of staff had not followed the unit policy of having a second check for pump programming.

Learning points

- Neonatal transfusion set up is complex and infusion pump programming errors are a common theme in paediatric SHOT reports
- The SHOT paediatric video discusses some of these issues (see 'Recommended resources')

In 6 clinical cases there were errors in the cold chain for example blood components being transfused after being out of the refrigerator for too long.

Of the 2 laboratory errors, 1 involved failure to quarantine a unit after a reactive screen was noted by the Blood Service. In the other case a loaned platelet incubator had not been subjected to usual change control and was subsequently found to have been out of temperature range.

Anti-D immunoglobulin (Ig) n=2

An older teenager who was carrying a D-negative fetus was erroneously given anti-D Ig and in the other case a teenager was administered anti-D Ig late.

Transfusion reactions n=50

Febrile, allergic, and hypotensive reactions (FAHR) n=35

FAHR reactions in children are largely due to platelet components similar to previous years. Most reports (19/24) related to apheresis units with only 5 cases that involved pooled platelets. There were no reactions reported in children less than 1 year of age.

Just under half, 14/35 (40.0%) of the overall reactions were allergic. Notably, 9/36 (25.0%) of all anaphylactic reactions reported to SHOT were in the paediatric age group (see Chapter 16, Febrile, Allergic and Hypotensive Reactions (FAHR)).

The use of antihistamine and hydrocortisone together is only required for moderate or severe allergic type reaction. For mild allergic reactions antihistamine only can be used. There is no role for either in the management of febrile only reactions (see 'Recommended resources').

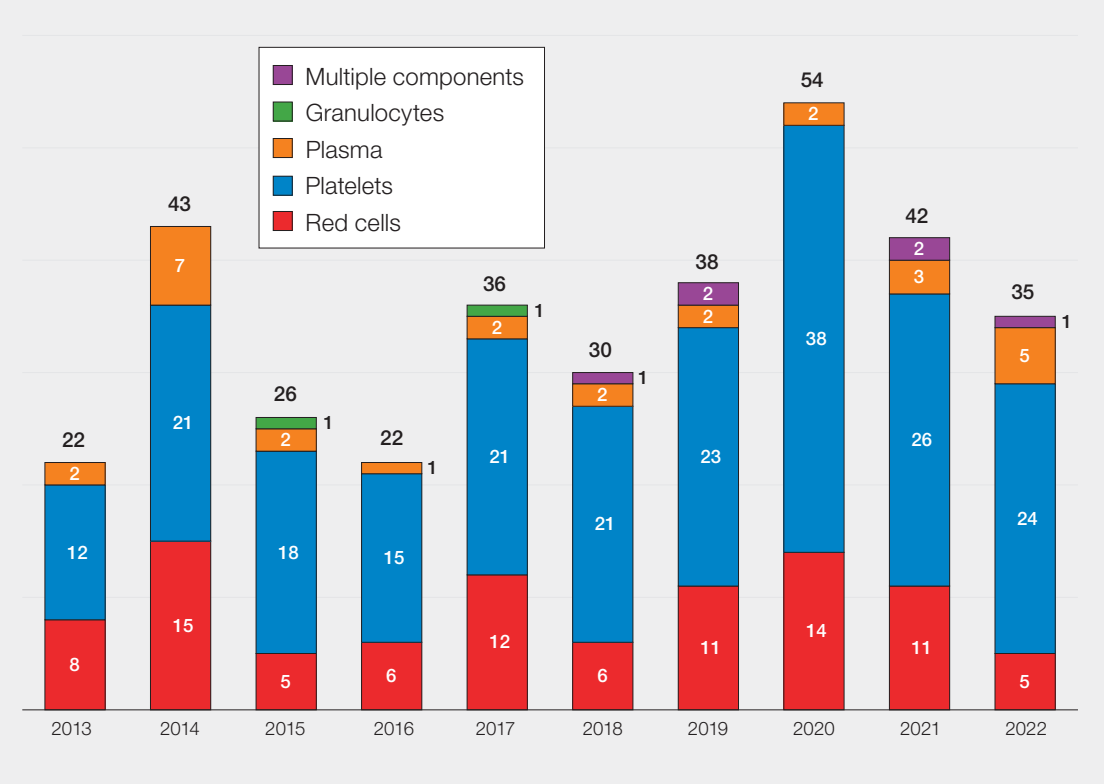


Figure 23.5: Summary of FAHR reports by component type from 2013 to 2022

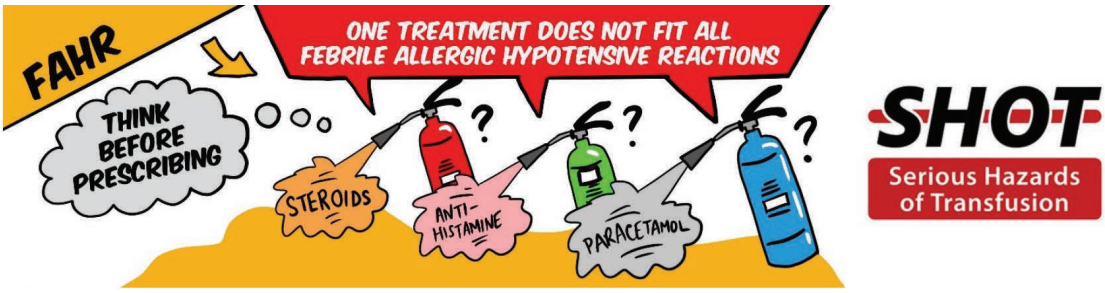
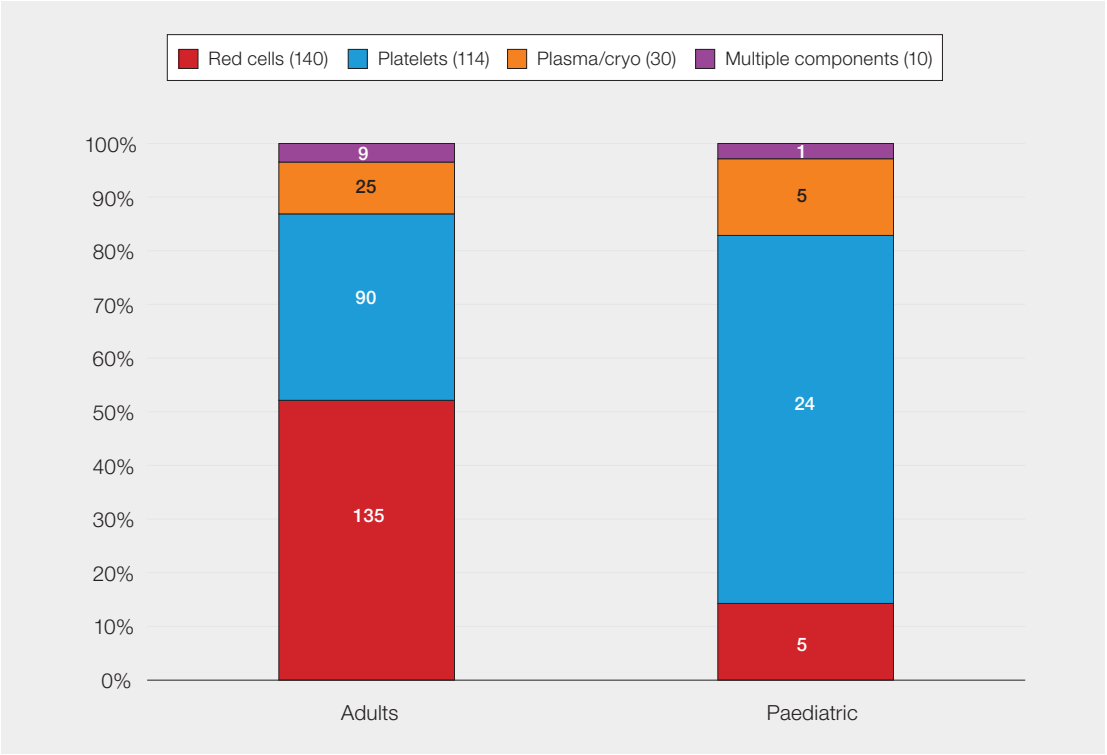
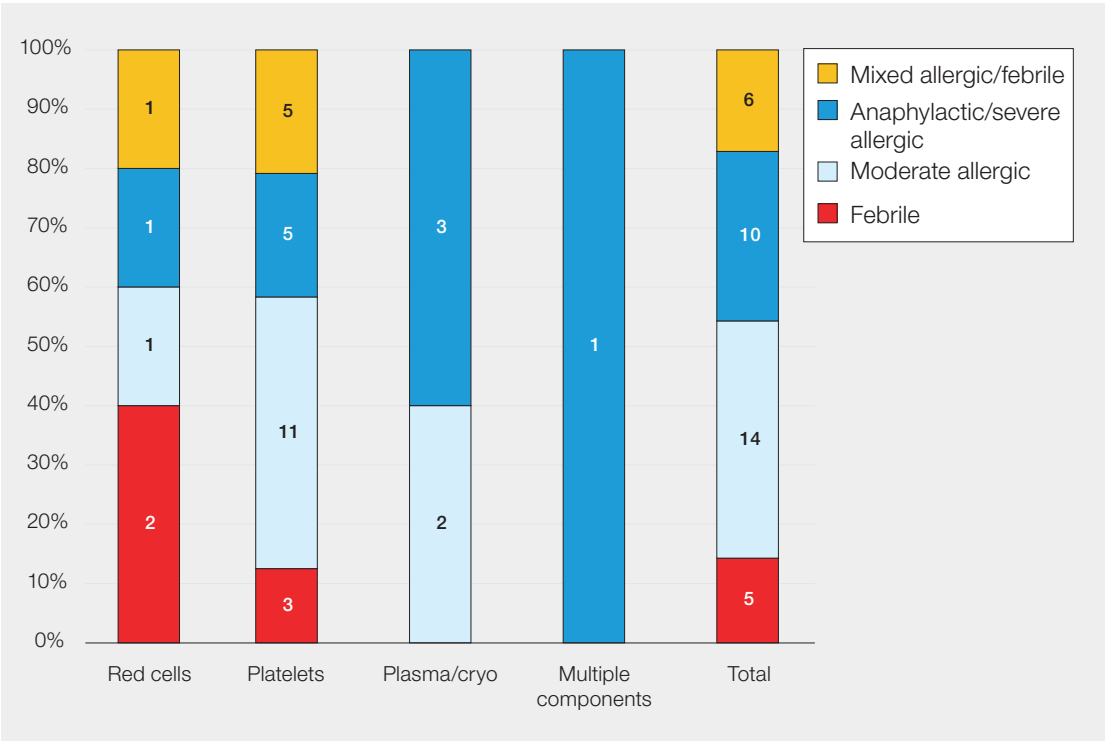


Figure 23.6: Paediatric febrile, allergic, and hypotensive reaction (FAHR) reports

a. Comparison of proportions of adult and paediatric FAHR related to different components



b. Percentages of reaction types of each component for paediatric reports



Haemolytic transfusion reactions (HTR) n=5

Of the 5 HTR cases, 4 involved patients with a diagnosis of SCD.

Two of the cases in young children with SCD involved hyperhaemolysis. Although in 1 of these cases a pan-reactive IgG autoantibody was also detected (auto anti-e).

The 3rd child with SCD developed a delayed HTR 10 days following an exchange transfusion. This patient was found to have developed an anti-S and anti-C and they had received an antigen-positive unit. The 4th case also involved the development of a new allo anti-Fy^{a} in a child with SCD. This patient had previously developed an allo anti-s and anti-N.

The final case involved a young child with hereditary spherocytosis who had previously been transfused 3 years ago. They developed a delayed HTR and an anti-Jk^{a} was subsequently found. This antibody was not detected on the initial antibody screen as the antibody titre had likely fallen below the limit of detection.

Pulmonary complications of transfusion in neonates and children

Diagnosis and classification of pulmonary complications in neonates and children remains difficult and still under-reported.

Transfusion-associated circulatory overload (TACO) n=3

There were 3 cases which met the criteria for classification as TACO. One of these is discussed in detail below.

Case 23.11: TACO following transfusion for severe anaemia in a neonate

A term neonate was born with a Hb of 44g/L secondary to severe fetomaternal haemorrhage. The neonate received an initial 18mL (5mL/kg) red cell transfusion via 'slow bolus' followed by 18mL/hr for 3 hours. Between 2-6 hours following transfusion the neonate developed increasing respiratory distress requiring intubation and ventilation. Furosemide was given with improvement in clinical status.

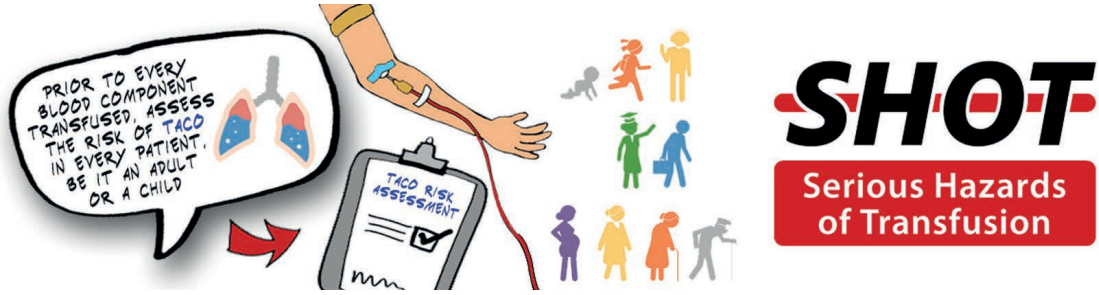
This case highlights that as for adult cases, severe anaemia can be a risk factor for TACO in neonates and children.

Of the other 2 cases, 1 involved a child with severe liver disease who developed pulmonary oedema after a red cell transfusion. This child had additional risk factors including low albumin, cardiac failure, renal impairment, recent pulmonary oedema and fluid overload. The final case was in a teenager who received massive transfusion of blood components following a major haemorrhage secondary to trauma/ penetrating injury.

Non-TACO pulmonary complications n=5

There were 4 cases of TAD. Two were following red cell transfusions, 1 following platelet transfusion, and 1 needed supplemental oxygen within 6 hours of granulocyte infusion.

One case was considered to meet the revised criteria for TRALI type II. This was a young child with neuroblastoma on chemotherapy.



Transfusion-transmitted infection (TTI) n=0

There were no cases of TTI in 2022.

Uncategorised complications of transfusion (UCT) n=2

There was 1 case of a neonate with Enterobacter sepsis who had an acute deterioration following a red cell transfusion. Transfused blood showed no growth of any pathogens. Enterobacter sepsis and prematurity were identified as causes of death on the death certificate. This was originally reported as a possible case of TANEC but had none of the clinical or radiological features of NEC.

The second case was an unusual report of a possible reaction during transfusion.

Case 23.12: Abdominal pain during transfusion

A young child developed abdominal pain part way through a transfusion and was subdued and lethargic. No other symptoms were reported, and the pain had settled following defaecation and 30 minutes after the end of the transfusion the child was back to normal. The team decided to give both chlorpheniramine and hydrocortisone prior to subsequent transfusions.

The relationship of the clinical features to the transfusion in this case is uncertain. The use of antihistamine and hydrocortisone prior to transfusions is discussed in the FAHR section above.

Paediatric error reports with no harm n=112

The paediatric figures for no harm/near miss events are summarised below but are not discussed in detail (see individual chapters for details).

RBRP n=20
Near miss cases n=40
Near miss-WBIT n=52

Correct patient identification is vital and these cases are discussed in Chapter 12a, Wrong Blood in Tube (WBIT), with patients in the maternity and neonatal setting being particularly at risk of these errors.

Conclusion

Key themes emerging from the reports submitted to SHOT and actions needed to improve transfusion safety include:

- 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)
- Gaps in staff knowledge regarding significance of test results and interpretation should be addressed

including actions to be taken in case of unexpected results, the significance of abnormal coagulation in children especially post exchange transfusion and when to seek specialist advice

- Effective, timely and clear communication between clinical teams and transfusion laboratories is especially important for children undergoing HSCT and patients with haemoglobinopathies as transfusion requirements can be complex
- Paediatricians and neonatologists should be able to recognise transfusion reactions that can occur in various clinical settings and initiate appropriate management

Recommended resources

SHOT Video: Paediatric SHOT
https://www.shotuk.org/resources/current-resources/videos/

SHOT Bite No. 4: Paediatrics
SHOT Bite No. 8: Massive Haemorrhage Delays
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: Delayed Transfusions in Major Haemorrhage
https://www.shotuk.org/resources/current-resources/videos/

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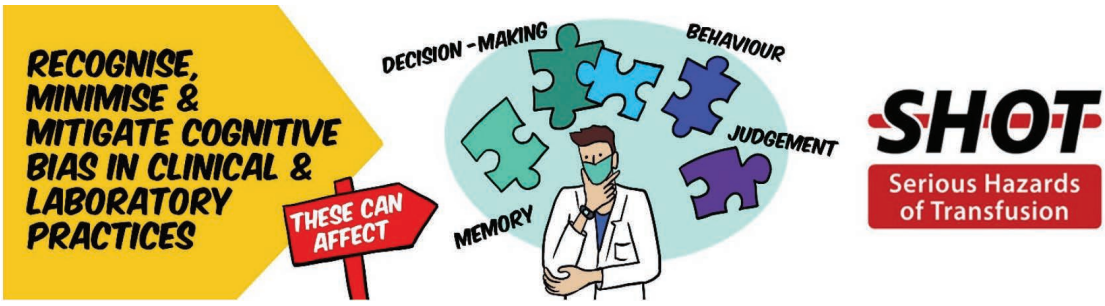


24 Haemoglobin Disorders n=57

Author: Joseph Sharif

Abbreviations used in this chapter

ADU	Avoidable, delayed and under/overtransfusion	**IBCT**	Incorrect blood component transfused
AHTR	Acute haemolytic transfusion reaction	**IT**	Information technology
APPG	All-party parliamentary group	**IVIg**	Intravenous immunoglobulin
BSH	British Society for Haematology	**NHS**	National Health Service
DAT	Direct antiglobulin test	**NHSBT**	NHS Blood & Transplant
DHTR	Delayed haemolytic transfusion reaction	**SCD**	Sickle cell disease
FAHR	Febrile, allergic and hypotensive reaction	**Sp-ICE**	Specialist Services electronic reporting using Sunquest's Integrated Clinical Environment
Hb	Haemoglobin		
HCC	Haemoglobinopathy Coordinating Centre	**SRNM**	Specific requirements not met
HSCT	Haemopoietic stem cell transplant	**UK**	United Kingdom
HTR	Haemolytic transfusion reaction	**WCT**	Wrong component transfused

Key SHOT messages

- Alloimmunisation and HTR are a significant risk of transfusion in SCD and may not be appreciated by medical teams
- This year saw the highest number of reports of HTR in SCD accounting for 22/49 (44.9%) of all HTR reported
- Hyperhaemolysis is a unique and potentially fatal complication of transfusion and contributed to major morbidity in 7 patients. All were in patients with SCD

Recommendations

- Haematology teams must be involved in the care of haemoglobinopathy patients presenting to secondary care and provide advice regarding transfusion. Specialist haematology advice should be taken regarding transfusion decisions
- For ad-hoc transfusion decisions it is important to seek transfusion history from the patient, transfusion laboratory and the national database (Sp-ICE or equivalent)
- All haemoglobinopathy patients should have a baseline extended red cell phenotype or genotype prior to transfusion (BSH Trompeter et al. 2020)

Action: Hospital transfusion teams, clinical teams looking after patients with haemoglobin disorders, laboratory management

Introduction

Transfusion in an important aspect of care in both SCD and thalassaemia. The intended benefits of transfusion must be balanced against the potential risks of serious transfusion reactions and adverse events. HTR is a particular problem in SCD; in the last 10 years, 125/454 (27.5%) of all HTR reported to SHOT occurred in patients with SCD (Figure 24.2).

NHS England haemoglobinopathy services support the provision of both specialist and non-specialist haemoglobinopathy services, enabling access to expert advice and management of complex patients (NHS England 2019). This service supports patients within England and the devolved nations each have their own arrangements for care provision. Updated standards and recommendations for clinical care of SCD in children and adults are available which help ensure that every individual with SCD has the best possible healthcare wherever they live in the UK (Sickle Cell Society 2018 and 2019).

There were a total of 57 reports in patients with a haemoglobinopathy diagnosis in 2022 and Figure 24.1 shows cumulative data for adverse transfusion events in patients with haemoglobin disorders from 2010, when SHOT started collating these reports, to 2022.

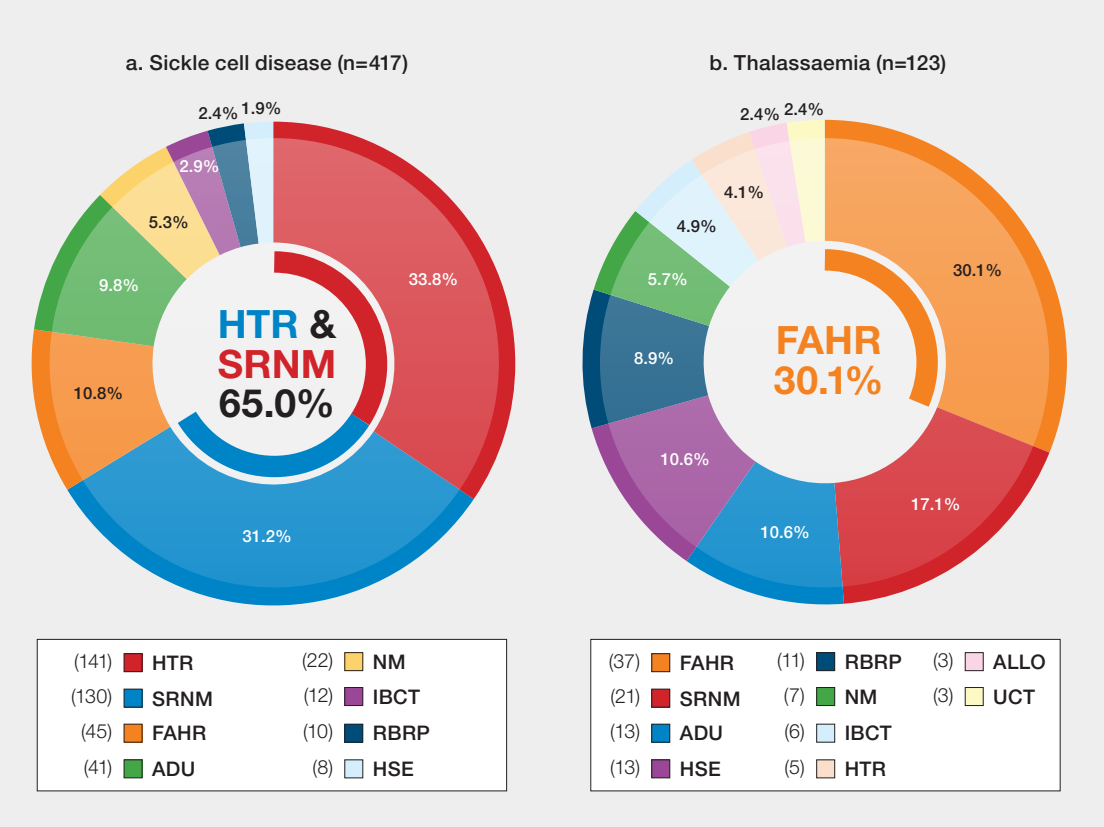


Figure 24.1: Cumulative data for adverse transfusion events in patients with haemoglobin disorders 2010 to 2022

FAHR=febrile, allergic or hypotensive reactions; ADU=avoidable, delayed or under or overtransfusion; IBCT=incorrect blood component transfused; SRNM=specific requirements not met; TACO=transfusion-associated circulatory overload; TAD=transfusion-associated dyspnoea; HTR=haemolytic transfusion reactions; TTI=transfusion-transmitted infection

Categories with 2 or fewer reports are not included in the figures

Deaths related to transfusion n=1

There was 1 death (imputability 2, probable) reported in a female in her 20s with SCD who presented with hyperhaemolysis 1 week following transfusion and developed acute respiratory complications.

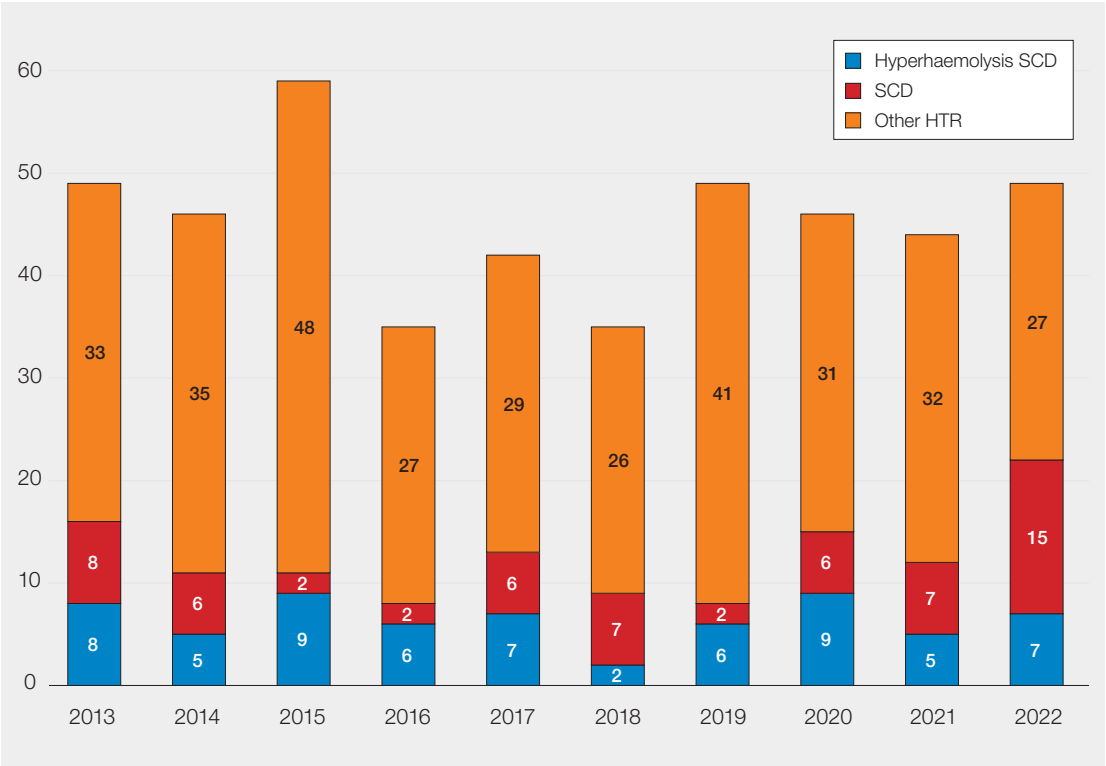
Major morbidity n=14

There were 14 reports associated with major morbidity including 10 HTR, 2 delayed transfusions, 1 FAHR and 1 IBCT-WCT.

Haemolytic transfusion reactions (HTR) n=22

There were 22 reports of HTR, all in patients with a diagnosis of SCD. This included 13 reports of DHTR, 7 hyperhaemolysis and 2 AHTR.

Figure 24.2: A summary of HTR occurring in SCD 2013-2022 out of a total of 454 HTR reports



HTR=haemolytic transfusion reactions; SCD=sickle cell disease

Case 24.1: Hyperhaemolysis treated with eculizumab

A man in his 20s with SCD presented with widespread pain and was generally unwell. This was following an admission at another hospital where he was treated for a sickle cell crisis and COVID-19 infection and received several red cell transfusions. Blood tests demonstrated haemolysis with a Hb nadir of 36g/L. There was an associated fall in reticulocyte count and raised ferritin of >15000ng/mL. Antibody screen and DAT were negative. He was treated for hyperhaemolysis with steroid, IVIg and eculizumab.

Case 24.2: Hyperhaemolysis following elective transfusion for surgery preparation

A middle-aged man with SCD underwent an elective red cell exchange transfusion in preparation for hip surgery. Due to a history of previous DHTR, he received steroids and IVIg prior to transfusion. Despite prophylactic measures, he developed further haemolysis and was treated with steroid, IVIg and eculizumab. No new antibody was reported.

Case 24.3: HTR following transfusion not matched for extended Rh group

A middle-aged female with SCD presented with flu-like symptoms and a Hb of 55g/L. A decision was made for top-up red cell transfusion. The red cell unit selected was not matched for extended Rh phenotype and the patient received C-positive units. The patient developed acute intravascular haemolysis and required intensive care admission. Limitations of IT with incomplete details in the transfusion request combined with potential gaps in staff knowledge contributed to this error.

Febrile, allergic and hypotensive reactions (FAHR) n=5

There were 5 reports of FAHR. Three reports were in patients with thalassaemia and 2 in SCD.

Case 24.4: Post HSCT thalassaemia patient experienced allergic reaction to platelet transfusion

A male patient in his 20s with thalassaemia was admitted to the haematology ward post HSCT and experiencing haematuria. The patient developed bronchospasm and urticaria 15 minutes into a transfusion of irradiated platelets. The transfusion was immediately stopped, and the patient was given antihistamines and hydrocortisone. His symptoms subsided within a few hours, and he fully recovered.

IBCT-specific requirements not met (IBCT-SRNM) n=12

There were 12 cases of IBCT-SRNM.

Case 24.5: An SCD patient with known antibodies presented at a new hospital

A teenage male with SCD and multiple red cell antibodies including anti-U and anti-f presented to a different hospital to which he normally attended, and a decision was made for transfusion. The laboratory failed to register a diagnosis of SCD from the request form. The haematology team also failed to provide the laboratory with a transfusion history. No antibodies were detected in the local laboratory and therefore the patient did not receive the specific requirements for red cell transfusion. There were no reported immediate clinical consequences.

Learning points

- The use of extended phenotype matched units has reduced the risk of alloimmunisation and HTR (BSH Davis et al. 2016)
- Education of clinical and laboratory staff regarding transfusion requirements for this group of patients is essential
- To enhance safety, IT alerts about specific transfusion requirements should be reliable, not easily overridden, displayed correctly and prompt timely actions
- For patients with multiple antibodies or a genotype which puts them at greater risk of developing rare antibodies, it is important that transfusion decisions are carefully considered. These decisions should be discussed with the patient due to the potential clinical consequences including difficulties in obtaining appropriate red cells
- It is important that unnecessary transfusions are avoided, each year the Annual SHOT Report highlights cases of avoidable transfusions. Healthcare professionals prescribing blood transfusion may not always appreciate the potential consequences including the impact on future provision of blood components in this group of patients

IBCT-wrong component transfused (IBCT-WCT) n=2

There was 1 case of ABO-incompatible transfusion in an SCD patient that resulted in major morbidity. This is described in Chapter 9, Incorrect Blood Component Transfused (IBCT) (Case 9.3), and can be found in the supplementary information for this chapter on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).

Case 24.6: Wrong blood component given to a patient with thalassaemia

A man in his 20s with thalassaemia attended for routine transfusion. Whilst the first red cell unit was being transfused it was realised that the blood component being administered was intended for another patient on the unit. The patient was group A and received group O blood. The patient also had a history of red cell alloimmunisation and therefore was at risk of developing subsequent antibodies. No clinical consequences were reported.

Avoidable transfusion, delayed or under/overtransfusion (ADU) n=7

Case 24.7: Delay in top-up transfusion in SCD resulted in clinical deterioration and the need for red cell exchange

A patient in his 20s with SCD was admitted with fever and chest pain. A diagnosis of acute chest syndrome was made and a plan for two units of red cells. The medical on call team later reviewed the patient due to ongoing hypoxia and discussed with the on call haematologist. The following morning the patient had become more unwell at which point it became apparent that the patient had not yet received the transfusion as planned from the previous day. Due to a deterioration in his condition an urgent red cell exchange was arranged.

Learning points

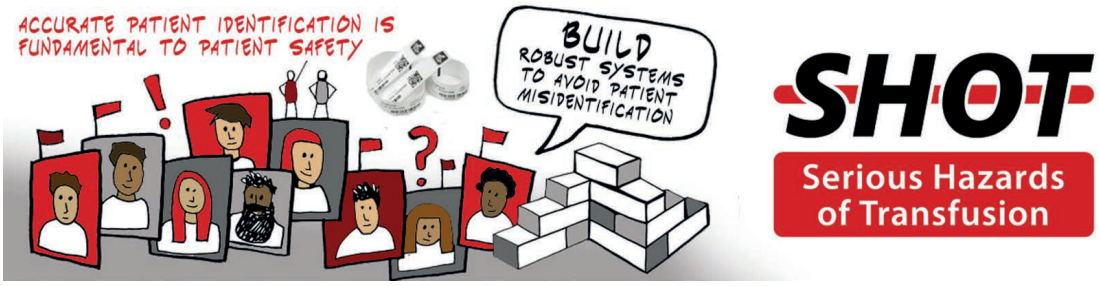
- Acute chest syndrome in SCD can be life-threatening and requires early recognition and close monitoring
- Early intervention with simple or 'top-up' red cell transfusion/s may prevent deterioration and senior decision makers should be involved (BSH Howard et al. 2015)
- Healthcare professionals may not appreciate when a transfusion is urgent and therefore it is vital that this is communicated to the relevant staff to prevent clinical deterioration

Near miss n=2

There were 2 cases of NM.

Case 24.8: Pre-administration transfusion checks prevented a wrong component transfused

Two patients with the same first name and a diagnosis of thalassaemia were sat next to each other in the day unit awaiting routine transfusion. A unit of red cells was taken from the refrigerator for one of the patients and during the pre-administration check, it was realised it was for the other patient and was therefore returned to the refrigerator.



Conclusion

Alloimmunisation and HTR are a significant risk for haemoglobinopathy patients, in particular those with SCD. To minimise this risk, it is important that each transfusion decision is carefully considered, balancing intended benefits with potential risks. A transfusion history should be obtained for all haemoglobinopathy patients requiring transfusion including any prior alloimmunisation and transfusion reactions. Clear communication between clinical and laboratory staff is essential to ensure specific transfusion requirements are provided.

Specialist haemoglobinopathy teams should be involved in the management and advise on transfusion.

The APPG report has highlighted inadequacies in healthcare for sickle cell patients (Sickle Cell Society 2021). SHOT supports the recommendations set out in the report. Education and training for all healthcare professionals is essential to ensure safe transfusion practice, reducing the risk of morbidity and mortality. To support safe transfusion in haemoglobinopathy patients, several new online resources have been developed by NHSBT and SHOT (listed below). These resources are intended for use within HCC and specialist hospital teams to support the development of training programmes for their haemoglobinopathy networks.

A key finding from a recent investigation by the Healthcare Safety Investigation Branch highlighted the lack of a minimum training requirement or nationally agreed content to improve staff knowledge about sickle cell disease or sickle cell crisis. The report recommends that NHS England reviews the existing training and competence requirements within sickle cell care provision and specifies the minimum training requirements and content for staff so that the content can then be delivered by HCC to increase knowledge about sickle cell disease and how to treat patients in sickle cell crisis (HSIB 2023).

Recommended resources

SHOT Bite No. 14: Haemoglobinopathies
SHOT Bite No. 15: Hyperhaemolysis
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: Haemolytic Transfusion Reactions in patients with Haemoglobinopathies
https://www.shotuk.org/resources/current-resources/videos/

Patient Blood Management England Video: Setting up and Performing a Manual Exchange Red Cell Exchange in Sickle Cell Disease (Under 40kg)
https://youtu.be/e2itKcfXQAE

Patient Blood Management England Video: Setting up and Performing a Manual Exchange Red Cell Exchange in Sickle Cell Disease (Over 40kg)
https://youtu.be/5QFiLziDxbc

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SHOT
Serious Hazards of Transfusion

Transfusion Errors in Transplant Cases n=58

25

Authors: Jennifer Davies and Shruthi Narayan

Abbreviations used in this chapter

ABOi	ABO-incompatible	**LIMS**	Laboratory information management system
BMS	Biomedical scientist	**NBTC**	National Blood Transfusion Committee
BSBMTCT	British Society of Blood and Marrow Transplantation and Cellular Therapy	**RCPath**	Royal College of Pathologists
BSH	British Society for Haematology	**SaBTO**	Advisory Committee on the Safety of Blood, Tissues and Organs
CMV	Cytomegalovirus	**SCRIPT**	SHOT Collaborative Reviewing and reforming IT Processes in Transfusion
FY1	Foundation year 1	**SOT**	Solid organ transplant
HEV	Hepatitis E virus	**SRNM**	Specific requirements not met
HSCT	Haemopoietic stem cell transplant	**TA-GvHD**	Transfusion-associated graft-versus-host disease
IBCT	Incorrect blood component transfused	**WCT**	Wrong component transfused
IT	Information technology		
JPAC	Joint UKBTS Professional Advisory Committee		

Key SHOT messages

- Timely, effective, and reliable communication with easy access to transplant protocols is vital to ensure safe transfusions in transplant recipients
- Preventable errors due to lack of staff knowledge and poor awareness of transfusion requirements in these patients continue to be reported

Recommendations

- Clinical teams should ensure the transfusion laboratory in both the transplant centre and any other organisations with whom the patient care is shared, either short-term or long-term, are fully informed about the transplant timetable, need for specific transfusion requirements, and ABO/D groups of the patient and donor
- National guidelines are needed that are suitable for both transplantation and transfusion professionals that cover the processes necessary for managing transfusions to transplant patients
- Patient involvement in all decision-making is encouraged and should include information about their specific transfusion requirements
- Laboratory staff should ensure the LIMS is updated in a timely manner, and that all laboratory steps are properly checked to detect errors before they result in wrong transfusions

Action: All clinical and laboratory transfusion staff

Introduction

This chapter covers HSCT- and SOT-related transfusion errors reported to SHOT in 2022.

Patients receiving such transplants present unique challenges in provision of blood component support, especially when donor and recipient are ABO or D non-identical.

For HSCT recipients, decisions on which ABO/D group of components for transfusion have to take into account the ABO and D mismatches and the transition period until the stem cells have engrafted and the patient converts fully to their new group. Approximately 40-50% of HSCT are ABOi (Worel 2008). Incompatibility may be major, where antibodies in the recipient's plasma have the potential to react with donor red cells (e.g., recipient group O and donor group A), or minor, where antibodies in the donor plasma react with recipient red cells (e.g., recipient group A, donor group O). Bidirectional incompatibility includes both major and minor mismatches. Antibodies in both the recipient and donor plasma can react with donor and recipient red cells respectively, e.g., recipient group B and donor group A.

Major and minor incompatibility each occur in approximately 20-25% of transplants, and bidirectional incompatibility in 5% (Worel 2008). The ABO and D group transfusion requirements of these patients change over time with the clinical course of the transplant. Poor communication between clinicians and the laboratory, with gaps in staff knowledge may result in serious transfusion errors.

The BSH has published guidance on the irradiation requirements for cellular components in patients at risk of developing TA-GvHD. This includes patients undergoing allogeneic and autologous transplant (and donors to avoid transfusion of viable leucocytes) (Foukaneli et al. 2020). In 2016 SaBTO recommended that transplant patients receive HEV-screened cellular blood components (SaBTO 2016) and universal screening was implemented in April 2017 in the UK (Harvala et al. 2019).

The 'Safe transfusions in haemopoietic stem cell transplant recipients' document has been developed by SHOT in collaboration with RCPath, NBTC and BSBMTCT. This supports safe transfusion decisions in HSCT recipients (see 'Recommended resources'). A national guidance document for transfusions in solid organ transplant recipients is lacking.

Summary of cases from 2022

A total of 58 cases were reported in 2022 which involved HSCT (n=50) or SOT (n=8) recipients. Figure 25.1 shows the distribution of all the cases reported. There were no deaths related to transfusion errors.

The largest category of cases, 28/58 (48.27%) were IBCT-SRNM. The majority of these (22/28) were failure to provide irradiated components (1 of which was also a failure to provide CMV-negative), and inappropriate use of electronic issue accounted for the remaining 6/28 cases.

Of the 22 cases of IBCT-WCT, 14 cases involved transfusion of components with the wrong ABO group to the recipient and 6 cases were instances where D-positive components were transfused rather than D-negative.

In the NM category, the pre-transfusion checklist identified the error in 6/8 cases highlighting the importance of safety checks to ensure safe transfusions.

Information about incident investigation was available in 54/58 cases and in 44 cases, a formal incident investigation to evaluate the causal and contributory factors was reported to have been carried out.

Reporters who recorded the single thing that could be changed that would make the incident less likely to recur (n=30) within all categories, mainly indicated improvements to electronic systems (12/30) and communication pathways for shared care patients (10/30).

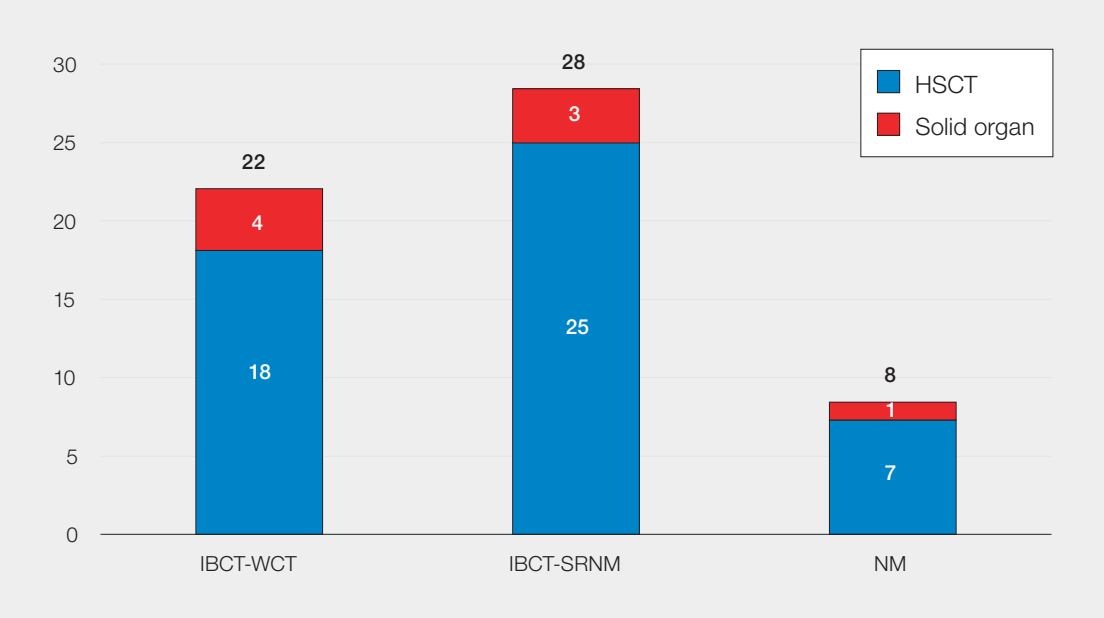

Figure 25.1: Total cases of IBCT-WCT, IBCT-SRNM and NM transfusion errors in transplant recipients reported to SHOT in 2022 (n=58)

HSCT=haemopoietic stem cell transplant; IBCT-WCT=incorrect blood component transfused-wrong component transfused; IBCT-SRNM=IBCT-specific requirements not met; NM=near miss

It is interesting to note that in 52/58 cases (89.65%), transfusion IT was implicated. Figure 25.3 shows the distribution of the IT issues in these cases. There was no information on the LIMS in 28 cases. The transfusion laboratory was not aware of the transfusion requirements in 14 of these cases and the LIMS was not updated appropriately even after the laboratory was notified in the other 14 cases.

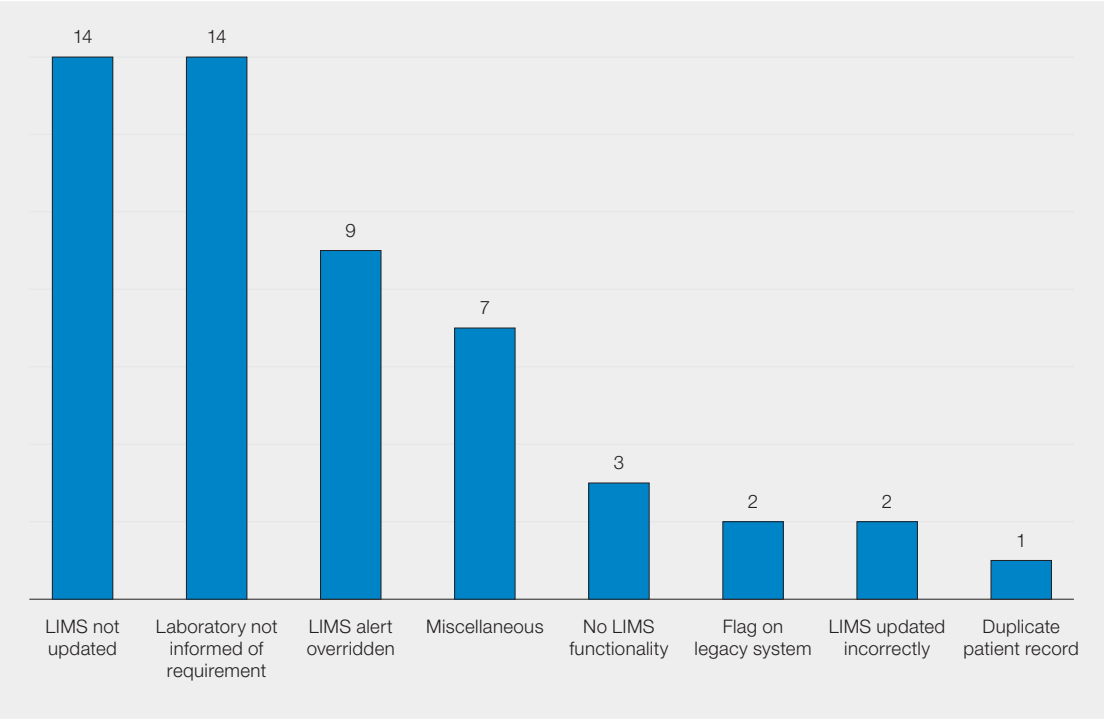

Figure 25.2: Distribution of IT issues in transplant errors (n=52)

LIMS=laboratory information management system

The miscellaneous category included issues with staff using a combined LIMS and missing a flag, complex mechanisms for adding flags, LIMS configurations that remove flags in certain scenarios and a BMS using a support staff log-in that did not display the flag.

Errors in the clinical setting accounted for 32/58 (55.2%) and laboratory errors for 26/58 (44.8%). In the IBCT-SRNM category errors occurred mostly in the clinical setting, 19/28 (67.9%), mainly failure to communicate requirements to the laboratory, compared to 9/28 (32.1%) in the laboratory. In contrast, most errors in the IBCT-WCT category occurred in the laboratory, 19/22 (86.4%), mainly errors with selection of inappropriate components, compared to 3/22 (13.6%) in the clinical setting.

Case 25.1: Incorrect ABO group transfused after incorrect advice

A shared-care patient received a HSCT at hospital 1. A letter confirming the transplant was uploaded to the clinical computer system at hospital 2. Blood components were requested for the patient post transplant approximately 3 weeks later and on two separate occasions. In both instances the request form stated, 'post transplant' and the BMS on duty sought advice from the supervisory BMS regarding component selection. The supervisory BMS did not investigate the type of transplant the patient had received and gave the incorrect advice to the BMS. The patient received blood components which was the same group as his pre-transplant group (B D-positive). They should have received group O D-positive blood components.

Selection of appropriate components for transplant patients is complex and advice is often required from staff working at supervisory level. Staff should ensure that they fully investigate cases where the patient has been noted to have received an HSCT before offering advice and they should access the transplant protocol and available guidance document to inform advice given.

Shared care

Gaps in communication between hospitals are a recurring theme in several reports submitted to SHOT. For example, when a patient is transplanted at a transplant centre, the information about the transplant, changing ABO/D group and specific requirements may not be communicated to the local hospital or its transfusion laboratory. The transplant may have taken place several months or years before, but patients will continue to need specific transfusion requirements.

Case 25.2: SRNM due to poor communication between hospitals

A unit of non-irradiated red cells was issued to a patient who required irradiated components. The error was detected when the clinical area returned the second unit, after noticing that it was not irradiated. The patient had two hospital numbers. The requirement for irradiated components was added to record 1, at which time there was only one hospital number. The laboratory received the first sample with the number for record 2. There was no mention of the irradiated requirement on the request form. The BMS failed to check for duplicate hospital numbers in deviation from local policy. The clinical area failed to notice that the requirements were not met prior to transfusion of the first unit.

Duplicate patient records on the LIMS can result in critical information being missed. Laboratories should have processes for identification and merging of duplicate records.

Commentary

Most transfusion-related errors in transplant patients are either transfusion of ABO-mismatched blood components, or failure to administer irradiated components putting the patient at risk of TA-GvHD. Poor

communication of vital information between teams involved in the patient's care (clinical and laboratory) and failure to heed/update the LIMS in the laboratory are the most common errors noted. These are the same errors noted in many other areas of transfusion practice and need to be addressed effectively. Errors in clinical communication are further compounded by the shared care of patients between transplant centres and the patient's local hospital, which necessitates the need for effective transfer of information between centres.

Embedded in many transplant protocols is the requirement to inform the laboratory staff of the patient's impending transplant and associated change in transfusion requirements particularly ABO and D group changes. However, it is apparent that the transfusion laboratory is not always being informed or following updated information, there are failures to adequately update the LIMS. More robust procedures are required to ensure this information is appropriately communicated to the laboratory and updated in the patient's electronic history. This is echoed by JPAC, which advises a clear post-transplant transfusion policy should be developed for all transplant patients and circulated to clinical and laboratory teams involved in their care. JPAC acknowledges previous Annual SHOT Reports which show component selection errors are common for patients who have changed blood group following HSCT (JPAC 2020). A checklist to ensure clear communication between clinical and laboratory teams in transplant patients can be found in the 2019 Annual SHOT Report (Narayan et al. 2020).

There is also confusion in some areas about transfusion in ABO-mismatched HSCT. This is likely potentiated by the complex transfusion schedule that exists for ABO-mismatched transplants in relation to changes in the ABO and D group (Schrezenmeier et al. 2019). SHOT data show that transfusion of the wrong ABO or D group in ABO-mismatched transplants continues to be a problem. Lack of support in LIMS for appropriate selection of components has been highlighted by Annual SHOT Reports and a survey by the SHOT SCRIPT group (see 'Recommended resources'). Users are often dependent on alerts or notes in the LIMS to make decisions about component selection rather than functionality in the LIMS that confirms the correct selection. LIMS functionality in terms of assigning blood groups to patients where testing results are indeterminate has also been implicated in flawed decision-making. Although improved functionality in the LIMS could reduce the risk of error, this does not negate the need for staff knowledge and skills. Training, educational activities and competency-assessments should include transfusion in transplant patients, for both clinical and laboratory staff. Decision making aids, such as the SHOT resource 'Safe transfusions in haemopoietic stem cell transplant recipients' (see 'Recommended resources') should be easily accessible and incorporated into procedures and guidance. There is paucity of guidance to support safe transfusions in solid organ transplants recipients and a BSH guideline is in the pipeline to address this. The British Transplant Society Guidelines for Antibody Incompatible Transplant (BTS 2016, reviewed 2020) does not include guidance on transfusion for ABO-incompatible solid organ recipients in the immediate post-transplant period, nor advice about communication protocols, which should include informing the transfusion laboratory of the recipient's specific requirements.

Recommended resources

SHOT Bite No. 18: Transplant Patients
SHOT Bite No. 20: IBCT-SRNM
https://www.shotuk.org/resources/current-resources/shot-bites/

SHOT Video: Transfusion errors in haemopoietic stem cell transplant recipients
https://www.shotuk.org/resources/current-resources/videos/

Safe transfusions in haemopoietic stem cell transplant recipients
Safe Transfusion Checklist
https://www.shotuk.org/resources/current-resources/

SHOT UK Collaborative Reviewing and reforming IT Processes in Transfusion (SCRIPT) surveys and resources can be accessed at this link: https://www.shotuk.org/resources/current-resources/script/

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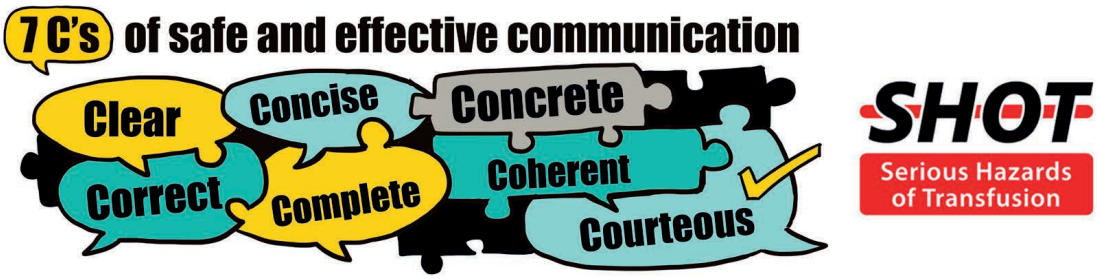


Immune Anti-D in Pregnancy n=52

26

Author: Susan Robinson

Definition:

Cases of D-negative pregnant women 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.

Abbreviations used in this chapter

BSH	British Society for Haematology	**IU**	International units
CffDNA	Cell-free fetal deoxyribonucleic acid	**IV**	Intravenous
DAT	Direct antiglobulin test	**NPP**	No previous pregnancies
FMH	Fetomaternal haemorrhage	**PP**	Previous pregnancies
HDFN	Haemolytic disease of the fetus and newborn	**PSE**	Potentially sensitising event
Ig	Immunoglobulin	**PV**	Per vaginal
IM	Intramuscular	**RAADP**	Routine antenatal anti-D Ig prophylaxis
IT	Information technology	**UK**	United Kingdom

Key SHOT messages

- Cases of immunisation are still occurring even where current best practice is being followed
- Obesity and delivery beyond 40 weeks remain potential risk factors for sensitisation in cases which are otherwise ideally managed
- There are ongoing missed opportunities where pregnancy management is not ideal
- Where a maternal D variant is detected, women should be assigned to a D-negative treatment pathway to ensure appropriate treatment and monitoring
- UK hospital uptake of maternal cffDNA fetal D screening is limited

Recommendations

- 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 review current training to avoid missed opportunities where pregnancy management is not ideal e.g., patient stories
- All UK hospitals should check that they have implemented a maternal cffDNA fetal D screening programme and that a local policy is available and consider audit to determine the barriers to uptake
- Hospital transfusion teams and women's services to check the advice in guidelines, policies and reflex pathways regarding women typed D variant is to assign a D-negative treatment pathway

Action: Transfusion laboratory management, maternity services, hospital IT departments

Introduction

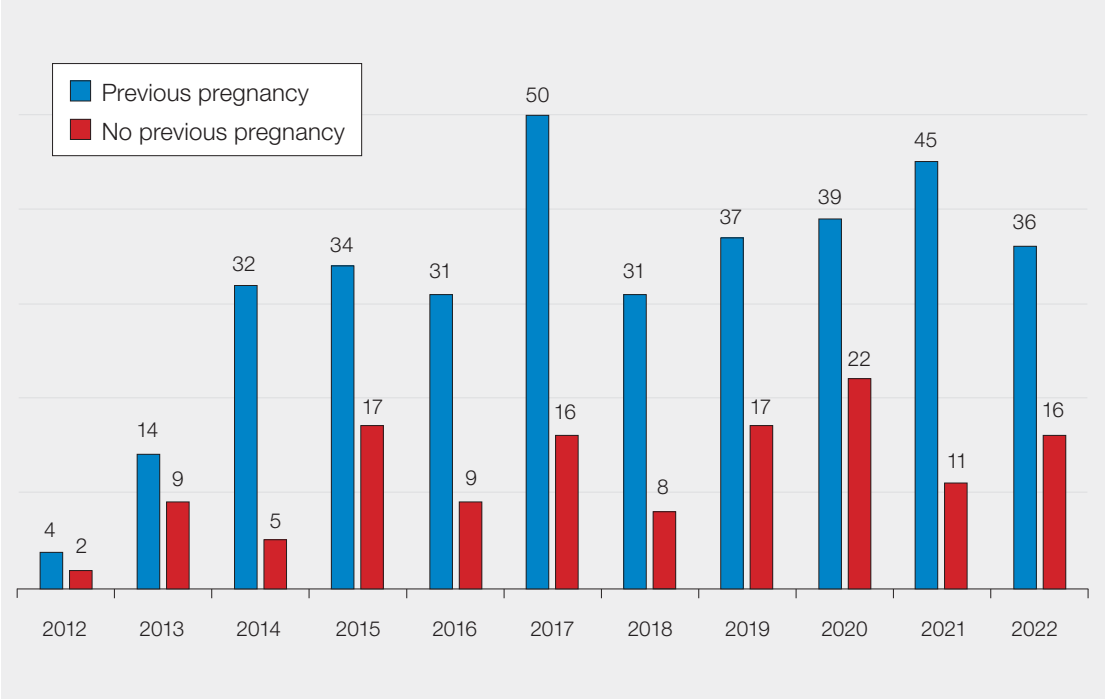
Since 2012 SHOT has been reviewing cases where immune anti-D has been detected for the first time in the current (index) pregnancy to improve understanding of the causes of continuing anti-D immunisations. Reporters are requested to provide data on booking weight, management of sensitising events during pregnancy and the administration of RAADP, both in the index pregnancy and the pregnancy immediately before the index pregnancy (if applicable).

Results

In 2022 a total of 52 cases were reported, 16 cases occurred in women with NPP, and 36 in women with PP. Reporting is fairly consistent however the available data would suggest that anti-D immunisation in pregnancy remains under-reported (see the assumptions and calculation provided in the 2018 Annual SHOT Report (Narayan et al. 2019)).

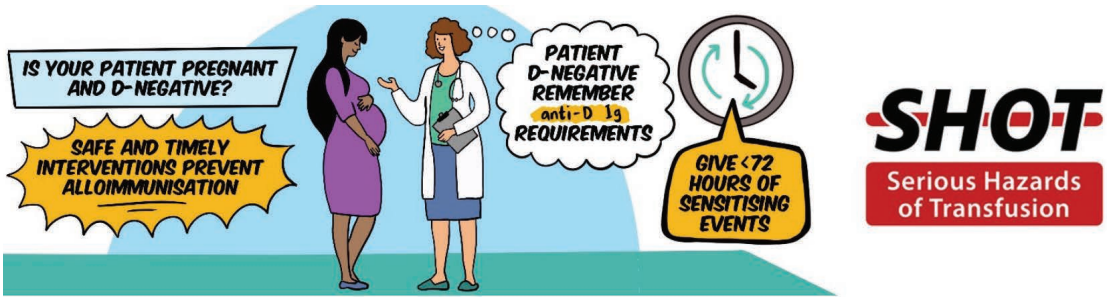
Cumulatively SHOT now has useful data on 132 women with NPP and 353 women with PP.

Figure 26.1: Number of reports of anti-D immunisation in pregnancy by year, 2012-2022



No previous pregnancy (NPP) n=16

For a detailed discussion of the NPP cases, and tables containing similar details to those published in previous Annual SHOT Reports, please see the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).



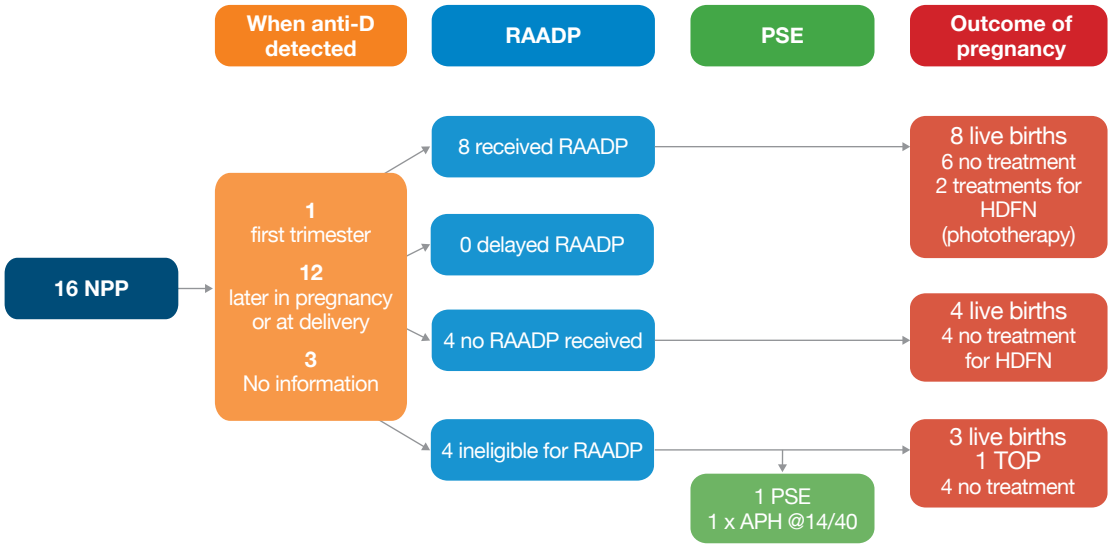


Figure 26.2: Summary of 2022 NPP data (n=16)

APH=antepartum haemorrhage; HDFN=haemolytic disease of the fetus and newborn; NPP=no previous pregnancy; PSE=potentially sensitising event; RAADP=routine antenatal anti-D Ig prophylaxis; TOP=termination of pregnancy

Illustrative cases

Case 26.1: Misinterpretation of the maternal blood group resulted in omission of anti-D Ig

A primiparous woman in her 20s booked in at 8 weeks. The maternal blood group was misinterpreted as D-positive. No RAADP was given at 28 weeks, and there were no PSE reported. Peripartum maternal anti-D was detected. A review of the maternal blood group report confirmed a D variant.

Women in whom the blood group is D variant must be treated the same as when blood group is D-negative.

Case 26.2: Immune or prophylactic anti-D 28-week sample

A primiparous woman in her early 30s was booked in at 9 weeks. The group and antibody screen detected the mother to be D-negative, and no alloantibodies were detected. The maternal sample for cffDNA at 16 weeks predicted the fetus to be D-positive. No PSE were reported. The maternal blood sample at 28 weeks was taken prior to RAADP administration which detected anti-D and was misinterpreted as prophylactic anti-D Ig. After a live birth at 40 weeks; the maternal antibody panel was 4+ anti-D, cord DAT 3+, maternal anti-D quantification was 156.7IU/mL. The neonate required phototherapy.

Case 26.3: Route of administration

A D-negative primiparous woman in her 20s of average weight, received 1500IU IM gluteal RAADP at 28 weeks gestation based on the cffDNA test which predicted the fetus to be D-positive. There were no PSE reported. Following delivery at 40 weeks a maternal blood sample detected anti-D, with a quantification of 27.7IU/mL.

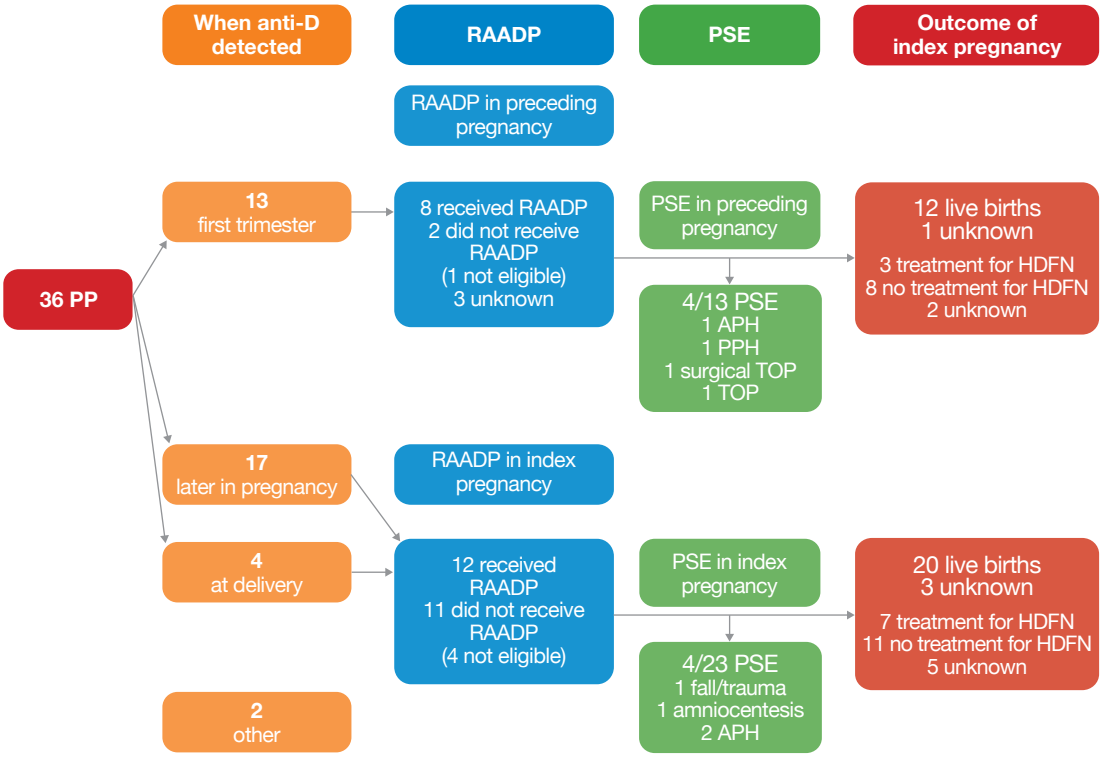
The management in this case was according to guidelines. It is important to note when IM gluteal injections are given, particular care should be taken to ensure that the injection is given into muscle as absorption may be delayed if it only reaches the subcutaneous tissues (BCSH Qureshi et al. 2014).

Previous pregnancies (PP) n=36

The index pregnancy in these cases refers to the current pregnancy – the pregnancy in which alloimmune anti-D was first detected.

For a detailed discussion of the PP cases, and tables containing similar details to those published in previous Annual SHOT Reports, please see the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/).

Figure 26.3: Summary of 2022 PP data (n=36)



APH=antepartum haemorrhage; HDFN=haemolytic disease of the fetus and newborn; PP=previous pregnancy; PPH=postpartum haemorrhage; PSE=potentially sensitising event; RAADP=routine antenatal anti-D immunoglobulin prophylaxis; TOP=termination of pregnancy

Illustrative cases

Case 26.4: Large fetomaternal haemorrhage

A D-negative woman in her late 20s, was booked in at 11 weeks. Her weight was 79kg, and she was gravida 2 para 1. Immune anti-D was detected at booking, and a D-negative baby was born at 36 weeks.

In the previous pregnancy RAADP was administered and from the details provided it appears that a suboptimal dose was given post delivery. Further details are provided here. Following an elective cesarean section at 39^{+1} a significant FMH of 63.1mL was recorded. If the anti-D Ig was administered IM the anti-D Ig dose required was calculated to be 8000IU (63.1x125=7887.5). Advice was provided that the dose required if the anti-D Ig was given IV. was equivalent to 50% of the IM dose. The calculation of anti-D Ig to be given IV should have been 100IU per mL (6310IU). This suggests the dose provided of 4500IU was not adequate. A Kleihauer at 72 hours reported a FMH of less than 4mL, no further anti-D Ig was provided and no further Kleihauer was performed.

As noted by the local reporting team 'The calculation of anti-D Ig to be given IV should have been 100IU per mL (6310IU)'. Healthcare professionals should refer to manufacturer's guidance depending on the product used (BCSH Qureshi et al. 2014). In addition, there was a delay in the repeat Kleihauer and an absence of further doses of anti-D Ig to clear the remaining FMH. Follow-up samples are required at 48 hours following an IV dose of anti-D Ig or 72 hours following an IM dose to check for clearance of fetal cells (BCSH Qureshi et al. 2014). Management of a FMH often spans a number of healthcare professionals and care should be taken to ensure local process provides continuity of care and management in accordance with guidelines.

Case 26.5: Prophylactic or immune anti-D, antenatal monitoring

A woman in her 20s, gravida 4 para 1 (2 miscarriages) booked at 8 weeks, with a booking weight of 66.5kg. Booking bloods did not detect any anti-D. A group and antibody screen at 28 weeks detected anti-D and the report noted probable prophylactic anti-D Ig and requested a further sample. A repeat sample was not sent. RAADP was provided at 28 weeks. At 35 weeks following a fall, prophylactic anti-D Ig was administered, however no Kleihauer was performed. A group and antibody screen detected alloimmune anti-D, quantification 5.2IU/mL. Following a scan at 36^{+6} weeks a decision was made to bring the planned elective caesarean section forward to 38 weeks. The prior live birth was a caesarean section. The mother delivered a D-positive baby, Hb130g/L, DAT 4+. The baby was monitored and re-admitted with evidence of ongoing haemolysis; Hb68g/L and the baby required red cell transfusion.

The management of this case highlights the complexity of the pathway with multiple points at which intervention and decision making according to guidelines may have increased awareness of the risk of haemolysis in pregnancy.

Case 26.6: Sensitisation in what appears to be ideal management

A D-negative woman, gravida 2 para 1 in her 30s was booked in at 9 weeks, booking bloods did not detect anti-D, booking weight 78.8kg. Maternal cffDNA at 16 weeks predicted the baby to be D-positive. The mother attended at 27 weeks following PV bleeding, a group and antibody screen was taken and the women was provided with 500IU anti-D Ig. The Kleihauer was negative however alloimmune anti-D, quantification 9.5IU/mL was detected. The highest level recorded in the pregnancy was 35.2IU/mL at 35 weeks. In the prior pregnancy the woman booked in at 9 weeks, received RAADP, no sensitising events had been identified, and the baby was born by vaginal delivery at 40^{+4} days. The previous baby was D-positive, postpartum anti-D Ig was provided and the Kleihauer was less than 2mL.

The mother and baby were monitored by the fetal maternal unit in the index pregnancy, the pregnancy resulted in a live birth at 37^{+3}. The baby was D-positive and received phototherapy.

Ideal management does not prevent all cases of HDFN, aside from the prior delivery at 40^{+4} and the PSE at 27 weeks which was adequately treated. No other factors were identified that would have potentially contributed to sensitisation.

Conclusions

The data this year detailed in the supplementary information on the SHOT website (https://www.shotuk.org/report-summary-and-supplement-2022/) demonstrate residual issues around ideal management of D-negative women during pregnancy to prevent immunisation. The 2022 data continue to illustrate missed opportunities where pregnancy management is not ideal. This is demonstrated in the NPP and PP RAADP and PSE data.

Two cases are described where women who are D variant have been incorrectly managed according to a D-positive pathway.

It is evident that the uptake of maternal cffDNA remains limited.

Further work needed

Hospital transfusion teams and women's services should review current training to avoid missed opportunities where pregnancy management is not ideal examples of training material include SHOT patient stories.

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SHOT
Serious Hazards of Transfusion

Acknowledgements

The Steering Group take this opportunity to thank the following individuals and organisations for their contributions without which the publication of this 26th Annual SHOT Report would not have been possible:

- The Blood Services of the United Kingdom for funding and support
- The Royal College of Pathologists to which SHOT is affiliated
- The Blood Services of the United Kingdom for the provision of data relating to the issue of blood components:
  - Central Planning Team, NHSBT
  - Mr James Smith, Senior Information Analyst, SNBTS
  - Mrs Lee Wong, Head of the Blood Health Team, WBS
  - Mrs Martina McCalmont, Senior Biomedical Scientist, Hospital Services Department, NIBTS
  - Mr Andy Rowley, Portfolio Manager, Critical Care - UK and Republic of Ireland, Octapharma Ltd for data relating to SD-FFP (Octaplas®)
- The expert group who reviewed TRALI cases:
  - Dr Tom Latham, NHSBT Bristol
  - Dr Peter Davis, Bristol University Hospitals NHS Foundation Trust
  - Dr Jill Clarkson, NHSBT Newcastle
  - Dr Andrew Charlton, NHSBT Newcastle
  - Dr Andrew Bentley, Manchester University NHS Foundation Trust
  - Dr Puneet Malhotra, St Helens and Knowsley Teaching Hospitals NHS Trust
  - Dr Margarita Gonzales, SNBTS
- Clinical and scientific staff, in hospitals and reference laboratories, who have contributed to the clinical and laboratory investigation of cases
- Toast Design Consultancy Ltd for maintenance of the SHOT website
- Dendrite Clinical Systems for the maintenance of the online reporting system
- Jenny Leonard for the illustrations
- ARC-UK Technologies for design and production of the report
- Hospital transfusion teams for submitting case reports to the scheme

All collaborators who have contributed to this Annual SHOT Report.

27 MHRA Report on Blood Safety and Quality Regulations (BSQR) in 2022

Authors: Chris Robbie and Mike Dawe

Abbreviations used in this chapter

BCR	Blood compliance report
BE	Blood Establishment
BSQR	Blood Safety and Quality Regulations 2005 (as amended)
BMS	Biomedical scientist
CAPA	Corrective and preventive action
CATPD	Component available for transfusion past de-reservation
CCE	Component collection error
CLE	Component labelling error
DEE	Data entry error
ECAT	Expired component available for transfusion
EI	Electronic issue
FR	Failed recall
GPG	Good Practice Guide
HBB	Hospital blood bank
HD	Handling damage
IAG	Inspection action group
IBCA	Incorrect blood component Accepted
IBCI	Incorrect blood component issued
IBCO	Incorrect blood component ordered
LIMS	Laboratory information management system
NBTC	National blood transfusion committee
PSIRF	Patient safety incident response framework
PTTE	Pre-transfusion testing error
QMS	Quality management system
RC	Root cause
RCA	Root cause analysis
SABRE	Serious Adverse Blood Reactions and Events
SAE	Serious adverse event
SAR	Serious adverse reaction
SOP	Standard operating procedure
SPE	Sample processing error
UNSPEC	Unspecified

Key MHRA messages

- The MHRA haemovigilance team has worked hard to improve the depth of investigations and improve the identification of root causes and corrective measures with reporters.
- There has been another increase in the number of investigation reports that have identified system errors or weak processes
- There has been a 35% increase it reports which have cited staffing and workload problems as the main root cause
- Hospital transfusion teams must review their own incidents alongside the findings in this chapter to identify their most frequently occurring SAE and root causes
- Attention should be made to the SAEs and root causes highlighted in this chapter to ensure these are being reported consistently and that QMSs are reviewed for robustness and effectiveness

Summary

There has been an increase in the total number of reports received during 2022. The increase is seen to be as a result of more SAR reports being received. As we recover from the effects of the Covid-19 pandemic and struggle to get back to normal and the way SAR reports are uploaded onto SABRE following review by the SHOT experts, this increase is probably more a reflection of a backlog of reporting

and assessment rather than a reflection of an increase in the number of reactions that have occurred. In fact, there has been a slight decrease in the number of SABRE reportable events, largely driven by a reduction in the number of storage errors reported. Again, this is most likely a result of clinical areas returning to normal and therefore improving the control of the storage of components.

Despite the reduction of SAE reports received, there has been an increase in the number of errors reported to be due to system errors identified in the investigation. The majority of the increase in reported system errors appears to be a direct result of the effects of staffing and workload problems experienced.

SABRE report data

Table 27.1 and Figure 27.1 show the total numbers of reports and the numbers of reports submitted as SAEs and SARs for the previous 10 years. Although the figures remain broadly similar to previous years, the data show a decrease in the number of SAEs and an increase in SAR reports resulting an increase in the total number of reports received.

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
SAE	705	762	764	1027	1076	1198	1197	1093	1143	1118
SAR	345	346	262	464	508	408	497	590	526	710
Total	1050	1108	1026	1491	1584	1606	1684	1683	1669	1828

Table 27.1: Submitted confirmation reports 2013–2022

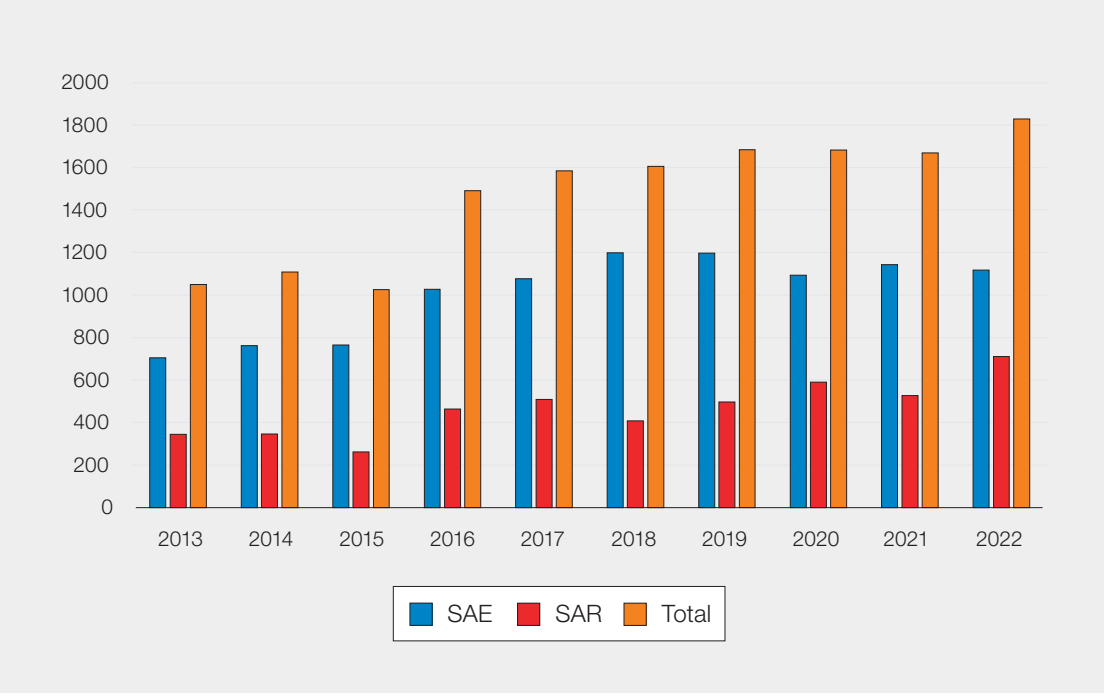


Figure 27.1: Submitted confirmation reports 2013-2022

SAE=serious adverse event; SAR=serious adverse reaction

Serious adverse events n=1118 (-25)

Definition: (BSQR 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 27.2: Total number of SAE reports by event category

Event category	Number of reports
Materials	1
Apheresis collection	2
Testing of donations	3
Processing	6
Whole blood collection	7
Distribution/HSE	22
Donor selection	70
Storage/HSE	245
Other	762
Grand total	**1118**

Table 27.2 shows the total number of SAE reports received by event category. Proportions of reports received remain similar to previous years, but there has been a slight increase in 'other' SAE and a drop in the number of storage SAE reported.

Storage data n=245 (-48)

Storage remains the second largest individual error category (after 'other') and comprises of all BSQR reportable Storage SAE in both the laboratory and clinical areas. The MHRA Senior Haemovigilance Specialist has broken this category down further to try and identify specific storage error sub-types, Table 27.3. For a description of the sub-categories used, see Appendix 1.

Table 27.3: SAE storage error sub-classifications

Storage sub-classification	2022 (+/- 2021)	2021 position
Incorrect storage of component	118 (-19)	1
Component expiry	38 (-12)	2
Sample expiry	29 (-11)	3
Return to stock error	22 (+5)	4
Security	14 (-2)	5
Failure to action alarm	8 (-5)	6=
Miscellaneous	7 (+1)	8
Storage temperature deviation	7 (-6)	6=
30 or 60 minute rule	2 (+1)	9
Total	**245 (-48)**	**x**

There has been a 16% reduction in the number of storage SAE with fewer reports seen in most of the storage sub-categories. While it would be difficult to pinpoint exact reason for this, it is presumed as hospitals have been getting back to normal since the COVID-19 pandemic, that arrangements for storage and training are returning to pre-pandemic levels and as such the numbers of reports has decreased as a result.

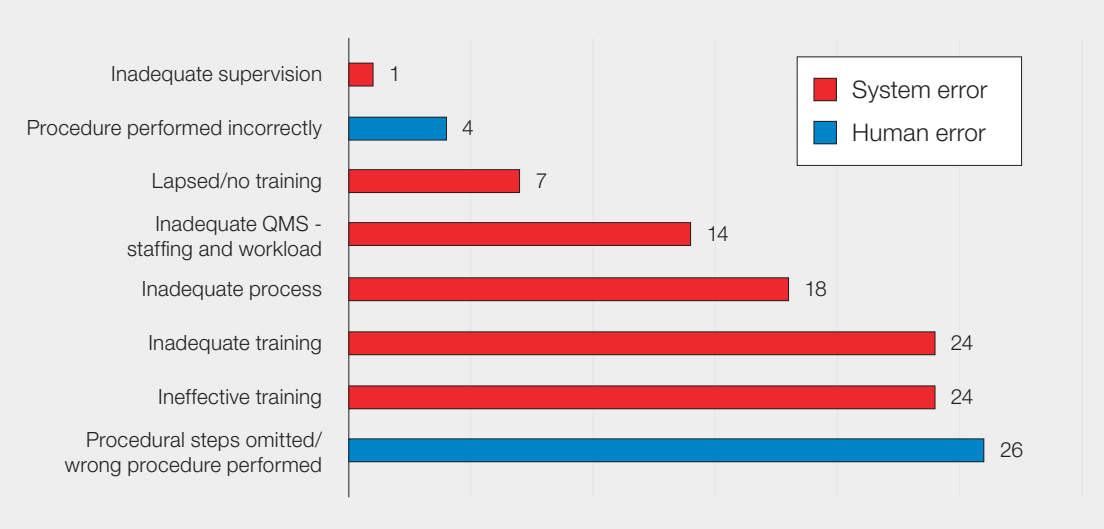


Figure 27.2: Root causes of Incorrect storage of components sub-category

QMS=quality management system

As the single largest sub-category of storage, Figure 27.2, shows the breakdown of Incorrect storage by root cause.

As last year, the majority of root causes of these types of error are System errors, especially relating to inadequate process design and the inadequate design, delivery and understanding of the training in the storage of components. In fact, only 25% of the errors are assessed as 'human error' with the remaining 75% a result of 'system errors'.

Despite a 14% reduction in the number of incorrect storage of component SAE, the root causes of these errors are similar to previous years and therefore there exists further room for improvement in this area.

Recommendation

- Review business continuity plans to ensure all changes to storage processes are adequately managed, ensuring the new processes are robust, covered with updated SOP and that re-training of staff is adequately planned and delivered

Action: Hospital transfusion teams

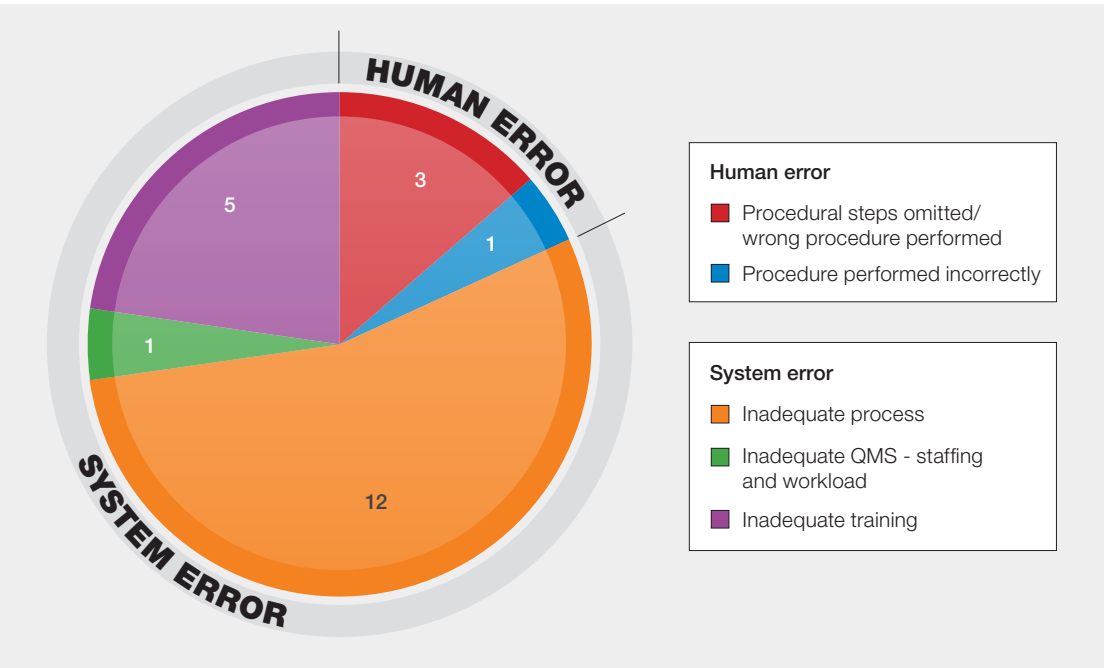


Figure 27.3: Root causes of the return to stock sub-category

QMS=quality management system

While not the second largest storage sub-category, there has been a 29% increase in return to stock errors in laboratories. The causes of error in this category demonstrate a split of 81% system errors compared to 19% human errors, with the largest proportion relating to inadequate process design.

Recommendation

- Review processes that involve the returning components to the supply chain ensure they are thoroughly robust ensuring that units are returned to stock prior to their expiry date being exceeded

Action: Transfusion laboratories

Other n=762 (+19)

Table 27.4: 'Other'

Other sub-category	2022 (+/- 2021)	2021 position
Sample processing error (SPE)	147 (+15)	3
Incorrect blood component issued (IBCI)	141 (-31)	1
Component collection error (CCE)	136 (-16)	2
Pre-transfusion testing error (PTTE)	124 (+40)	5
Component labelling error (CLE)	115 (+15)	4
Data entry error (DEE)	62 (+2)	6
Failed recall (FR)	15 (-5)	7
Incorrect blood component ordered (IBCO)	9 (+6)	10=
Unspecified (UNSPEC)	4 (-6)	8
Component available for transfusion past de-reservation (CATPD)	4 (NC)	9
Expired component available for transfusion (ECAT)	3 (+1)	12
Incorrect blood component accepted (IBCA)	1 (NC)	13
LIMS Failure	1 (+1)	14
Handling damage (HD)	0 (-3)	10=
Total	**762 (+19)**	**x**

Table 27.4 shows the number of reports in the 'other' category of SAE. There has been a slight increase (2.5%) in events that fall into this category and some quite marked changes in numbers of reports for the top 5 categories which have been explored in greater detail below.

Last year's report noted a significant drop in the number of pre-transfusion testing error SAE received which was considered to be unexpected. The numbers of reports in this category have now returned to previous levels and therefore the reduction of PTTE SAE in 2021 would appear to be unexplained. Please see Appendix 2 for a description of the sub-categories.

Human and system error categories and human factors

The BSQR (2005) requires that 'preventable causes' of SAE are investigated and reported. The GPG (2018) 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.'

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'. It must be stressed that the term 'human factors' is not a fancy term now used to describe 'human error'. 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 27.5 shows the breakdown of reports in the human/ system error sub-categories.

Human error sub-category	Total 2022 (+/- 2021)	2021 position
System error/ Inadequate process	275 (+2)	2
Human error/ Procedure performed incorrectly	227 (-66)	1
Human error/ Procedural steps omitted/wrong procedure performed	176 (-4)	3
System error/ Inadequate QMS – staffing and workload	140 (+52)	5
System error/ Ineffective training	125 (-3)	4
System error/ Inadequate training	80 (-7)	6
System error/ Incorrect procedure	43 (+6)	7
System error/ Lapsed/no training	22 (-2)	8
System error/ Inadequate supervision	10 (-2)	9
Total	**1098 (-24)**	**x**

Table 27.5: Human/system error sub-categories, 2022

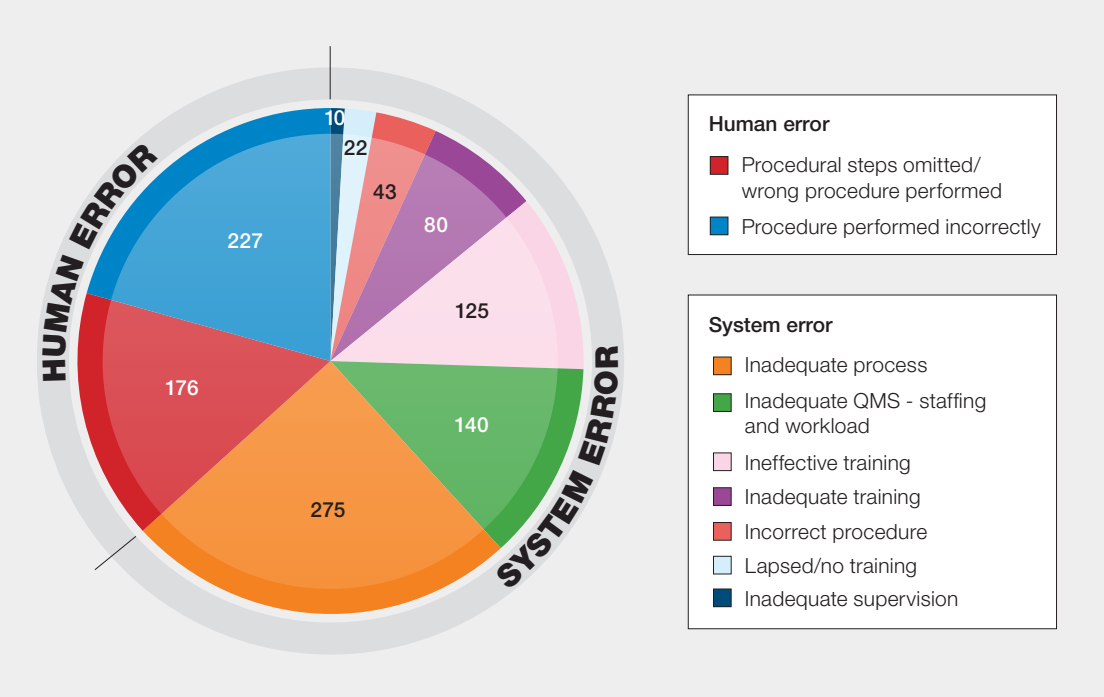


Figure 27.4: Human/system error sub-categories

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 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

The MHRA haemovigilance team has done much work in trying to improve the quality of SAE investigations undertaking several site visits and training presentations specifically dealing with investigations and RC and CAPA. The team has been much stricter in terms of accepting Confirmation reports and many have

been returned to encourage reporters to investigate and report to a much greater depth to encourage them to identify the system-based problems and improve the quality of the CAPA.

Table 27.5 shows that due to fewer SAE reports being reported, there has been a slight decrease in the number of SAE human error reports. While the proportions of reports remain largely the same to previous years, there has been a marked reduction in the number of reports attributed to slips, lapses or omissions by individuals. In fact, there has been a 17% reduction in 'human error' reports.

In line with evidence from inspections and anecdotally, there has been a marked increase in the number of reports attributed to the effects of staffing, workload, and skill-mix with a 35% increase in reports in this sub-category.

Overall, data shows that currently SAE are 37% due to 'human error' and 63% a result of failures in the QMS. It is anticipated that further efforts to improve the depth and coverage of investigations will further help to improve the identification of system improvements.

Recommendations

- All reporters must continue to thoroughly investigate all SAEs, even those with no actual harm to patients. It is through thorough investigation 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
- Ensure that training regimes adequately cover the process or task being trained
- Ensure that any changes to processes are adequately planned, including the planning and delivery of training programmes
- 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
- Trusts are advised to ensure that they have an effective capacity plan, or similar document in place
- Occasions where the capacity plan cannot be met should be raised as a quality incident and addressed with suitable RC and CAPA

Action: Hospital transfusion teams

MHRA/SHOT and NHS England

There have been several confirmation reports that were submitted to MHRA that appeared to lack adequate investigation of root cause. Additionally, many confirmation reports are submitted late or delayed without adequate justification. On further discussion with the reporters, it has become clear that this is often due to NHS Trusts in England implementing the recommendations of NHS England's Patient safety incident response framework. While MHRA and SHOT support the aims of PSIRF, the investigation and reporting requirements of the BSQR and the GPG are a legal responsibility and should not be adversely affected.

For information on PSIRF and the impact on haemovigilance reporting and investigation of transfusion incidents in England see https://www.shotuk.org/reporting/.

Top 5 SAE

The 'top 5' SAE have been presented slightly differently to previous year's reports. This year we have decided to pick the top 5 SAE other subcategory and then give a breakdown of all the root causes for that category.

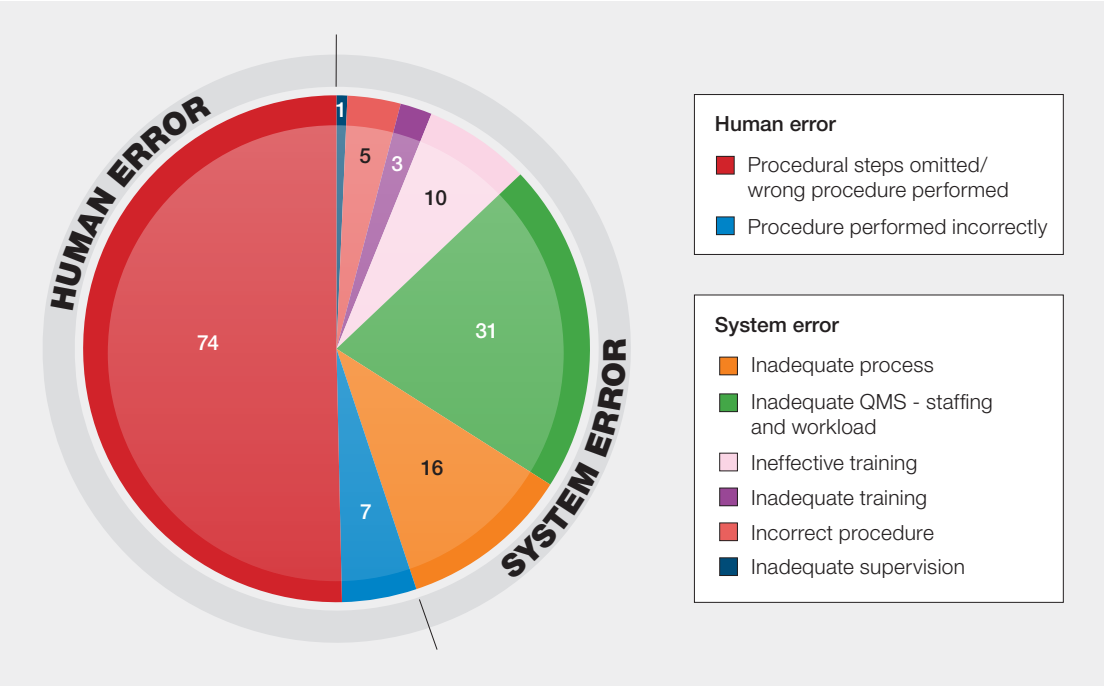


Figure 27.5: Sample processing error (SPE)

QMS=quality management system

For the first time, sample processing errors are the most commonly reported SAE sub-category, overtaking Incorrect blood component issued. The process is largely manual and relies on many checks prone to slips and lapses of concentration. It is therefore no surprise that 55% of these reports are reported to be due to human error. However, 21% are recorded to be due to staffing and workload issues. Investigations into SPE, including the regular trending and monitoring of these errors should therefore try to go further to attempt to determine if these errors are genuinely due to slips or lapses only or whether further system improvements such as the elimination and reduction of distractions to assist staff conducting these tasks.

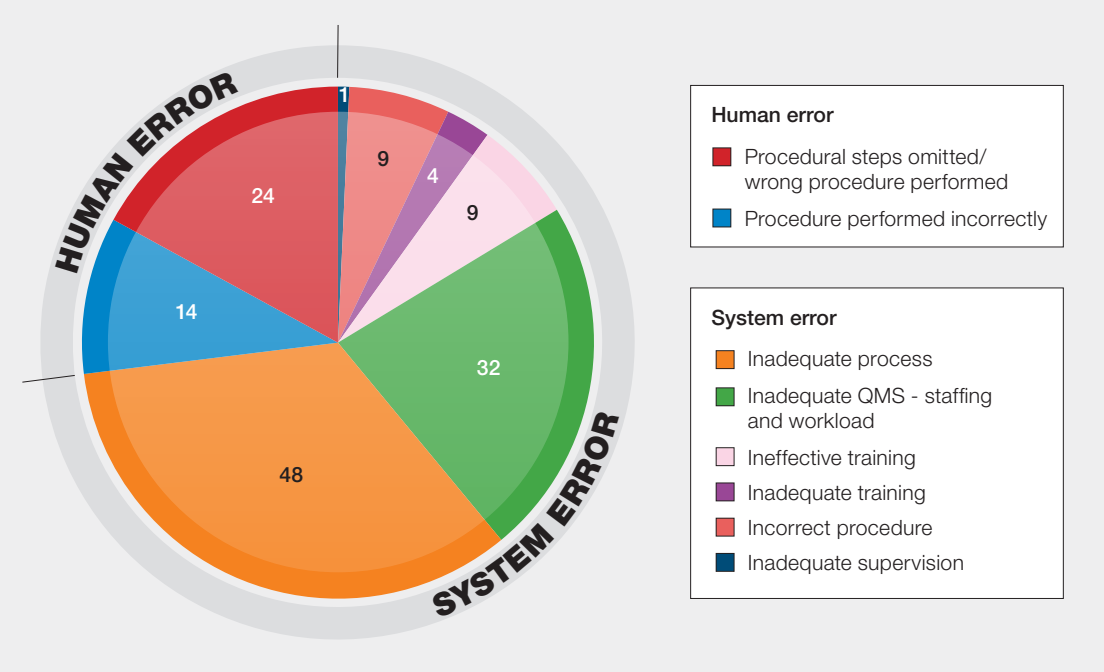
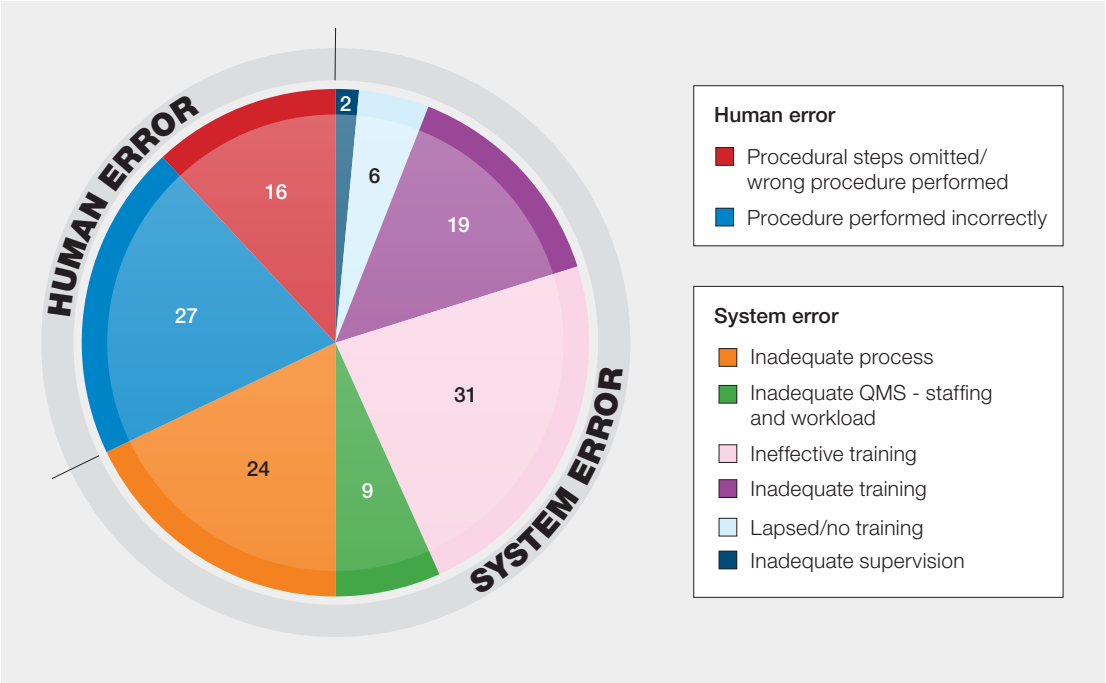


Figure 27.6: Incorrect blood component issued (IBCI)

QMS=quality management system

Nearly three quarters of Incorrect blood components issued (73%) are related to system errors and the rest (27%) are due to slips lapses and omissions. The largest proportion are due to inadequately designed processes or a combination of system errors. Nearly a quarter (23%) are a direct result of staffing and workload issues which affect the selection of the correct requirements for patients.

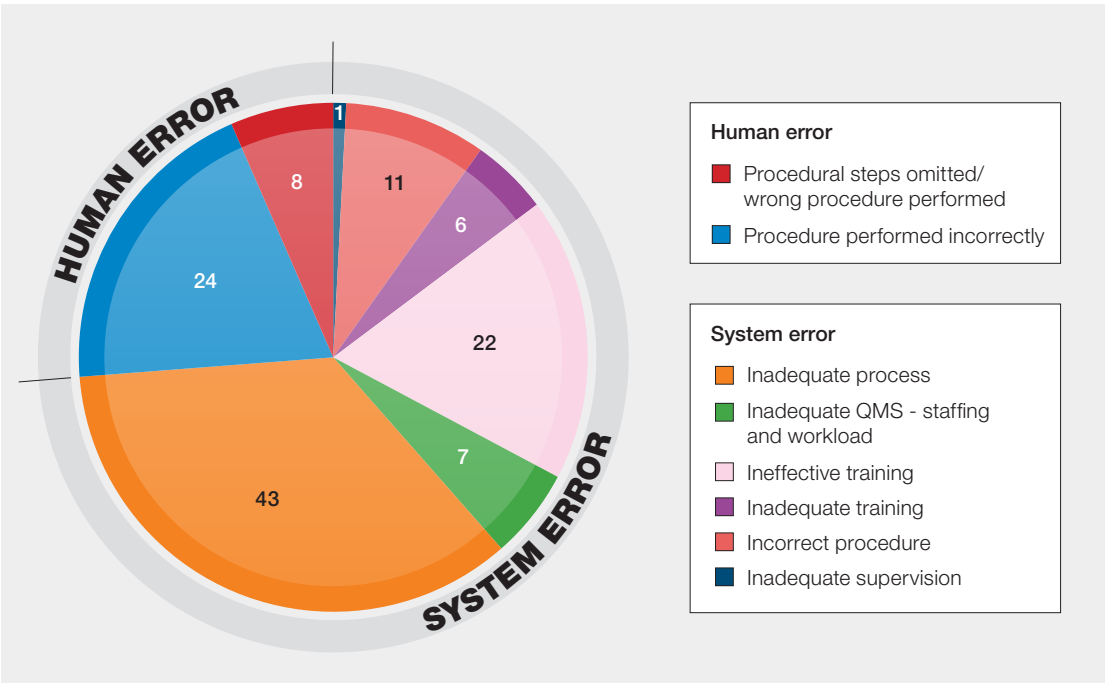
Figure 27.7: Component collection error (CCE)



QMS=quality management system. 2 equipment failures are not included in the figure

As a largely manual process that relies on visual checks around 32% of component collection errors are reported to be a result of human errors. However, where investigations have been conducted to an acceptable level of depth 68% of reports have been concluded to be a result of some form of system error. Training issues account for 41% whether that is because people haven't been trained at all or because training has been poorly delivered or not clearly understood.

Figure 27.8: Pre-transfusion testing error (PTTE)



QMS=quality management system. 2 equipment failures are not included in the figure

The most commonly reported cause of pre-transfusion testing errors are inadequate processes (35%). While most of these would suggest that processes are not as robust as they could be, there is significant evidence to suggest that other system factors are involved such as incorrect procedures (9%) and training issues (18%). The data would therefore suggest that testing processes would be improved by;

- reviewing processes and training to ensure they are robust
- making full use of equipment capabilities

- producing effective documentation that directs staff to follow procedures correctly
- ensuring that training is thoroughly understood

Many reports that fell into the Ineffective training sub-category indicated that staff involved lacked experience so support should be given to staff even after training to ensure that they fully understand the process correctly.

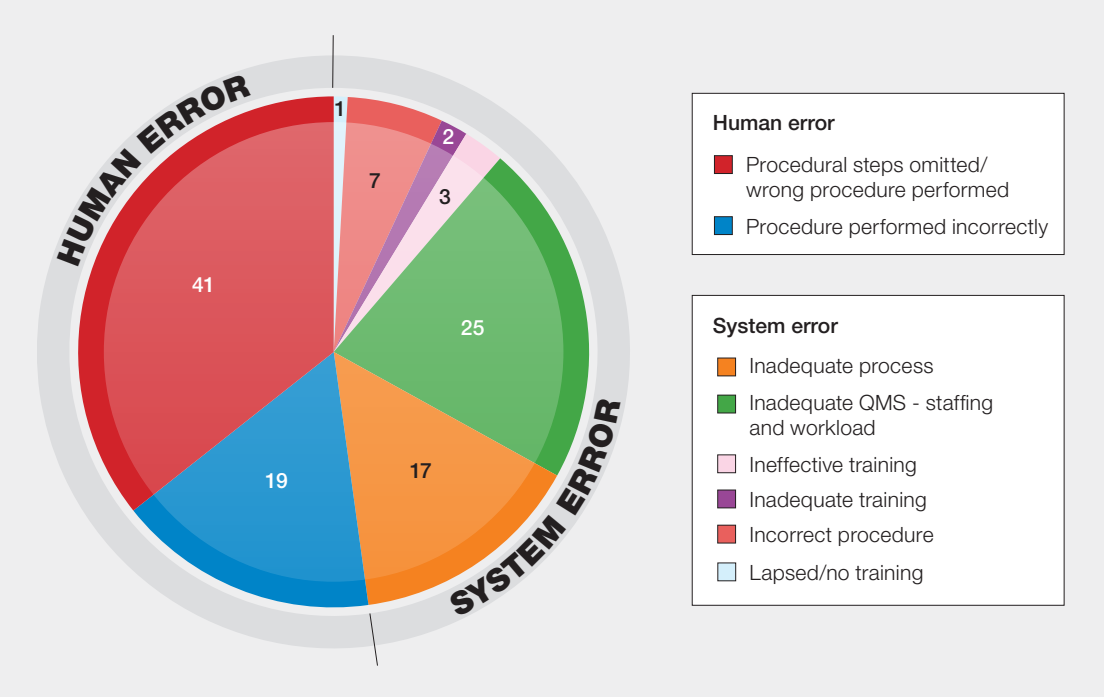


Figure 27.9: Component labelling error (CLE)

QMS=quality management system

As a largely manual process, over half (53%) of component labelling errors are reported to be due to human error where labels are not thoroughly verified at the point of attachment. Reports that have been investigated to a greater depth, however, do demonstrate system weaknesses where these checks are rushed due to high workload or lack of staff at the time of the error (22%). Inadequate processes were also described to be the cause of 15% of reports. Either these were a combination of system factors, or because the process for printing, checking and labelling components had not been thoroughly defined leaving staff to improvise their own procedures for labelling which were later found not to be robust.

Recommendations

Review QMS to ensure the processes involved in the most frequently occurring SAE are robust. Ensure that

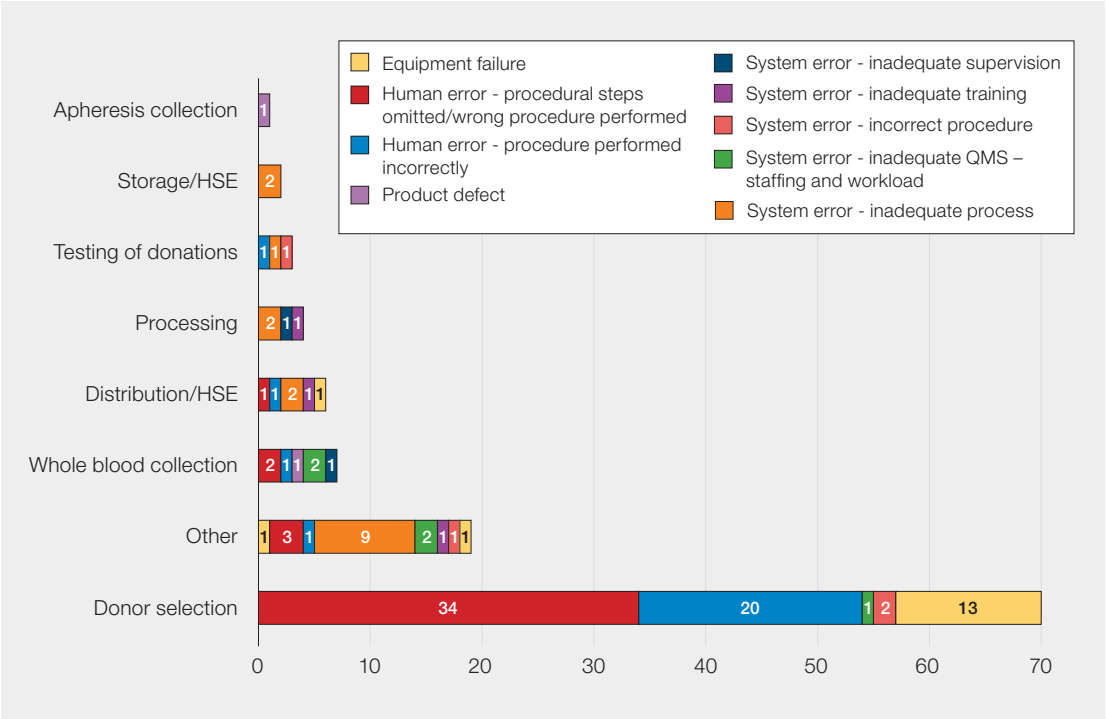
- The process is thoroughly defined
- That procedures are written giving full and clear instructions how to perform the task
- That training is planned, adequate, delivered and understood

Action: Hospital transfusion teams

Blood establishment reporting n=112 (+5)

Although reports from 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 27.10 displays the reported BE SAE in 2022.

Figure 27.10: Blood establishment SAE event category by specification

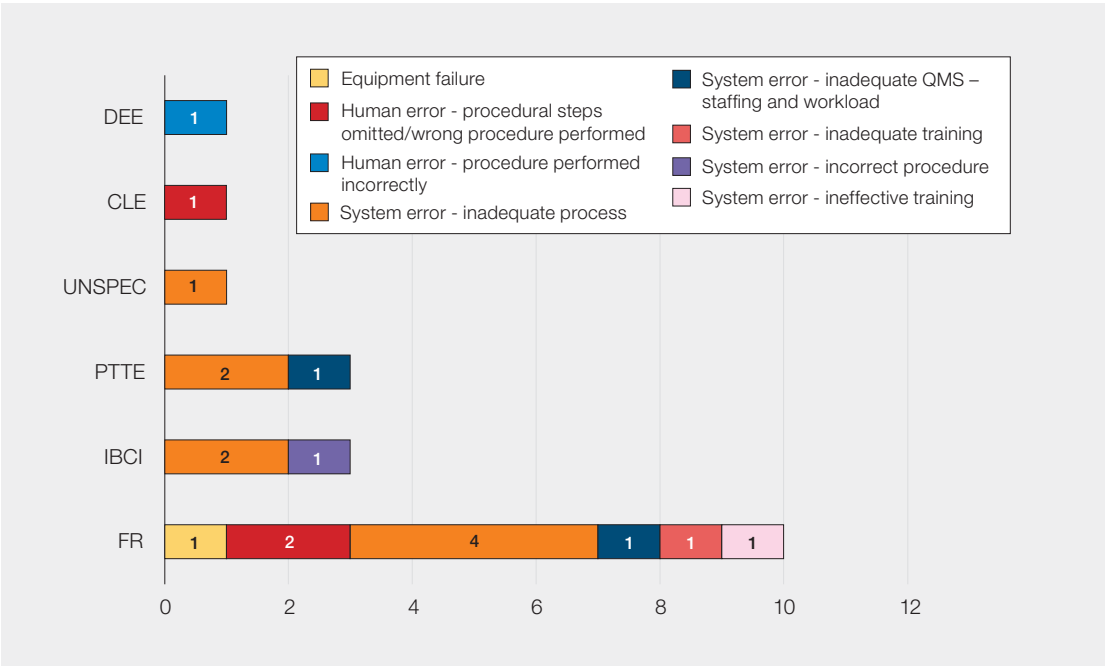


QMS=quality management system; HSE=handling and storage errors

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 27.11 shows a breakdown of the 19 reports which fall into the 'other' category.

Figure 27.11: BE reports in 'other' category



See Appendix 2 for key to category abbreviations; QMS=quality management system

Comment from Julie Staves, Chair of the NBTC Laboratory Managers' Working Group

I always look forward to reading the Annual SHOT Report, and the information provided by the MHRA is always especially interesting. It is pleasing to see a reduction in the number of component storage errors in 2022. As we know these are usually preventable errors, and as such, are either primarily a system or human factors issue. If you haven't already done so I'd like to ask you to review your systems for component storage to pick up on any system errors and look for a simple solution to prevent these happening. Errors associated with returning units to stock remain a concern, and again I would urge you to review these.

The other laboratory-associated errors remain a mix of types. Of concern to me is an increase in sample processing and pre-transfusion testing errors. These are tasks which are part of the routine of a transfusion laboratory and as such should be the ones we pride ourselves at doing well. It is not possible from this data to determine the root cause of this increase, but it does indicate that we should not become complacent with routine things.

Serious adverse reactions (SAR)

Definition: (Ref 2) 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 fresh frozen plasma), or coagulation factor concentrates should be reported to the MHRA via the Yellow Card scheme (http://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 27.12.

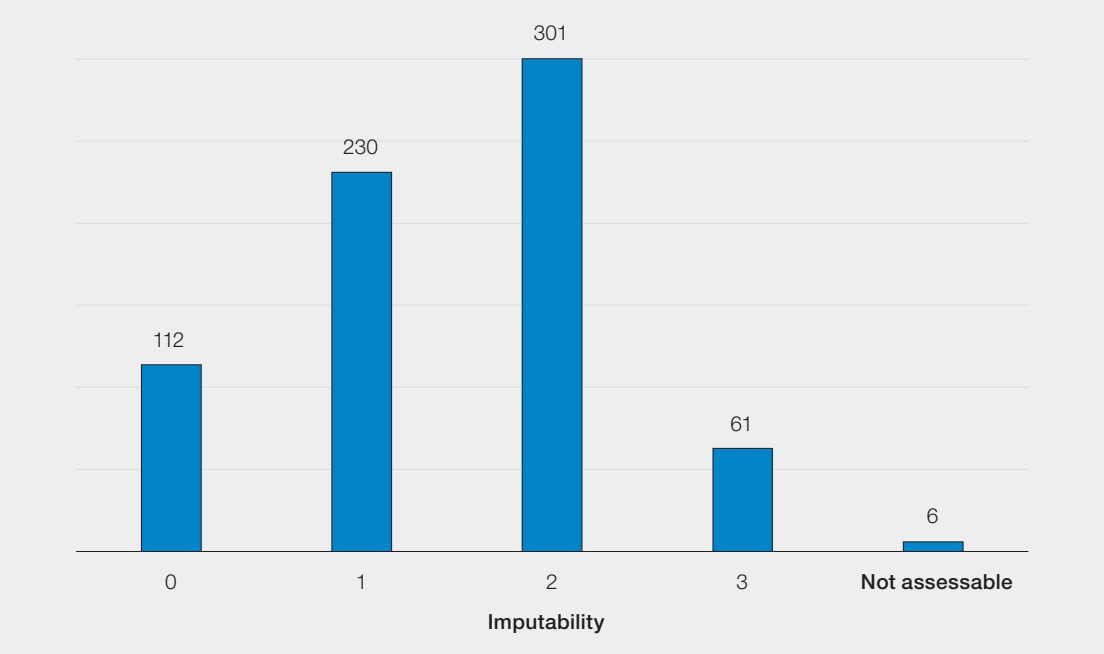


Figure 27.12: SAR reports, by imputability, reported to SABRE in 2021

MHRA Inspection activity on hospital blood banks

Author: Mike Dawe

The MHRA inspectorate have continued to verify blood compliance reports and have conducted 27 inspections since April 2022. A total of 295 BCR were submitted for review for the reporting period 01 April 2021 to 31 March 2022.

The BCR were scored and discussed at a meeting of the BCR Assessment Team (BAT) in August 2022.

An overview of the compliance management escalation processes used by the GMP inspectorate, including information on the IAG and CMT 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/

There have been 2 referrals to IAG or CMT so far from this cycle of inspections. Summary of significant issues identified at inspected sites include:

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
- inadequate 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:

- The absence of a root cause
- Failure to consider the potential for harm as well as actual harm
- The lack of an adequate justification for human error being identified as a root cause
- Tracking and trending systems not effectively employed to identify recurring problems

The availability of trained and competent staff

Initial training and ongoing competency are generally appropriately managed. However, 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.

Recall

Although there was evidence that external and internal recalls had been regularly performed, the systems in place lacked sufficient detail regarding that actions were to be taken within pre-defined periods of time.

For further information on MHRA and the Regulation of Blood please refer to the MHRA website: www.gov.uk/topic/medicines-medical-devices-blood/blood-regulation-safety

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

HAEMOVIGILANCE TEAM UPDATE 2022

Whilst Mike is seconded to the Inspectorate team and unable to conduct site visits and training in person, the Haemovigilance team continues to provide an education service. During 2022 there has been one face to face education session and 11 online education events. The team also supports SHOT, UKTLC, NBTC and Regional HTT meetings on request.

If you are interested in finding out more about how the Hemovigilance Team could support you, contact

E Mail: Mike.Dawe@mhra.gov.uk,
Chris.Robbie@mhra.gov.uk

Other useful contacts

gmpinspectorate@mhra.gov.uk – For matters regarding inspections and inspector advice
BCRBF@mhra.gov.uk – Any advice regarding Blood Facilities
bcr@mhra.gov.uk – For advice regarding the Blood Compliance Report

References

BSQR. The Blood Safety and Quality Regulations ISBN 0110990412 (2005). http://www.legislation.gov.uk/uksi/2005/50/contents/made [accessed 04 May 2022].

GPG (2018). Good Practice Guidelines for Blood Establishment Required to Comply with Directive 2005/62/EC

For information on PSIRF and the impact on haemovigilance reporting and investigation of transfusion incidents in England click below

https://www.shotuk.org/reporting/

Appendices

Appendix 1: Storage subcategories

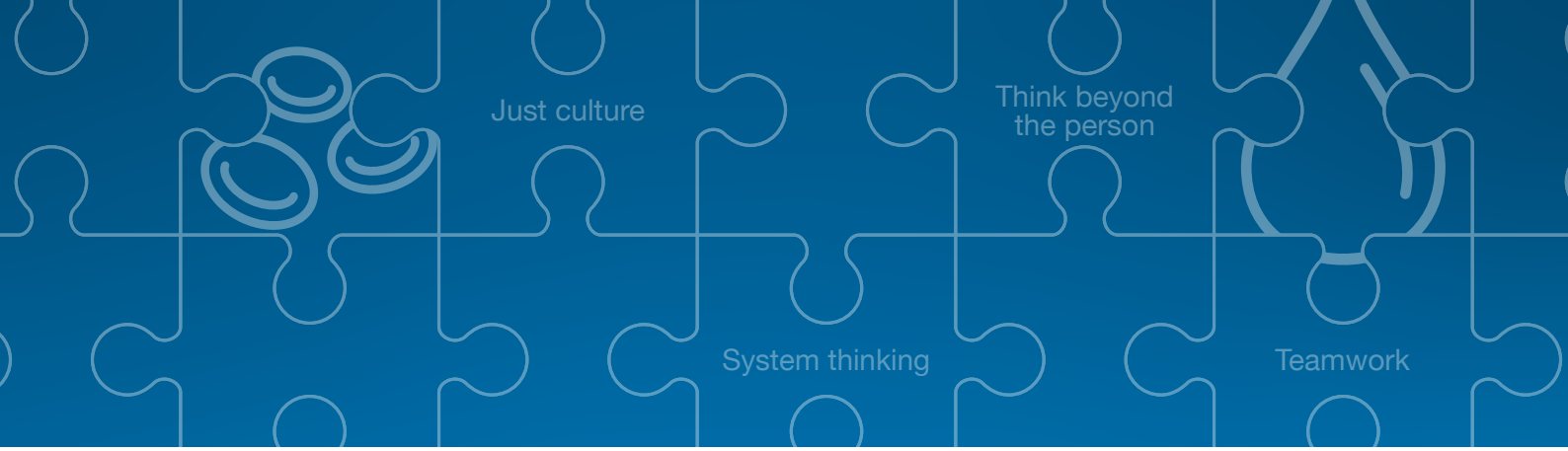
Component expiry	A component has time expired and not been removed from the storage location according to laboratory procedures
Incorrect storage of component	A component has not been stored in the correct location
Sample expiry	A sample has expired and the component has not been removed from the supply 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



If you would like more information on SHOT please contact:

The SHOT Office,
Manchester Blood Centre,
Plymouth Grove,
Manchester
M13 9LL

Telephone: 0161 423 4208
Email: shot@nhsbt.nhs.uk
Website: www.shotuk.org

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